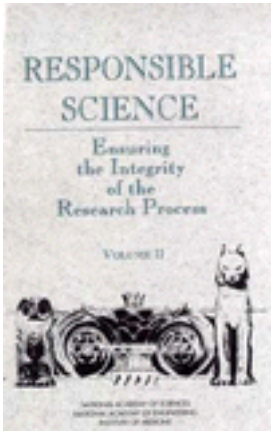

Responsible Science, Volume II: Background Papers and Resource Documents

Panel on Scientific Responsibility and the Conduct of Research, National Academy of Sciences, National Academy of Engineering, Institute of Medicine

ISBN: 0-309-58493-0, 288 pages, 6 x 9, (1993)

RESPONSIBLE SCIENCE

Ensuring the Integrity of the Research Process
Volume II

Panel on Scientific Responsibility and the Conduct of Research
Committee on Science, Engineering, and Public Policy
National Academy of Sciences
National Academy of Engineering
Institute of Medicine

NATIONAL ACADEMY PRESS
Washington, D.C. 1993

NOTICE: This volume was produced as part of a project approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. It is a result of work done by an independent panel appointed by the Committee on Science, Engineering, and Public Policy, which has authorized its release to the public.

Part A of this volume has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee and by the Committee on Science, Engineering, and Public Policy. Both consist of members of the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine.

The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Frank Press is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Robert M. White is president of the National Academy of Engineering.

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences in its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

The Committee on Science, Engineering, and Public Policy (COSEPUP) is a joint committee of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. It includes members of the councils of all three bodies.

Library of Congress Catalog Card Number 92-10780

International Standard Book Number 0-309-04788-9

Available from:
National Academy Press
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

B-026
Printed in the United States of America
First Printing, February 1993
Second Printing, March 1996

PANEL ON SCIENTIFIC RESPONSIBILITY AND THE CONDUCT OF RESEARCH

EDWARD E. DAVID, JR. (*Chairman*), President, EED, Inc.

PHILIP H. ABELSON, Deputy Editor of *Science* and Science Advisor, American Association for the Advancement of Science

VICTOR R. BAKER, Regents Professor and Professor of Geosciences and Planetary Sciences, Department of Geosciences, University of Arizona

ALBERT BARBER, Vice Chancellor for Research, University of California, Los Angeles

MICHAEL BERMAN, President, The Duberstein Group, Inc.

JOHN DEUTCH, Institute Professor of Chemistry, Massachusetts Institute of Technology

VAL L. FITCH, James S. McDonnell Distinguished University Professor of Physics,Princeton University

MARYE ANNE FOX, M. June and J. Virgil Waggoner Regents Chair in Chemistry, University of Texas at Austin

PETER GALISON, Co-Chairman, History of Science Program, Stanford University

BERNARD GERT, Stone Professor of Intellectual and Moral Philosophy, Dartmouth College

IRA J. HIRSH, Mallinckrodt Distinguished University Professor of Psychology and Audiology, Washington University

JENNY L. McFARLAND, Postdoctoral Fellow,Department of Brain and Cognitive Sciences, Massachusetts Institute of Technology

LAURIE E. McNEIL, Associate Professor, Department of Physics and Astronomy, University of North Carolina at Chapel Hill

RICHARD A. MESERVE, Partner, Covington and Burling

FRANK M. RICHTER, Professor and Chairman, Department of Geophysical Sciences, University of Chicago

ARTHUR H. RUBENSTEIN, Professor and Chairman, Department of Medicine, University of Chicago

HOWARD K. SCHACHMAN, Professor,Department of Biochemistry and Molecular Biology, University of California, Berkeley

HOWARD E. SIMMONS, JR., Vice President and Senior Science Advisor, E.I. du Pont de Nemours and Company, Inc.

ROBERT L. SPRAGUE, Professor in the College of Medicine and Director of the Institute for Research on Human Development, University of Illinois at Urbana-Champaign

SHEILA WIDNALL, Associate Provost and Abby Rockefeller Mauze Professor of Aeronautics and Astronautics, Massachusetts Institute of Technology

PATRICIA K. WOOLF, Lecturer, Department of Molecular Biology, Princeton University
KEITH R. YAMAMOTO, Professor and Vice Chairman, Department of Biochemistry and Biophysics, University of California, San Francisco

Staff

ROSEMARY CHALK, Study Director
BARRY GOLD, Senior Staff Officer
SUSAN MAURIZI, Editor
DAVID H. GUSTON, Research Assistant
MARYANN SHANESY, Administrative Secretary
ELIZABETH BLOUNT, Secretary

COMMITTEE ON SCIENCE, ENGINEERING, AND PUBLIC POLICY

Staff

LAWRENCE E. McCRAY, Executive Director
BARBARA A. CANDLAND, Administrative Assistant

*Term expired June 30, 1991.

Preface

In 1989, the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine initiated a major study to examine issues related to the responsible conduct of research. The Committee on Science, Engineering, and Public Policy convened a 22-member study panel to review factors affecting the integrity of research in science as it is carried out in the United States today and to recommend steps for reinforcing responsible research practices. The panel was also asked to review institutional mechanisms that exist for addressing allegations of misconduct in science. Finally, the panel was asked to consider the advantages and disadvantages of formal guidelines for the conduct of research.

Between May 1990 and June 1991, the panel held seven meetings, and it heard from a broad range of individuals about factors that affect integrity and misconduct in the research environment. In addition, the panel drew on several published studies and reports, commissioned six background papers to aid in its deliberations, and considered numerous policy statements developed by research universities and professional societies to address issues related to responsible research practices and misconduct in science.

The panel's findings and recommendations were published in March 1992 as *Responsible Science: Ensuring the Integrity of the Research Process,* Volume I (National Academy Press, Washington, D.C.).

Volume II of the panel's report, this volume, includes the six commissioned background papers as well as selected institutional guidelines, reports, policies, and procedures. These materials were considered by the Panel on Scientific Responsibility and the Conduct of Research, and they provided guidance for the development of several chapters of Volume I. All six background papers have been reviewed as part of the Academy's report review process. The institutional statements reprinted in Volume II have been selected to convey the diverse approaches for addressing different aspects of misconduct or integrity in science within research institutions.

In two cases, the panel reviewed early drafts of documents—the ethical guidelines prepared by the American Physical Society and the report of the Committee on Academic Responsibility of the Massachusetts Institute of Technology. The final reports of these organizations, which were adopted after the panel had completed its deliberations, are included here to ensure that the most current material is available for the interested reader.

Further information about institutional policies and procedures reprinted in this volume should be requested from appropriate officials at the relevant university, research laboratory, or professional society.

This study was undertaken with both public and private sector support. The following agencies of the federal government provided support for the study: the Alcohol, Drug Abuse, and Mental Health Administration, the Department of Agriculture, the Department of Energy, the Department of Health and Human Services, the National Institutes of Health, and the National Science Foundation.

The William and Flora Hewlett Foundation and the Alfred P. Sloan Foundation also awarded grants in support of the study.

Additional support was provided by funds from the National Research Council (NRC) Fund, a pool of private, discretionary, nonfederal funds that is used to support a program of Academy-initiated studies of national issues in which science and technology figure significantly. The NRC Fund consists of contributions from a consortium of private foundations including the Carnegie Corporation of New York, the Charles E. Culpeper Foundation, the William and Flora Hewlett Foundation, the John D. and Catherine T. MacArthur Foundation, the Andrew W. Mellon Foundation, the Rockefeller Foundation, and the Alfred P. Sloan Foundation; from the Academy Industry Program, which seeks annual contributions from companies concerned with the health of U.S. science and technology and with public policy issues with technological content; and from the National Academy of Sciences and the National Academy of Engineering endowments.

Contents

Part A

Background Papers

1

Fostering Responsible Conduct in Science and Engineering Research: Current University Policies and Actions

Nicholas H. Steneck

INTRODUCTION

Modern universities are commonly seen as serving three main functions. They educate students. They foster research. Through education, research, and other activities, they serve society.

As both the place where future researchers are trained and the place where much of the nation's research is conducted, universities are vital to science and engineering. A century or two ago, science and engineering were not dependent on universities and higher education. Today they are. Were universities to abdicate their roles in science and engineering, society would have to invent new institutions to train future scientists and engineers and to conduct much of the research that has become vital to the future of society.

The role that universities play in science and engineering encompasses both privileges and responsibilities. Much of the financial and social support that universities enjoy today is based on their capacity to contribute to science and engineering. The support for science and engineering is, in turn, accompanied by a great deal of autonomy, accepting the premise that as professionals, scientists and engineers should be given intellectual or academic freedom. These are the privileges. In return, society assumes that university scientists and engineers will act in ways that serve the best interests of society, however those interests are defined.

This paper describes and analyzes some of the actions universities are taking to foster responsible conduct in science and engineering research, beginning with the most passive steps, those that simply seek to establish normative rules, and progressing through three degrees of proactive policies: monitoring research, promoting discussion, and undertaking institutional reform. Throughout, the term "responsibility"

Nicholas H. Steneck is professor of history and director of the Historical Center for the Health Sciences at the University of Michigan.

is taken in its most challenging sense. It is assumed, following the stated policies of many universities, that the sought after goal is setting high standards, not minimum standards. That is to say, "responsibility" is taken to imply more than simply following the letter of the law or not engaging in blatant misconduct (plagiarizing, falsifying data, conflicts of interest, and so on). Responsibility is taken to imply discharging the duties or meeting the obligations of a professional in an exemplary way. It is this broad understanding of responsibility, rather than the narrow sense of avoiding fraud or misconduct, that is the main focus of this report, as applied to science and engineering research at universities.

Although this report focuses on science and engineering, it is important to note that there is very little about science and engineering research that is truly unique, other than its subject matter and its particular research methods. Humanists engage in funded research projects; they collect, interpret, and publish data; and they train graduate students and postdoctoral fellows. Accordingly, it is not possible when discussing university policies and actions designed to foster responsible conduct in science and engineering research to focus exclusively or even mostly on actions and policies directed to scientists and engineers. The context of university policy and action is much broader than this. However, broader policies, when combined with policies and actions that do focus more on science and engineering, can potentially do a great deal to foster responsible conduct in science and engineering research. Some of that potential is now being realized on university campuses across the country. The ways in which it is being realized form the subject of this report.

NORMATIVE RULES

The least burdensome, but not necessarily the most effective, way to foster responsible conduct in science and engineering research is to establish and publicize responsible behavior. Most professional organizations, including those for science and engineering, have published materials relating to professional conduct, such as Sigma Xi's influential *Honor in Science*[1] or the National Institutes of Health's widely used *Guidelines for the Conduct of Research.*[2] These materials have bearing on science and engineering research on university campuses and are commonly used (formally and informally) by universities for establishing standards for responsible behavior.

Universities have not been as eager as professional societies and the federal government to adopt comprehensive normative rules for responsible conduct in research.[3] Most do have general codes of

conduct that apply broadly to faculty, administrators, staff, and/or students. However, their expectations for researchers are more commonly set out within the context of administrative policies dealing with specific problems, such as fraud or misconduct in research, conflict of interest, intellectual property rights, human and animal use in experimentation, computer use, and so on. Piece by piece, these polices provide normative rules that cover most of the major concerns regarding responsible conduct in science and engineering research.

Misconduct Policies

In response to increasing concern over cases of research misconduct and spurred on by Public Health Service requirements in 1985,[4] major research universities have adopted procedures for investigating allegations of misconduct. Although differing in detail, most follow a common format. First, the importance of integrity, the rarity of misconduct, and the need to maintain high standards are stressed. Then, definitions of misconduct, and the need to maintain high standards are stressed. Then, definitions of fraud or misconduct, reaching conclusions, and, when called for, meting out punishment are discussed.

The normative portions of these policies are found in the definitions of misconduct. Some are very short—a sentence with a few examples: "The word *fraud* means serious misconduct with intent to deceive, for example, faking data, plagiarism, or misappropriation of ideas."[5]

Others include more extensive inventories of unacceptable behavior. The University of Michigan misconduct policy gives definitions for:

- Falsification of data,
- Plagiarism,
- Abuse of confidentiality,
- Dishonesty in publication,
- Deliberate violation of regulations,
- Property violations, and
- Failure to report observed fraud.[6]

A similar list is given under "Definition of Academic Misconduct" in the University of Maryland misconduct policy:

- Falsification of data,
- Plagiarism,
- Improprieties of authorship,
- Misappropriation of the ideas of others,

- Violation of generally accepted research practices,
- Material failure to comply with federal requirements affecting research, and
- Inappropriate behavior in relation to misconduct.[7]

Variations of these and other lists, along with explanations and examples, are found in most university policies for dealing with misconduct in research.

The bounds established for unacceptable behavior by inference provide normative guidelines for acceptable behavior. For example, the Maryland misconduct policy defines "improprieties of authorship" as:

> Improper assignment of credit, such as excluding others; misrepresentation of the same material as original in more than one publication; inclusion of individuals as authors who have not made a definite contribution to the work published; or submission of multi-authored publications without the concurrence of all authors.[8]

This statement could easily be rewritten as a set of normative rules for responsible behavior in research: researchers should properly assign credit to others for the work they have done; present original material in only one publication; include in publications only the names of those who have contributed to research; and include the names of coauthors in publications only after seeking permission to do so. In this way, the reactive misconduct policies in place in the major research universities can become proactive statements of expected or normative behavior in research.

Conflict-of-Interest Policies

Normative statements about research can also be found in conflict of interest policies. Again, as with the misconduct policies, the primary intent is to clarify what should not be done, but by inference or logical extension, proper conduct is also defined. The form of conflict of interest policies is not as uniform as that of misconduct policies, thus making it more difficult to identify the normative statements about research conduct. Nonetheless, these policies do provide another source of information that is applicable to scientific and engineering research.

Researchers at Ohio State University can receive guidance on honoring confidences gained during research if they know that their university's conflict of interest policy refers them to the State of Ohio government code of ethics, which states that:

> No present or former public official or employee shall disclose or use, without appropriate authorization, any information acquired by him in the course of his official duties which is confidential because of statutory provisions, or which has been clearly designated to him as confidential when such confidential designation is warranted because of the status of the proceedings or the circumstances under which the information was received and preserving its confidentiality is necessary to the proper conduct of government business.[9]

If "university business" is construed as "government business," then researchers should understand that information given in confidence, such as information received when reviewing manuscripts for publication and grant requests for peer review, cannot be disclosed or used for personal gain. The State of Ohio statutes thus provide normative rules for handling manuscripts, shared data, student theses, and the like: researchers should honor confidences and not use or disclose information received in confidence without getting permission to do so.

Researchers at Pennsylvania State University can find normative rules for directing graduate students and postdoctoral fellows in their institution's conflict of interest policy, which states that it is wrong to direct students into research activities that are designed primarily to serve personal interests rather than to further their [the students'] scholarly achievement."[10] While not easy to apply in difficult cases, i.e., when there is a genuine conflict between the obligations to a grantor and to those hired under the grant, one normative rule that applies to such situations is again made clear: researchers who serve as mentors to students assume obligations to those students and should not compromise these obligations for personal gain or career advancement.

In the same vein, a set of questions set out in a Johns Hopkins University School of Medicine conflict of interest policy statement provides, again by inference, a fairly sophisticated set of guidelines to help researchers sort out responsibilities:

> Does the secondary commitment detract from the ability of a faculty member to discharge his primary obligations to The Johns Hopkins University School of Medicine?
>
> To what extent is the opportunity for outside commitment offered because of the University affiliation and thus, to what extent should the financial rewards be shared with the University?[11]

The normative rules inferred in these questions and the subsequent explanations help clarify for researchers how they should sort out their obligations when they have responsibilities to more than one constituency.

Miscellaneous Research Policies and Other Documents

Similar guidance can be found in other research policies and documents relating to the conduct of research on university campuses. At the University of Michigan, the Division of Research Development and Administration provides researchers with a document that describes, summarizes, or contains verbatim policies and procedures relating to:

- conflict of interest,
- the responsibilities of project directors,
- account and grant administration,
- export control restrictions,
- the transfer of university equipment,
- restrictions on lobbying, and
- biosafety monitoring.

The latter refers to policies relating to human subjects research review, animal research, radiation safety, biological research review (recombinant DNA research), and occupational safety and environmental health.[12] Subsequent forms and/or policy statements issued by the human- and animals-use committees, the radiation safety committee, and so on provide further guidance on responsible conduct in research, as, for example, questions and guidance on the humane use of animals (discussed below under monitoring).

The normative rules scattered throughout university policies and documents relating to science and engineering research are an important first step for promoting responsible conduct. In defining what is illegal, unethical, and irresponsible, they suggest what is legal, ethical, and responsible. They also provide guidance on fiscal responsibility, safety, the responsible use of human subjects, the humane treatment of animals, the use of computers, the handling of data, and other matters. Therefore, even those universities that do not have comprehensive codes of ethics for science and engineering research, which is the majority, do provide researchers with guidelines for responsible conduct. If these "guidelines" are combined with the various federal regulations and professional statements about professional conduct in research, the total package does provide fundamental rules for determining what is responsible and irresponsible in the conduct of research.

As basic as this first step might seem, it is without question needed. There are researchers who do not know what is meant by plagiarism or the ownership of ideas. There are researchers who believe that words and phrases can be borrowed from someone else's publications without attribution as long as original ideas are not plagiarized.[13] There are

researchers who believe that they "own" not only the data generated in their laboratories but also the ideas. Practicing researchers do not always understand the basic normative rules that help to determine responsible conduct in research. Students and beginning researchers may have less understanding. Publications such as Sigma Xi's *Honor in Science,* the codes of conduct published by professional societies, and the research policies of universities are thus useful documents for raising consciousness and establishing a knowledge base for fostering responsibility in research.

The effectiveness of normative rules in fostering responsibility is, however, limited. First, as disjointed and piecemeal as they are on most campuses, they do not make it easy for researchers to comprehend and consider all the responsibilities raised by modern science and engineering. As conditions exist on many campuses, the burden for integrating rules and resolving contradictions is often left to the individual. Given all of the other pressures on modern-day researchers, it may not be reasonable to expect them to read through three, four, or more policies to find out what they should or should not be doing.

In addition, simply stating how researchers *should act* in no way guarantees that they *will act* in this way. This is particularly true if the normative rules aim at unrealistically high standards. Researchers today are rarely able to meet all of their obligations in an exemplary way. More commonly obligations exceed the time available to meet them. Increasing competition for research funds means that more hours must be spent writing and submitting grant applications. More time spent on applications means less time working in the laboratory, advising or teaching students, and reviewing manuscripts. Corners have to be cut. What are needed, therefore, in addition to normative rules for ideal behavior, are guidebooks for how to survive in the increasingly competitive world of academic science and engineering research.

Policy statements about normative or ideal conduct become useful when they are explained, elaborated upon, and illustrated with examples. They also become useful when they deal with the difficult rather than the obvious. There seems to be little doubt that most researchers do not, and know that they should not, manufacture data or forge experimental results. It may be less clear, however, how results should be presented in grant applications, when "enough data" are needed to give confidence that a project will succeed but "enough work" remains to be done to justify getting the grant. How "preliminary" should "preliminary research" be?

To the extent that most normative rules leave many questions unanswered, they fall short of the fostering that is needed to render science and engineering research as responsible as it could be. They do

provide important general rules. They also satisfy legal requirements and soothe consciences. But this approach to fostering responsible conduct in research may not be effective, particularly if the rules are not accompanied by other actions. Given the pressures on researchers today, they often are not only busy but also cynical. When their laboratory space and salaries depend on the research dollars generated and their promotions on the number of articles published, they can have a hard time believing the normative rules are anything more than guidelines for staying out of trouble. If this is the case, the sense of responsibility that researchers have will be minimal at best. Recognition of this fact has prompted universities to take additional steps to foster responsible conduct in research.

MONITORING RESEARCH

Universities today routinely monitor their research programs, among other reasons because they are required to do so. They must ensure fiscal responsibility. They must supervise the use and treatment of animals and human subjects. They must comply with environmental and workplace regulations. And they must enforce their own policies regulating such activities as classified and proprietary research. Monitoring is the second way universities foster responsible conduct in science and engineering research. It is an active rather than a passive way to foster responsibility.

At the University of Michigan, one monitoring process for research is triggered by an internal form that must be completed by all researchers prior to submitting projects for support (internal or external). The form lists 13 areas of concern that must be checked "yes" or "no."[14] If "yes" is checked for an area, subsequent information or action is required. For the more important areas, such as the use of human subjects, vertebrate animals, and radioactive materials, the researcher is referred to a series of special peer-review committees for approval. These committees review the applications both for their compliance with specific laws and regulations and, in some cases, for problems that could raise questions about responsibility.

For example, researchers using vertebrate animals in research are required to submit an additional form to the University Committee on the Use and Care of Animals. This form asks researchers to explain why they must use animals in their research, why they cannot use "lower" animals or fewer animals, and why the amount of pain inflicted, if any, cannot be reduced. They are also required to identify the person in charge of the animals during experimentation, to give the latter's

qualifications, and to indicate how the work will be supervised. The form on which this information is recorded contains explanations of each of the questions, which, in essence, provide brief lessons in the responsible use of animals in research. If the answers given on the forms are not satisfactory or if they raise questions about the use of animals, the researcher is asked to appear before the Use and Care Committee to discuss the project. In this way, researchers are encouraged to think about and justify their responsibilities when they use animals in research and, simultaneously, their use of animals is monitored.

The same procedure is followed for the use of human subjects at Michigan, with the university having a total of twelve peer committees to review grant requests prior to submission.

Again, detailed questions are asked that compel researchers to think about their responsibilities before they begin their work. Medical researchers must tell whether they are using subjects that are:

- Children (age < 18),
- Pregnant women,
- Fetuses,
- Mentally incompetent,
- [Of] questionable state of mental competence or consciousness,
- [A result of] human in vitro fertilization,
- Prisoners or other institutionalized persons, or
- Others who are likely to be vulnerable.[15]

If they are, they must provide a "rationale for and justify their [each subject's] involvement."[16] Providing the rationale again compels researchers to think about their responsibilities. If a rationale is unclear of unsatisfactory, then the researcher must discuss the research with colleagues on a review committee. The human subjects committees also require justifications for the use of human subjects, explanations of the likely benefits to the subjects from the research, and a description of the steps that have been taken to minimize risks—requirements that again compel researchers to think about their responsibilities and, in gray areas, to discuss their responsibilities with colleagues.

Similar monitoring of responsibility in science and engineering research takes place in other ways on most university campuses. Researchers and universities are required bylaw to monitor the use of radioactive materials, some biological materials, and hazardous chemicals. Most universities also now routinely require researchers to file conflict of interest statements and property rights statements with every grant application or on some regular basis. The monitoring

inherent in these requirements forces researchers to think about their responsibilities in ways that might not otherwise occur to them and to think about relationships and obligations that might otherwise be ignored.

Responsibility is also routinely monitored through peer review for promotions or annual reviews for salary increases. These reviews provide faculty with opportunities to monitor the work of their colleagues, looking, for example, for the possibility of duplicate publication of the same material, misattribution of authorship, or the sloppy use/misuse of data. Similarly, student evaluations are routinely used to determine how well faculty are discharging their duties as teachers. Such evaluations are not used, but could be adapted, to determine how well faculty discharge their duties as research mentors.

Asking researchers in advance how they will exercise responsibility is intrusive. It requires an investment of time to answer questions for no apparent reason. Moreover, in subtle ways it represents a shift in burden. Rather than presuming that researchers act responsibly and then raising questions when there is reason to believe someone has acted irresponsibly, asking researchers to discuss their research conduct in advance or to be subjected to constant scrutiny during research places a burden on them to demonstrate that they will act or are acting responsibly. In other words, monitoring presumes guilt rather than assuming innocence. It is also compulsory rather than voluntary. It requires that certain standards be met rather than making responsibility a matter of personal initiative. As such, monitoring does not find a comfortable home in professional communities that are accustomed to openness and trust.

Why, for example, should researchers be required to demonstrate in advance how they will comply with rules, regulations, and standards for responsible behavior, if those rules, regulations, and standards are clearly spelled out? We do not require the same researchers to file forms before leaving for work in the morning explaining that they will travel in a licensed car using seat belts and driving at safe, legal speeds. We presume that they know the laws and will obey them, intervening only when there is reason to believe that the law is not being obeyed. Similarly, for science and engineering to develop freely and in a collegial atmosphere, some degree of responsibility must be assumed. If every aspect of research were subject to monitoring, either in advance or in process, the burdens of time and cost could rapidly overwhelm the research enterprise.

For these reasons, it is unlikely that universities will or should use monitoring to any great extent to ensure that research is undertaken responsibly. At the present time, active monitoring is undertaken only

when it is required, e.g., in the use of animals, human subjects, dangerous chemicals, conflict of interest, and so on. If used sparingly, primarily as a tool to get researchers to think about particular issues such as the use of animals in research, monitoring can be an effective device for fostering responsible conduct in science and engineering research. If overused, monitoring and the enforcement of compulsory rules of behavior will rapidly become a burden that can destroy the freedom and collegiality that are essential to the vitality of science and engineering research in particular and all academic life in general.

PROMOTING DISCUSSION

If universities do not directly check responsibility, through monitoring, how else can responsibility be fostered? A third approach to encouraging responsibility is to ensure that researchers at least are aware of the normative rules for undertaking research by bringing the rules to their attention and promoting discussion. At the University of Michigan Medical School

> all faculty receive and have the obligation to read *Guidelines for the Responsible Conduct of Research* (1989). … This document is also distributed to all Department administrators for subsequent distribution to all postdoctoral fellows, graduate students and research technical staff.[17]

If reading and being informed are all that are required for ensuring responsibility, then this simple policy will go a long way toward fostering responsible conduct in science and engineering research.

Increasing numbers of research universities have chosen to be more aggressive in bringing the responsibilities of researchers to their attention. Their approaches vary, depending on where within administrative structures initiatives derive and how they are most conveniently implemented. However, the goal of each is basically the same: to foster discussion.

Harvard University provides a good example of a top-down approach to promoting discussions of professional ethics, including research ethics. The former president of Harvard University, Derek Bok, has long been a proponent of fostering discussions of ethics in the university setting.[18] He was instrumental in raising funds to establish two major professional ethics programs at Harvard, one in the Kennedy School of Government, the other a separate Program in Ethics and the Professions. The latter fosters scholarly research on professional ethics and serves as a resource for other units seeking to take steps to foster professional responsibility.[19] These and other influences have prompted

the medical faculty to revise their rules for research conduct and to join with others in sponsoring symposia on research ethics.[20] The result will undoubtedly be an increased level of discussion of the importance of and special problems pertaining to research conduct. How much impact this will have on students and faculty remains to be seen.

The University of Colorado, Boulder, has taken a different approach to fostering discussions of professional responsibility in research. The Regents of the University of Colorado system vested authority for dealing with research misconduct in a series of standing committees. Besides conducting investigations of "suspected or alleged misconduct," these committees are charged by the regents to "promote exemplary ethical standards for research and scholarship."[21] The Boulder campus decided to form one joint Standing Committee on Research Misconduct and included "Education of Academic Community" in its charge. The written definition of this task reads:

> Deans, directors, chairs and graduate advisors shall be reminded annually of *University of Colorado Administrative Policy on Research Misconduct and Authorship* and their responsibility to inform all faculty, students, and staff of (1) the need for integrity in research performance and (2) the role of the Standing Committee in considering allegations of research misconduct.[22]

In practice, the committee has adopted a much more ambitious role in fostering responsible conduct in research.

Under the leadership of Alan Greenberg, associate professor of mechanical engineering, the Boulder campus's Standing Committee on Research Misconduct is playing down its policing duties in favor of a more positive image. The committee plans to send a short, personal letter to all faculty members describing its goals and expressing a desire for dialogue. The letters are being sent to faculty because they are seen as the key to a responsible research environment. Later, through faculty and appropriate administrative units, the committee hopes to expand its reach to graduate education. In each case, the committee's main goal will be to make researchers (and future researchers) aware of and responsive to the existing normative rules for exercising responsibility in research. The committee is not seeking to write new rules; it is simply trying to make researchers more aware of the rules that are already in existence.[23]

The impetus for more discussion at Colorado comes from within. A supportive administration and an ambitious committee have determined that researchers should and hopefully will spend more time talking about their responsibilities as researchers. At other universities, there is more discussion today than a few years ago, in part as the result of an outside influence—the National Institutes of Health's new

requirement for the inclusion of some material on "the responsible conduct of research" in institutional training programs. The requirement states that

> all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program.[24]

Those universities that have training grants or are anticipating applying for them are now in the process of planning "formal and informal activities" that will meet this objective.[25]

One way to satisfy the new NIH requirement is to foster discussions about responsibility in research settings. Several years ago, Floyd Bloom of the Scripps Clinic and Research Foundation decided this was precisely what he needed in his laboratory and began planning special sessions to discuss problems that had arisen or could arise in the course of research. The special sessions were well received. Three have been turned into video tapes that are now circulated to others with similar needs.[26] If other universities follow this lead, the new NIH training grant requirement should at a minimum serve to promote discussions of the normative rules for responsible conduct in science and engineering research. If the rules are rigorously enforced, the impact could be even greater.[27]

In evaluating the role of discussion in fostering responsibility, an important distinction needs to be made. "Responsibility" is both an academic subject and a matter of practical importance. As an academic subject, "responsibility" can be studied, researched, discussed, and written about in the same way as any other academic subject. There is more than enough that is controversial in the consideration of conflict of interest, the ownership of ideas, the responsible use of humans or animals for experimental purposes, or any other aspect of research to engage scholars who specialize in research ethics in discussion for years to come. However, "responsibility" is also a matter of practical importance. Every day, in small and large ways, individuals who engage in science and engineering research must decide for themselves what it means "to be responsible" and then act. For them, responsibility is not a matter of intellectual curiosity but of practical necessity.

At the present time, there is no lack of academic or scholarly discussions of research ethics, both in general and as applied to science and engineering.[28] The major science and engineering journals routinely publish articles and editorials on the responsibilities of researchers. Most major scientific and engineering meetings have had sessions devoted to the responsibilities of researchers. Scholars who study the

social, ethical, and professional side of science and engineering publish articles on responsibility in research. Science educators discuss ways to foster responsibility through science education. The researcher who wants to become better educated on responsibility in science and engineering has no lack of material to consult. The problem that exists today, if there is a problem, is getting this material to researchers who barely have time to keep abreast of developments in their own fields.

It therefore seems logical to assume, for convenience if for no other reason, that the discussion of responsibility in science and engineering research should begin in the settings in which that research is undertaken, with mentors and their advisees talking about their work, the way it is being undertaken, and its consequences. It is in these settings that the norms of professional conduct are set and passed on. The discussions can be informal and personal. They can also be enriched by adding some organization and involving others, who bring different perspectives to bear on difficult problems. However they are planned or undertaken, the important point is that discussions of responsibility in research should begin in the laboratory and in the classroom. They should, however, not end there.

There are at least two problems that arise if the discussion of responsibility is left exclusively to research settings. First, relying on discussions in research settings to address problems of responsibility is not efficient. To get different points of view on difficult problems it is usually necessary to involve philosophers, social scientists, lawyers, theologians, and others who are removed from the problems and can bring special expertise to bear on them. Generally the number of "outsiders" who are prepared to discuss issues relating to responsibility in science and engineering research is limited. To ask them to come to every science and engineering laboratory or department on a campus is not realistic.

A second problem is that research settings may not be conducive to the discussion of some difficult problems that arise in these settings. Junior researchers or graduate students who feel their work is not being fairly cited in a publication may not feel comfortable discussing authorship with their mentors. Students who disagree with a mentor's way of interpreting data may have qualms about raising this issue in a laboratory meeting. Ideally, of course, discussions should be open to any questions or points of view, but settings in which there are problems associated with responsibility are not ideal.

For these and other reasons, other, more generic settings need to be provided for discussions of responsibility in science and engineering research on university campuses. Departmental and university forums allow opportunities for researchers to consider and talk about their

responsibilities with colleagues in other fields. Lecture series are a useful device for raising consciousness. Orientation programs for new graduate students, postdoctoral fellows, and even faculty can provide information and along with that the message that responsibility in research is taken seriously at the university. There are many ways to promote discussion of issues associated with responsible conduct in science and engineering research. The more ways a university tries to promote discussion, the stronger the message it sends about its commitment to responsibility.

UNDERTAKING INSTITUTIONAL REFORM

As efforts to promote discussion have grown, new institutional arrangements have emerged for their support and coordination. The strategies employed differ significantly from campus to campus. Their goals are basically the same: to provide opportunities for the consideration of professional responsibility and related issues within the normal context of education and university life.[29]

It is impossible in this paper to discuss all of the different ways in which the professional responsibility of scientists and engineers is being addressed through institutional reform. Changes have been suggested for the entire spectrum of science education, from elementary schooling to postdoctoral studies, clinical training, and even continuing education. This section provides a few examples, focusing on advanced undergraduate education, graduate education, and two campuswide programs.

Undergraduate Education

Beginning in the late 1960s and early 1970s, hundreds of courses were instituted at the undergraduate level to address what became known as STS (science, technology, and society) studies. In the 1980s, some of these courses added material dealing with professional responsibility.[30] To provide additional support, a significant number of universities (over 100) developed STS programs. STS programs were and remain particularly popular at schools that train large numbers of scientists and engineers, such as MIT, the Illinois Institute of Technology, and Rensselaer Polytechnic Institute, to name only a few.[31] For some students, the discussion of professional responsibility fostered by undergraduate STS programs begins their introduction to the norms

of professional life as scientists and engineers. For others, it may be not only their first but also their last formal contact with these issues.

A few schools have gone beyond the single-course/program approach and attempted to change completely the way undergraduates are educated. In 1986, the University of Minnesota College of Agriculture received a two-year grant from the Kellogg Foundation to formulate a curriculum that would provide students with "enhanced learning opportunities in leadership, communication, problem identification and solution, teamwork skills, interdisciplinary approaches, nutritional issues, environmental awareness, societal values and international perspectives." The Kellogg funds were used to provide students with opportunities for discussion, personal interaction, and case-based learning throughout the curriculum. As with all such programs, the long-term effects will be difficult to measure. Short-term, Project Sunrise's directors are pleased enough with the results to heartily recommend their approach to others.[32]

Research, per se, is generally not a major component of undergraduate education. Some undergraduates have research experiences, but they usually do not start thinking seriously about research until graduate school and their first independent work as researchers. Nonetheless, attitudes and knowledge gained during the undergraduate years can play a major role in determining the future responsibility of scientists and engineers. Attitudes about personal and social responsibility gained during undergraduate years can be transferred to graduate work and the laboratory. Knowledge about professional life and its role in society can provide a framework for questioning and seeking solutions when potential problems arise in the research environment. Just as basic mathematics, chemistry, physics, or biology can be essential for careers in science and engineering, so too basic knowledge about the social and values dimensions of science and engineering can be essential ingredients for being a responsible scientist or engineer. For many scientists and engineers, the only opportunity they have to gain such knowledge comes during their undergraduate years. This is particularly true for engineers, who can more easily engage in research without pursuing graduate studies.

Graduate Education

Graduate education (including professional and postdoctoral studies) provides a second setting for formal instruction on professional responsibility, either in general or as related specifically to science and engineering research. As noted above, it is during these years that

scientists and engineers begin to think seriously about research.[33] It is also during these years that they have increasing opportunities to consider questions of responsibility. At the present time, most instruction on responsibility at the graduate level takes place informally through discussions in laboratory settings and between mentors and their students (see "Promoting Discussion," above). A few schools have instituted special programs, recognizing that graduate education provides an ideal atmosphere for more formal instruction on responsibility.

The University of Texas Health Science Center requires that all entering graduate students take a 17-week course titled "Philosophical Issues in Science." The course meets weekly for one hour, at lunchtime. To encourage participation, the Dean of the Graduate School of Biomedical Sciences, William Butcher, provides a free lunch and some course materials. The course covers a wide range of topics, from the history and philosophy of science to discussions of research techniques, honesty in science, animal and human experimentation, and laboratory safety. As currently taught by Stanley Reiser, M.D.-Ph.D., it continues to draw support, both from students and administration.[34]

Adding formal instruction on responsibility and related issues at the graduate level is problematic. It is at this level that educational paths start to diverge and specialize dramatically. For the most part students are no longer in large, common classes. Their programs are full, their time limited, and their needs more focused on particular problems. For these and other reasons, there has not been a parallel STS movement at the graduate level. Still, if the Texas experience is at all indicative, there clearly is room for some instruction in common about responsibility and related problems at the graduate level.

Campuswide Programs

The promotion of the activities discussed in this section and previous sections can be accomplished more effectively if there is some coordination. It is for this reason that a few campuses have sought to establish campuswide programs aimed at one or more aspects of the problems and issues associated with professional responsibility.

Emory University has recently established its Center for Ethics and Public Policy and the Professions under the directorship of Robert DeHaan, professor of anatomy and cell biology. Similar programs have been or are being established on a number of campuses to encourage and support the discussion of professional ethics.[35] The Emory center has formulated a set of guidelines for responsible conduct in scholarship, since the center is now fully operational, which will include major

sections on scientific research. It is also planning major educational initiatives, working through a series of subcommittees of the center's main Steering Committee. One of the educational initiatives will likely be targeted at graduate education. Other initiatives will target specific audiences or problems, such as a program ("AIDS Training Network") designed to help physicians and researchers consider professional problems raised by the AIDS epidemic. Overall, the Emory center is focused squarely on fostering responsibility, based on the assumption that future scientists, physicians, and other professionals (Emory does not have a school of engineering) should have read and thought about their responsibilities before they become and as they are becoming professionals. The reforms anticipated will be campuswide.[36]

The Poynter Center for the Study of Ethics and American Institutions at Indiana University has for a number of years taken an active campus and national role in promoting discussions of professional ethics. In line with similar centers, it has sponsored courses; encouraged curricular innovation, both on its own campus and other campuses; and organized a number of national symposia. Its director, David Smith, is also the prime organizer of the new Association for Practical and Professional Ethics. The Poynter Center has recently begun a major new initiative, "Catalyst: Indiana University's Program on Ethics in Research," which is seeking to "increase awareness about research ethics issues among students and faculty, through discussion and through the introduction of course units on research ethics. …"[37] The impact is intended to be campuswide, introducing the discussion of research ethics issues into as many different forums and settings as possible, but with some direction and coordination from a single program.

OBSERVATIONS AND CONCLUSIONS

The examples given in this report leave little doubt that universities are seeking to foster responsible conduct in research. The ways vary considerably, from simply publishing rules for appropriate and inappropriate conduct to bringing the discussion of responsibility into research settings, changing courses of study, and instituting campuswide programs. The variations in turn reflect differing commitments and opinions on need. There are those who believe that there is very little that universities can do to foster responsible conduct among scientists, engineers, or any of the other professionals they train or hire. There are others who believe that universities not only can make a difference but also have an obligation to do so. To test whether this range of

opinion exists, all one has to do is raise the question of making more room for ethics in the curriculum at a meeting of science or engineering faculty on any university campus.

Those who favor minimal involvement tend to believe that responsibility is learned early in life and outside the classroom, not in university settings. Norms such as honesty, integrity, and reliability, it is argued, are applicable to life in general and are therefore fostered (or not fostered) well before individuals make decisions to become researchers. For those individuals who do eventually become researchers, their sense of responsibility (of morality) adopted early in life may be all that matters when they become scientists and engineers—an assessment that leads some to conclude that responsible researchers are "born," or at least trained early, if not "made."

While it may be true that early education can guide scientists or engineers through some sticky professional problems, it certainly will not help them resolve problems that involve genuine ethical dilemmas. What should a researcher do if she believes she can see a pattern in data being collected but is not sure? What should an engineer do if he is asked to work on a project that might be injurious to the environment or put large numbers of persons out of work? What should clinical researchers or physicians do if they are concerned about the dangers of AIDS research? How should priorities be sorted out when an unread thesis, an unreviewed journal article manuscript, and an unwritten research proposal are all sitting on a scientist's or engineer's desk demanding attention and the time for that attention is limited? Even those who honestly want to act responsibly to follow cherished principles are at times put in situations where principles and general attitudes about responsibility give no clear answers.

Pressures on researchers are real. Data must be interpreted, written up, and published. Names must be included or not included on journal articles. Experimental results are property that someone owns. The ownership of ideas is important; it has a bearing on promotion, and ideas can sometimes be sold for profit. Conflicts of interest exist. Future scientists and engineers must be trained. Public and private interests do compete. Researchers have responsibilities to more than one constituency. Superiors do not always make responsible decisions. The modern practice of science and engineering is complex. It is unlikely that anyone can intuitively know how to act or will instinctively want to act responsibly in every situation. Therefore, even if it is true that basic moral character is set before students come to universities and that basic moral character is what determines whether scientists, engineers, and other researchers act responsibly in research settings,

there is still much that universities can do to remind and clarify for researchers what it means to be "responsible."

How much universities will ultimately do to foster responsible conduct in science and engineering research will, no doubt, remain proportional to perceived needs. As long as the present public concern continues about fraud in science, conflicts of interest by researchers, the questionable "good" of some projects, the high cost of research, and other problems, it is likely that universities will seek to do more to foster responsibility. Moreover, whether universities believe so or not, there can be no doubt that the public believes that universities have obligations to foster responsibility, including in science and engineering research.

The stance universities take on their obligations to foster responsibility will, in turn, ultimately determine how much is done. This fact became apparent in talking with colleagues on different campuses, some of whom had active programs on their campuses to foster responsible conduct in research and others who had tried to develop such programs but failed. Where there was a supportive atmosphere, programs, courses, discussions, and so on flourished. Where supportive atmospheres have been lacking, some very well intentioned efforts have failed.

What are the ingredients of a supportive atmosphere? Ideally, an administration that is willing to devote some of its time, attention, and support to activities that will foster responsible conduct in science, engineering, and scholarship in general, plus a faculty that has the willingness to devote some of its time and energies to students, campus service, and discussion of the role of science and engineering in modern society. Where either one of these ingredients has been lacking, steps to foster responsibility have been slow in coming. The best-intentioned faculty have a difficult time making changes without administration support. Administrators cannot make changes without the support of faculty, unless they have been able to raise large amounts of money to make changes.

The atmosphere present on any one campus is, of course, the product of many influences.[38] The size of research budgets has a great deal to do with how much time researchers have to devote to students, to service, and to thinking about anything other than how to get the next grant. The type of research undertaken can influence the way groups of researchers act. The pressure or incentives for advancement, some of which are internal, others external, influence how researchers spend their time. For administrators, research is only one of their concerns. They have to listen to many voices and respond to many calls for action, some of which are louder than others. In sum, the amount that can be

done to foster responsible conduct in science and engineering research is dependent on many factors, not all of which can be controlled or predicted with any certainty.

Granting that there is uncertainty, it is nonetheless instructive, encouraging, and exciting to learn of and think about the variety of actions that faculties and administrators on university campuses are taking to ensure that science and engineering research will remain responsible activities in the future. Their efforts surely will not be irrelevant to the role science and engineering play in American society in the decades that lie ahead.

NOTES

1. Sigma Xi, 1986, *Honor in Science*, Second edition, Sigma Xi, New Haven, Conn.

2. National Institutes of Health (NIH), 1990, *Guidelines for the Conduct of Research at the National Institutes of Health*, NIH, Bethesda, Md.

3. There are exceptions to this generalization. For example, Harvard University has a general set of guidelines that gives brief normative rules under the headings "Supervision of Research Trainees"; "Data Gathering, Storage, Retention"; "Authorship"; "Publication Practices"; and "Laboratory Guidelines." See Harvard University Faculty of Medicine, 1988, *Guidelines for Investigators in Scientific Research*, Harvard University, Cambridge, Mass. Additional guidance can usually be found in handbooks on administrative procedures published by the offices that oversee research (for an example, see n. 12 below).

4. U.S. Department of Health and Human Services, 1985, *Interim Public Health Service Policies and Procedures for Dealing with Possible Misconduct in Science*, PHS, Washington, D.C.; following directives in the Health Research Extension Act of 1985 (42 U.S.C. section 289B), which required that each entity receiving a grant submit with its application assurances that (1) it has established procedures for handling allegations of misconduct, and (2) it will report any allegation to PHS.

5. California Institute of Technology, 1989, *Policy on Research Fraud*, California Institute of Technology, Pasadena.

6. University of Michigan, 1986, *Interim Policy Statement on the Integrity of Scholarship and Investigating Allegations of Misconduct in the Pursuit of Scholarship and Research*, University of Michigan, Ann Arbor; based on the earlier report by the Task Force on the Integrity of Scholarship, 1984, *Maintaining the Integrity of Scholarship*, University of Michigan, Ann Arbor.

7. University of Maryland at Baltimore and the University of Maryland, Baltimore County, 1989, *Policies and Procedures Related to Allegations or Other Evidence of Academic Misconduct*, University of Maryland, Baltimore, pp. 2-4. Variations of these lists and brief discussions of misconduct can be found in: University of California, Los Angeles (UCLA) School of Medicine, 1988, *Policy and Procedures for Review of Alleged Unethical Research Practices*, UCLA, Los Angeles; University of Chicago, 1986, *Report of the Provost's Committee on Academic Fraud*, University of Chicago, Chicago; University of Colorado, 1988, *Administrative Policy Statement: Misconduct in Research and Authorship*, University of Colorado, Boulder; University of Minnesota, 1989, *Policies and Procedures for Dealing with Fraud in Research, Interim Administrative Policy*, University of Minnesota, Rochester; and University of North Carolina (UNC), 1989, *Policy and Procedures on Ethics in Research*, UNC, Chapel Hill.

8. University of Maryland, *Policies and Procedures*, 1989, p. 2.

9. State of Ohio, "The Ohio Revised Code, Chapter 102: Public Officers—Ethics," p. 7, as referred to in Scott, M. H., 1984, "Ethical Standards," a memorandum, Ohio State University, Columbus, Ohio.

10. Pennsylvania State University, 1989, *Policy on Conflict of Interest*, Pennsylvania State University, College Park.

11. Johns Hopkins University School of Medicine, 1984, *Conflict of Commitment Guidelines for Full-Time Faculty*, Johns Hopkins University, Baltimore, pp. 6, 8.

12. University of Michigan, 1990, *Administration of Sponsored Projects*, Division of Research Development and Administration, University of Michigan, Ann Arbor (revised annually). Not mentioned on this list, but also relevant, would be rules on computer use and the treatment of employees. To one extent or another, all major research universities have similar sets of rules. See, for example, Stanford University, 1990, *Research Policy Handbook*, Stanford University, Palo Alto, Calif. The handbook is "comprised of selected policy statements and guidelines which support the research enterprise at Stanford."

13. It is interesting to note that some university policies on one or another aspect of responsible conduct are generously borrowed from the policies already adopted at other universities without giving attribution. The bounds between undisputed plagiarism and the "acceptable borrowing" of words, phrases, and introductory and descriptive materials are not as easily drawn as some imagine.

14. The 13 areas are use of human subjects; use of vertebrate animals; use of radioactive materials; carcinogens; recombinant DNA; biological hazards; proprietary materials; classified research; other restrictions on openness of research; subcontracting; potential conflict of interest; work off university property; and study of another country. See University of Michigan, n.d., *Proposal Approval Form*, University of Michigan, Ann Arbor.

15. University of Michigan Medical School, n.d., *Application to the Institutional Review Board (IRB) for Approval of Research Involving Human Subjects*, University of Michigan, Ann Arbor.

16. University of Michigan, *Application to the IRB*, n.d.

17. University of Michigan Medical School, 1989, *Program in Principles of Scientific Integrity for National Research Service Award (NRSA) Applicants*, University of Michigan, Ann Arbor; and University of Michigan Medical School, 1989, *Guidelines for the Responsible Conduct of Research*, University of Michigan, Ann Arbor.

18. Bok, D., 1982, *Beyond the Ivory Tower: Social Responsibilities of the Modern Research University*, Harvard University, Cambridge, Mass; see especially chaps. 6 and 7.

19. Interview, Dennis Thompson, director, Program in Ethics and the Professions, Harvard University, November 1990.

20. Interview, Morton Litt, Office of Research Issues, Harvard University Medical School, November 1990.

21. University of Colorado, n.d., *Administrative Policy Statement: Misconduct in Research and Authorship*, University of Colorado, Boulder.

22. University of Colorado, Boulder, 1990, "Operating Rules and Procedures of the Standing Committee on Research Misconduct," October 1.

23. Interview, Alan Greenberg, Mechanical Engineering, University of Colorado, Boulder, November 1990.

24. National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), 1989, "Requirement for programs on the responsible conduct of research in National Research Service Award institutional training programs," *NIH Guide for Grants and Contracts* 18(December 22):1. The requirement was effective July 1, 1990.

25. The deadline for the first applications affected by this rule was January 10, 1991. It will therefore be some months before the initial impact of the new requirement can be reviewed. For the NIH's initial thoughts on compliance, see Department of Health and Human Services (DHHS), 1990, *PHS Workshop: Education and Training of Scientists in the Responsible Conduct of Research*, March 8-9, Public Health Service, Washington, D.C.

26. Based on presentation given by Floyd Bloom at the workshop described in DHHS, *PHS Workshop*, 1990, and on subsequent telephone conversations.

27. Universities have also taken action in response to the NIH requirements for dealing with misconduct in research (see n. 5 above). However, this requirement simply calls for rules to deal with misconduct and therefore does not emphasize fostering responsible conduct.

28. For example, programs such as the recent symposium titled "Ethical Issues in Research," sponsored by the FIDIA Research Foundation, Georgetown University, April 29-30, 1991.

29. The institutional reforms discussed below generally have foci that are much broader than science and engineering per se. However, fostering responsibility in sciences and engineering research certainly finds a home under the broader umbrellas of these reforms.

30. For a description of one such course recently developed at Florida State University, see Gilmer, P. J., and M. Rashotte, 1989/1990, "Marshalling the resources of a large state university for an interdisciplinary 'science, technology, and society' course," *Journal of College Science Teaching* (December/January):150-156.

31. For a summary of the development of STS studies, focusing particularly on research, see Hollander, R., and N. Steneck, 1990, "Science- and engineering-related ethics and values studies: characteristics of an emerging field of research," *Science, Technology, and Human Values* 15 (January):84-104.

32. University of Minnesota College of Agriculture, 1990, *Project Sunrise Third Annual Report: July 1989 - June 1990*, University of Minnesota; and conversations with Mark L. Brenner, associate dean, University of Minnesota Graduate School.

33. It is recognized that there are differences between science and engineering. Generally, engineers get more deeply into their subjects during their undergraduate years than do scientists.

34. Presentation given by R. William Butcher at the workshop described in DHHS, *PHS Workshop*, 1990, and subsequent conversations with Stanley J. Reiser.

35. Other broad programs have been or are being established at Indiana University, Dartmouth College, Wayne State University, Harvard University, and Princeton University, to mention only a few. Special discipline- or profession-based programs (e.g., medical ethics or engineering ethics) exist on many campuses.

36. Interview, Robert DeHaan, Department of Anatomy and Cell Biology, Emory University, November 1990, and a brief conversation with Billy E. Frye, vice president for academic affairs and provost, Emory University.

37. Conversations with David Smith, director, Poynter Center, Indiana University, and from descriptions of the Catalyst Program.

38. One influence that is not specifically related to science and engineering research but that may have a bearing on how much respect policies relating to responsibility in research receive is the gender bias that is found in many of these policies. Some still exclusively use male pronouns. Equally insensitive is the practice of noting in a footnote that "Masculine parts of speech are hereafter presumed to include the feminine" (Harvard University Faculty of Medicine, 1990, *Policy on Conflicts of Interest and Commitment*, Harvard University, Cambridge, Mass.; see also University of Michigan, 1989, *Guidelines*). The lack of sensitivity to inclusively is one more factor that bears on atmosphere and helps or undermines efforts to foster responsibility.

2

Professional Societies and Responsible Research Conduct

Mark S. Frankel

INTRODUCTION

Recent disclosures of fraud and other highly questionable behavior in the conduct and reporting of scientific research have prompted scientists, their institutions, and the larger public to reexamine research practices and the present blend of formal and informal mechanisms intended to promote responsible research conduct. The traditional preference of scientists for autonomy over their own affairs as an alternative to increased public control makes it incumbent upon the scientific community to find ways to ensure that individual scientists are competent and perform according to high ethical standards. It is an effort that scientists are increasingly willing to undertake, both to ensure the integrity of science and to maintain public confidence in the scientific enterprise.

In this paper I examine the various ways by which scientific and engineering societies attempt to foster responsible research conduct. The focus is on what a sample of societies is doing, rather than on pointing to societies that have not undertaken similar kinds of activities. By documenting the former, my purpose is to identify a range of policies, procedures, and programs that might suggest approaches for other societies. I begin with a statement of why professional societies should and can play a role in fostering responsible research practices, followed by a description of the approaches adopted by the societies in implementing that role. I then report on the specific efforts undertaken by a select group of societies,[1] first describing standards of conduct relating to responsible research practices and then highlighting society activities intended to reinforce those standards. I conclude with an

Mark S. Frankel is director of the Scientific Freedom, Responsibility, and Law Program at the American Association for the Advancement of Science in Washington, D.C.

assessment of the societies' efforts thus far and a discussion of additional measures that they might take to promote responsible research conduct.

THE PROFESSIONAL SOCIETY ROLE: THE RATIONALE

Although individual scientists must bear ultimate responsibility for their actions, promoting ethical conduct need not be solely the responsibility of the individual. Indeed, exclusive emphasis on the individual ignores the importance of social structures in shaping individual consciences and behavior. There is clearly a role for scientific and engineering societies to play in influencing the moral tone and ethical climate in which research is conducted.

"To be a professional is to be dedicated to a distinctive set of ideals and standards of conduct,"[2] and the evolution of any profession is, in large part, characterized by its efforts to define the expected character and proper conduct of its members. Members of a scientific discipline, like other professional groups, are bound together by similar aspirations, values, and training, and as such are a community whose members "are distinguished as individuals and as a group by widely shared goals, beliefs about the value of those goals, … about the appropriate means for achieving them, and about the kinds of relations which in general should prevail among themselves, and in many cases between themselves and others."[3] The scientific disciplines, then, are a prominent normative reference group, whose values and standards of appropriate research practices serve as guides by which individual scientists organize and perform their work and by which outsiders can understand and evaluate their performance.

The commitment of individual professionals to the values central to their profession is what leads society to grant the professional group as well as individual members the authority and resources to pursue their self-determined work in the public interest. The scientific community has been vested by society with the power to determine who may enter the community, what knowledge and skills must be acquired to achieve professional status as a scientist, and by what standards of conduct individual scientists will be judged. In large measure, then, a scientist is defined by his or her relationship to the group or discipline, and the professional community is charged with developing means for ensuring that individual members act responsibly. This reliance on self-regulation by the scientific group is consistent with the American tradition of limited government and has distinct advantages over the obvious alternative—public regulation.

Such regulation, as manifested, for example, in administrative rules, is typically designed to stipulate what cannot be done; it rarely prescribes what should be done. It defines the floor, not the ceiling of expected behavior. But surely we expect more from scientists as advocates for responsible research practices. By appealing to their moral consciences and their collective commitment to ensuring the integrity of science, we seek to evoke from scientists a higher standard of behavior than that which can be commanded through regulation. And when that evocation is supported by professional norms that represent a distillation of collective reflection and experience, the likelihood of ethical behavior is substantially increased.

Furthermore, there are several practices that most researchers would consider deplorable and capable of compromising the integrity of science, such as gift authorship, repetitive publication, and the selective presentation of research findings. Yet, these are not matters that ought to be subjected to the heavy hand of regulation. Rather, they are examples of practices that are more amenable to change through the process of critical self-examination that the professional community brings to bear on research practices and ethics, periodically reassessing them in the light of changing conditions and shifting perceptions of what constitutes proper behavior.

The scientific and engineering societies are distinct and easily identifiable institutions, and as visible, stable, and enduring entities, they act as the custodians of the disciplines' core values and distinctive traditions. They function as an important source of identity for individual scientists and engineers, enabling them to maintain a conception of themselves as members of a particular tradition rather than simply as technicians. And the collectivization of appropriate professional norms and their transmission by the societies to individual scientists can be an effective means of subordinating individual interests to the collective purposes of the discipline. Hence, while the profession "does not produce the next generation [of scientists] biologically, it does so socially,"[4] and over time the behavior of individual members can be (and is) explained by references to it.

As publishers of major scientific journals, the societies are also well positioned to influence research publication practices directly, to serve as an influential forum for the open discussion of key ethical issues, and to educate scientists and engineers regarding acceptable research conduct.

Finally, the scientific society performs an important mediating influence between its members and outsiders. For members, the society is expected to be a strong voice in educating outsiders about the values and norms of the discipline and in securing public support for their

work. For outsiders, the scientific society is a countervailing force to the private purposes of individual members. "We rely on the group to guarantee that its members fulfill their agency obligations. … and we trust professionals because the exercise of … discretion at the individual level is governed by rules which are prescribed and enforced by the group."[5] The societies are gatekeepers, whose oversight of the trust relationship between individual members and outsiders is critical to the advancement of science.

For all of the above reasons, the scientific and engineering societies deserve recognition and support for their role in fostering responsible research practices by their members.

THE SOCIETIES' SELF-ACKNOWLEDGED ROLE AND APPROACH TO PROMOTING RESPONSIBLE RESEARCH CONDUCT

As organized, self-governing units, the scientific and engineering societies have publicly acknowledged a role for themselves in promoting ethical practices by their members, as evidenced by the wide range of society policies and activities related to research ethics described in the next section.

The specific actions undertaken by the societies generally follow one of two approaches, or some blend of them. The most common approach for those groups examined here is for the society to accept primary responsibility for the adoption, application, interpretation, and enforcement of research standards, which may include the initiation of a broad range of supporting activities. Examples of this approach will be discussed in the following section.

The other approach is for the society to promulgate guidelines for the proper conduct of research, but to defer to others for their adaptation and application, i.e., to the institutions where the research is conducted. This is the approach adopted by the Association of American Medical Colleges (AAMC). In *The Maintenance of High Ethical Standards in the Conduct of Research* (June 1982), the AAMC affirms its belief "that faculties and their institutions have the primary responsibility to maintain high ethical standards in research and to investigate promptly and fairly when misconduct is alleged," and offers its set of guidelines as a foundation upon which local institutions can develop programs and processes for promoting ethical research conduct.[6] This same approach also applies to the AAMC's 1989 *Framework for Institutional Policies and Procedures to Deal with Misconduct in Research*[7] and to its 1990

Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research.[8]

The Society for Neuroscience is an example of a scientific society that combines the two approaches. Its Policy on Scientific Misconduct "supports the principle that academic institutions should develop and have in place procedures to deal with allegation of scientific misconduct."[9] However, the society also acknowledges "a special responsibility and interest surrounding those scientific activities for which it is directly responsible—publication of *The Journal of Neuroscience* and presentations at the Annual Meeting." So although the Society for Neuroscience has chosen not to promulgate general ethical standards for research conduct for its members, it has adopted guidelines governing articles or abstracts submitted for publication to its *Journal* or *Neuroscience Abstracts*.

PROFESSIONAL SOCIETY STANDARDS OF RESPONSIBLE RESEARCH CONDUCT

The adoption of ethical standards is a visible and explicit pronouncement of professional norms, which are central to understanding what constitutes proper professional conduct as well as the expectations about the kinds of character professionals should possess. Such standards embody the collective conscience of a profession and are testimony to the group's recognition of its ethical responsibilities. Moreover, the development and periodical revision of such standards also present scientists and engineers with the opportunity for critical self-examination regarding research norms in the light of changing conditions both inside and outside the professions. It is a time for testing the profession's established norms against the experience of its members and the priorities of the larger society.

There are several different functions[10] that such standards can play in promoting responsible research conduct.

- First, in the absence of guidelines of ethical behavior, scientists and engineers may experience anxiety or uncertainty about the kind of behavior that is expected of them in morally ambiguous situations. Standards of conduct can help professionals to evaluate alternative courses of action and to make more informed choices based on the collective experience and distinct traditions of their discipline.
- Second, standards of conduct constitute a basis for evaluating the behavior of colleagues or for the public's evaluation of professional

performance, thereby serving as a means for holding individual scientists and engineers as well as the group accountable.

- Third, standards that reflect widely held professional norms contribute to the socialization of new professionals into the distinct practices and traditions of the profession, thereby securing their support of them at an early stage in their careers.
- Fourth, standards can promote responsible research conduct by making it an affirmative duty for scientists and engineers to report errant colleagues, thereby creating a monitoring system in which each professional assumes a responsibility for upholding the group's integrity.
- Fifth, having research standards may make is easier for scientists and engineers to resist pressures from others that might otherwise lead them to cut ethical corners.
- Sixth, with established standards in place, legislative, administrative, and judicial bodies may accord them considerable weight when adjudicating allegations of misconduct. As a result, the discipline's norms for responsible research conduct may receive further support in the public arena.

Given the potential value of research standards, this section continues by examining those standards adopted by a range of scientific and engineering societies. The focus will be on guidelines that go beyond mere exhortations to be honest and open in conducting and reporting one's research. Rather, I am more interested in standards that attempt to offer substantive guidance to researchers on such matters as authorship practices, plagiarism, training and mentorship, access to and retention and sharing of data, conflict of interest, treatment of confidential or proprietary information, the reporting of research findings, and the responsibilities of scientists in addressing error or misconduct.[11]

Authorship Practices

Publication is the hard currency of science—it is the primary yardstick for establishing priority, the chief source of recognition from one's peers, and the standard on which advancement of science is based. As pressures for publication increase, authorship practices have come under increasing scrutiny as scientists wrestle with issues of credit and responsibility.

Nine of the scientific and engineering societies (American Anthropological Association [AAA], American Association of University Professors [AAUP], American Chemical Society [ACS], American

Federation for Clinical Research [AFCR], American Political Science Association [APSA], American Psychological Association [APA], American Sociological Association [ASA], Ecological Society of America [ESA], Society of Neuroscience [SN]) studied have established new or proposed standards that address authorship. The standards typically address the proper ways for determining authorship and acknowledging contributions, and they describe the responsibilities of authors. With regard to establishing legitimate coauthorship, two criteria stand out clearly—that coauthors be those who (1) have made significant scientific contributions to the work and (2) share responsibility for the results. All other "lessor contributions" should be acknowledged in a footnote or in a special acknowledgments section. Some of the guidelines offer examples of the latter—clerical assistance, advising about statistical analysis, arranging for research subjects, and modifying a computer program. Only one society (SN) explicitly refers to "honorary authorship," which it considers "not appropriate," and four societies (AAA, ACS, APSA, ASA) specifically obligate authors to acknowledge the work of students.

Four of the societies (AAUP, ACS, AFCR, APA) address the responsibilities of authors. They delegate responsibility to the first or submitting author of a paper for its contents and the accuracy of all primary data, for determining all legitimate coauthors, and for specifying the order in which the authors' names appear. Two sets of standards (ACS, APA) require the lead author to obtain all coauthors' assent to coauthorship. Finally, two societies (ACS, AFCR) caution against reporting research results in a fragmented manner.

The purpose of these provisions on authorship seems to be twofold: to establish ways of properly allocating publication credit and for holding scientists accountable for the content and methods of their work. As such, they seek to reinforce the ethical principle of fairness, minimize inflated achievement claims, and increase the possibility of tracing questionable research practices to their origins.

Plagiarism

While several societies refer in general terms in their ethics guidelines to the obligation of scientists and engineers to accord proper credit to the contributions of others, two (AAUP, American Historical Association [AHA]) have adopted independent statements specifically addressing plagiarism. Both statements stress the scholar's responsibility to acknowledge every intellectual debt.

The AAUP statement emphasizes that "greatest care" must be taken not to appropriate the work of students to the scholar's benefit. The AHA stresses the importance of good work habits as a shield against plagiarism; observing the basic rules of good notetaking and good writing will help scholars avoid the sloppy work that makes it difficult to guard against plagiarism.

Data Management

Paralleling the mounting concern in the scientific community with issues related to data retention, access, and sharing, several scientific societies have adopted explicit policies or guidelines governing such matters as what data ought to be accessible to whom, the timing of such release, and the factors that might affect sharing (e.g., confidentiality pledges).

Data retention and sharing are viewed by the societies as essential for assuring scientific quality and for helping to distinguish error from misconduct. Six societies (AHA, AFCR, APA, American Society for Microbiology [ASM], SN, Society of Professional Archaeologists [SOPA]) have explicitly addressed the issue of data retention with varying degrees of specificity. The responsibility for retention is typically assigned to the principal investigator. Three of the societies (AHA, ASM, SOPA) call on the investigator to deposit raw data in some central repository, where it can be accessible to others, while another cautions that provisions be made for maintaining confidentiality when storing and disposing of records. Three societies take different positions regarding the period of time for retaining the data, with one (AFCR) prescribing an indefinite period, another (APA) stipulating a minimum of five years after publication, and the third (SN) defining the time frame as being as long as there is a reasonable need to refer to them.

Data access and sharing are matters that at least seven societies (AHA, APA, American Physical Society [APS], ASM, ESA, Institute of Electrical and Electronics Engineers [IEEE], SOPA) have addressed. Where the time at which data sharing should occur is referred to at all, the obligation to share follows the point at which the original investigator has completed his or her analysis of the data and should be consistent with the researcher's prior rights to publication. One society (APA) prescribes that researchers clarify in advance with all appropriate parties the expectations for sharing data.

Two societies (APA, SOPA) refer to the credentials of requesters of data, stipulating that they be competent or qualified, while only one

(APA) addresses the responsibility of the recipients of shared data by obligating them to "obtain permission from research participants, whenever possible, to utilize the data." One society (SOPA) places access by others to data into a specific time frame, declaring that after ten years, the researcher waives the "right of primacy with respect to analysis and publication of the data," which should then "be made fully accessible for analysis and publication by other[s]."

Three societies (APSA, ASA, ASM) note that any sharing of data should not incur more than reasonable costs and that the requester may be expected to pay those costs. Six (AHA, APA, APS, APSA, ASM, IEEE) explicitly identify either privacy claims, promises of confidentiality, or national security/ classification and proprietary considerations as legitimate counterclaims to data sharing, with one (AHA) of the six stipulating that researchers "must challenge unnecessary restrictions."

These provisions concerning all aspects of data maintenance reflect clear intent to establish data retention and sharing as a legitimate professional responsibility of scientists. But the precise boundaries of that responsibility can be affected by such delimiting factors as privacy rights, confidentiality pledges, proprietary concerns, national security interests, the priority rights of the original investigator, the credentials of the requester, and the costs associated with sharing. Clearly, there are a number of competing interests at play here, and the societies, while assigning considerable value to data retention and sharing in the conduct of research, have recognized the importance of other factors in advancing science, and in deciding when, how, and with whom to share.

Training and Mentorship

The importance of training and mentorship has increasingly gained currency as an essential component in promoting responsible research practices. For example, the Institute of Medicine recently recommended that "scientific organizations … develop educational and training activities and materials to improve the integrity of research" and that academic institutions "monitor the supervisory and training practices of their faculty and research staff to ensure that adequate oversight is provided for young scientists."[12] Also, effective July 1, 1990, all research training grant applications to the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration must include a description of the types of instructional activities on the responsible conduct of research that will be incorporated into the proposed research training program.[13]

The scientific and engineering societies have also recognized the importance of training and mentorship by including them among the professional responsibilities of their members. Two of the societies (ASM, International Epidemiological Association [IEA]) declare that researchers should serve as exemplary role models for their trainees, to demonstrate by example their commitment to the highest possible ethical standards. The other approach, adopted by five societies (AAA, AAMC, AFCR, AHA, ASM), is to urge scientists to use the education and research settings as an opportunity to ensure that trainees and students understand the values and ethical prescriptions governing research. Three societies (AAMC, AHA, ASM) stress the value of informing students of the profession's ethical guidelines in the classroom.

A few of the societies elaborate on what is expected of mentors. One (AFCR) holds them responsible for supervising the trainee's design of experiments, reviewing all original data and overseeing their interpretation, and helping to develop reports of the results. In addition, mentors have an obligation to be sure that trainees are aware of government and institutional guidelines governing research. Two societies (AAA, ACS) obligate mentors to encourage and support students in their studies, with one (ACS) urging regular guidance, direction, and periodic evaluation of students/trainees, and help in developing initiative and independent thinking of supervises. Both societies address the responsibility of their members to advise and assist in career development. Finally, two societies (AFCR, ACS) identify obligations of students/trainees, which include maintaining honesty, integrity, and diligence in conducting research, and consulting with mentors with enough frequency so that they are kept informed of their progress or problems.

To the extent that the societies explicitly recognize professional responsibilities as part of the mentorship and training activities of their members, it is increasingly likely that resources and materials designed to help them effectively discharge those responsibilities will begin to emerge. There will be a need to test and evaluate diverse approaches and to disseminate information on particularly effective techniques for transmitting professional norms to students/trainees.

Conflict of Interest

The societies' concerns with conflict of interest, at least as reflected in their guidelines or standards, arise in the context of peer review as well as in the conduct and sponsorship of research. Twelve of the

societies examined had guidelines with provisions on conflict of interest. Four (APA, ASA, ASM, IEEE) were rather general in scope, urging scientists to recognize conflicts of interest, to avoid relationships that might precipitate such conflicts, and to disclose conflicts to affected parties. The other eight societies (Association of Academic Health Centers [AAHC], AAMC, ACS, American Institute of Professional Geologists [AIPG], APSA, ESA, IEA, Society for Epidemiologic Research [SER]) offered more detailed guidance.

In relation to peer review, there are prescriptions (ACS, APSA, ESA) that researchers decline to review the work of others where conflicts of interests are involved. One society (ACS) urges that the reviewer return the manuscript promptly, informing the editor of the conflict. Alternatively, the reviewer could return a signed review stating his or her interest in the work and deferring to the editor's discretion as to whether to accept it. Another society (ESA) prohibits members from "purposefully delay[ing] publication of another person's manuscript to gain advantage over that person."

Recognizing that conflicts of interest may bias the collection, analysis, interpretation, and reporting of data, other guidelines (ESA, IEA, SER) focus on the relationship between researcher and sponsor, stressing the importance of the researcher's independence and his or her moral obligation to hold the public interest above the narrow interests of sponsors where they seek to exert undue influence on the presentation of findings. Researchers are called upon to disclose all relevant financial, personal, or professional relationships that might lead to a conflict of interest—for themselves as well as for family members—to their institutions and in public speeches and writings, and to disclose such relationships related to the sponsor of the research (AAHC). Other provisions discourage arrangements involving confidential information that may not be shared with colleagues; prescribe policies that ensure that students and trainees are not exploited in the service of sponsored research; and address compensation arrangements in support of clinical studies, cautioning that payment not be linked solely to the enrollment of research subjects or contingent upon a specified outcome (AAHC).

One society (AIPG) addresses very specifically the relationship of its members to employers or clients. It admonishes members not to seek to profit economically from information gained without written permission of the employer or client, not to use his/her employer's or client's resources for private gain without the consent of the employer or client, and not to accept, without the employer's or client's written consent, an assignment by another if the interests of the two conflict.

Overall, the conflict of interest provisions of the societies examined reflect an attempt to balance the value of sponsored research against the

risks of conflicts of interest—real or apparent. They also seek to minimize the effects of bias on the peer review process. They have succeeded in identifying key areas of concern, but as yet have not sought to formulate more detailed criteria for recognizing a potential conflict and determining when disclosure is required.

Reporting of Research Findings

The expectation of publication based on research underlies most of the provisions pertaining to the reporting on one's results. Nevertheless, at least three societies (AAA, AAHC, ASA) have legitimized restrictions or delays in publication based on such factors as proprietary rights, patent preparation, or potential harm to clients, collaborators, or participants. For the most part, deciding when or how to publish—or when to trigger those factors that might justify delays or other restrictions—is the sole responsibility of the investigator.

Two societies (APA, ASA) proscribe their members from suppressing disconfirming or other significant data in their reports, while another society (SOPA) proscribes its members from entering into contracts that prohibit the scientist from including his or her interpretations and conclusions in the contract report. One society (APA) prescribes that scientists acknowledge the existence of alternative hypotheses; one (APSA) that members disclose any "material condition" imposed by sponsors or others on their research and publication; and another (ASA) that members state all significant qualifications on their findings in reporting their research; and yet another (IEEE) declares that members be "realistic in stating claims" based on available data. At least three of the statements (APA, APSA, ASA) prescribe that scientists acknowledge the sources of funding for their research in their public reports; another (AAA) simply prescribes "candor concerning sponsorship." One society (ASM) emphasizes the responsibility of scientists for the timely release of research reports, while another (SOPA) establishes a ten-year time frame for publication, after which the researcher waives his or her right of primacy with respect to publication.

While the societies view the reporting of research results as an integral part of the research process and a professional responsibility of scientists, at least in some cases they are prepared to accept constraints on the discharging of that responsibility. They have explicitly recognized a limited set of considerations that might justify publication delays or restrictions, leaving to the investigator the responsibility to determine when such considerations outweigh the prescription to publish.

Treatment of Confidential or Proprietary Information

Several societies have recognized that working with confidential or proprietary information creates special responsibilities on the part of scientists and engineers. There is a general disposition toward prescribing that confidential or proprietary information (including manuscripts under review) not be used or reported without permission from the persons (or their legal representative) from whom it was obtained. However, at least two societies (APA, ESA) identify explicit exceptions to this general prescription: where withholding the information would present a clear danger to others or where it is appropriate to comply with a legal requirement (APA), and where confidentiality would contribute to "unnecessary or significant degradation of the environment" as well as jeopardize public health or safety (ESA).

One society (AHA) calls on members to clarify the conditions of confidentiality prior to beginning one's work, to press for changes in the confidentiality requirements when they are "unsatisfactory," and to inform the readers of their publications of the rules of confidentiality that governed their work. Another society (APSA) imposes an obligation on researchers to seek changes in the law so that the confidentiality of sources "may be safeguarded." Yet another (APA) establishes a professional obligation to inform people at the outset of the limits of confidentiality that will affect their professional relationship. Finally, two societies (AIPG, SOPA) proscribe members from using confidential information obtained during the course of work for an employer or client in any way that adversely affects their interests, except with their consent or when disclosure is required bylaw.

The provisions referred to above are an attempt by the scientific and engineering societies to balance the traditional patterns of free exchange in science with promises to withhold certain information from public view. There is an assumption at work here that finds confidentiality agreements essential for some types of research to proceed. They are accepted without necessarily being encouraging. Having entered into such agreements, scientists are obligated, with a few exceptions, to honor them. To do otherwise is presumed likely to do more damage to science than would occur by the withholding of information.

Addressing Error or Misconduct

In addition to promulgating standards of conduct to promote responsible research conduct, scientific and engineering societies also address the researcher's responsibilities when he or she confronts abuses or errors, or the potential of such, by others. For two societies (AFCR, ESA), being responsible means acknowledging and correcting error when it is detected.

Another approach endorsed by some of the societies to promote responsible research practices and the integrity of science is for scientists to take seriously their self-policing responsibilities and speak out against improper practices and violations of research norms. One society (AHA) describes as "troubling" the reluctance of scholars to speak out about their suspicions of misconduct; one may infer from this a duty of scholars to be more forthcoming in reporting their suspicions. Six other societies (AAUP, AFCR, AIPG, APA, ASM, ESA) acknowledge more explicitly these responsibilities on the part of researchers. In the case of one society (APA), if the violation does not lend itself to an informal solution or is of a serious nature, then the scientist should bring it to the attention of appropriate committees of the profession. Another society (AFCR) encourages investigators to alert their laboratory chiefs or institutional officials when they know of a violation of the profession's standards. A third (ASM) obligates researchers to bring to public attention premature, false, misleading, or exaggerated statements, and to protect and cooperate with others who identify such misconduct. One society (SOPA) makes it a professional responsibility to report violations of its Code of Ethics "to proper authorities," while three societies (AAUP, AIPG, ESA) declare that suspected misconduct should be brought to the attention of the appropriate body within the profession, with two of them (AAUP, ESA) urging that affected parties also be notified.

By including such provisions as part of their conduct standards, the societies are encouraging scientists to view the reporting of misconduct as a positive step for maintaining the quality of science, rather than as an uncollegial act. They are acknowledging that dishonest work ultimately damages all of science and that it is in the enlightened self-interest, indeed an affirmative duty, of individual scientists as well as the community of scientists to voice their disapproval of scientific misconduct and to pursue such allegations conscientiously.

REINFORCING PROFESSIONAL STANDARDS

Many of the societies examined here recognize that the adoption of standards for responsible research is an important but not sufficient step toward fostering proper research practices. A set of standards must be viewed as only one part of a larger effort intended to promote responsible conduct. In seeking ways to reinforce their prescriptive role, the societies have at their disposal a range of activities relating to education, recognition, and enforcement.

Education

The educational activities of the societies are intended to inform members of their standards and what the societies are doing to enforce them, to offer guidance to members in interpreting them, and to educate members in a more general way about the ethical issues confronting researchers and how the research community and others are responding.

Informing scientists about society standards takes many forms. The AHA plans to print its statements on ethics as a pamphlet for distribution to all academic departments of history. SOPA requires that all archaeologists accepting certification sign a pledge to abide by its Code of Ethics and Standards of Research Performance. A frequently used mechanism for alerting members to standards is the societies' journals and newsletters, where they will publish drafts of new standards or revisions for which member approval will be sought.

Society publications are also used to inform members of enforcement efforts. The APA, for example, requires its Ethics Committee to publish an annual report in its journal, *American Psychologist*, on the types of complaints investigated, cases adjudicated, and their disposition. And the AHA intends to begin publishing soon in its newsletter semiannual reports on cases of misconduct reviewed by the association.

The APA has published its "Rules and Procedures" for investigating, adjudicating, and reporting on alleged violations of its Ethical Principles in its journal, *American Psychologist*. Six of the societies examined for this study included such rules and procedures as a companion document to their standards, while others have incorporated them into their bylaws.

Some societies have taken steps to elaborate on their basic principles of research conduct as a means of helping members to interpret their application in specific situations. One approach is to publish more detailed, supplementary guidelines in particular areas of research. Prime examples of this are the APA's "Guidelines for Ethical Conduct in the

Care and Use of Animals," "Guidelines for the Use of Drugs in Research by Psychologists," and "Ethical Issues in Psychological Research on AIDS." Another approach is to publish illustrative cases, describing how they were handled by the society in light of its prescribed standards. This is the approach recently undertaken by the AHA and one that the APA has also pursued for several years through a series of casebooks, the latest of which was published in 1987.

Many of the societies examined for this study have sought to better inform and educate their members about the ethical issues associated with research by encouraging coverage in their society journals and newsletters and by sponsoring open forums at national or regional meetings. Others, such as the American Association for the Advancement of Science (AAAS) and the AAMC, have organized invitational workshops that have examined those issues in a rigorous fashion.

Some societies have issued special publications exploring in some depth one or more components of responsible research conduct. Examples include Sigma Xi's *Honor in Science*[14] and ACS's *Trade Secrets ... Ethics and Law.*[15] The APS has distributed *On Being a Scientist*, a publication of the National Academy of Sciences,[16] to every student member. Only one society contacted for this study (ACS) indicated that it was currently planning to develop educational materials dealing with science and responsibility.

Recognition

One way to foster attention to the value that the research community attaches to responsible research conduct is to bestow public recognition on those scientists and engineers who exemplify model conduct in their own research, who display qualities of leadership in promoting responsible research practices among scientists and engineers, or who responsibly speak out against research misconduct. Although there appears to be no such recognition specifically intended for these purposes, there is at least one case where it has been accorded, and the potential for it to be done elsewhere.

The annual AAAS Scientific Freedom and Responsibility Award recognizes exemplary responsible behavior in science and engineering across a wide range of conduct, and in 1989 the AAAS selected Robert Sprague as co-recipient of the award. Sprague was the researcher who first suspected research fabrication on the part of psychologist Stephen Bruening and was cited for "his courage and persistence in reaffirming the highest standards of scientific integrity by initiating the censure of

a research colleague who fabricated data …." In 1990, the American Institute of Chemists (AIC) established a new "Ethics Award" to recognize outstanding contributors to ethics in the chemical profession. In addition, several other scientific and engineering societies have established awards for exemplary service to the profession or the public, or for contributions to the ethics of the profession, all of which could include efforts by researchers who, in one way or another, contribute in critical ways to ensuring the integrity of research.

Enforcement

A number of societies have designed procedures for disciplining members who have violated their ethical standards and, in fewer cases, for supporting members who are placed at risk by their efforts to live up to those standards. Besides disciplining or supporting particular individuals, these procedures can perform other functions as well. They send a message to all members as well as the institutions in which they work that the society considers deviation from the standards of responsible research a serious matter. This will put potential wrongdoers on notice that there will be a price to pay for misconduct, and it will increase the confidence of others in the integrity of their discipline's research base. Examples of disciplinary and support actions may also serve an interpretive function if the society's enforcement procedures allow for "opinions" to be issued.

For those societies with enforcement procedures, three types of approaches can be identified. One approach, adopted by the AAAS, does not link the procedures to any specific set of ethical standards adopted by the association. Rather, the AAAS uses the National Science Foundation's definition of scientific misconduct, and its procedures apply only to AAAS staff and their collaborators engaged in research or publication ventures.

A second approach is for societies to adopt enforcement procedures applicable to publication practices or the submission of abstracts for meetings and to implement them through journal editors, or publication or program committees. The ASM has published its procedures in its newsletter and instructions for authors; the SN has published its procedures as part of its Policy on Scientific Misconduct.

The most common approach used by the societies examined here takes the form of procedures to enforce their ethics guidelines or research standards. Nine societies have developed detailed enforcement procedures, only some aspects of which are briefly described here. In the case of one society (ESA), no enforcement mechanism applies to

regular members, but those members who seek certification renewal may have it denied if the society's Code of Ethics is violated. Seven societies assign specially constituted standing committees with responsibility for implementing their enforcement procedures, and the range of sanctions that may be applied include the following: private or public reprimand, censure, probation, suspension, denial of recertification, stipulated resignation, imposed rehabilitation or educational training, required supervision, and expulsion from the society.

Three societies (ASA, AHA, APSA) include the option of trying to mediate a disputed matter, while two (AHA and APA) will consider referring the matter to other organizations with a request for arbitration or resolution. Two societies (AHA, APSA) state that they will not normally pursue a complaint if it is under litigation, while another (APA) explicitly declares that litigation will not be a bar to its consideration of complaints. The other societies are silent on this matter.

There is wide variation in the position the societies take with regard to notifying other parties of the outcome of their investigations. One society (IEEE) leaves notification of the membership to the discretion of its Board of Directors; no reference is made to any other parties who might be notified. In the case of expulsion or stipulated resignation, the ASM identifies the member and the sanction in its newsletter. If the charges are dismissed, the accused is given the option of whether the decision is published. If the AHA decides that the matter is "indicative of a larger problem," it may publish an advisory opinion or guideline in the association's newsletter. SOPA provides for publication of disciplinary action, and its Board of Directors is given discretion as to whether to inform other "individuals, corporations, government agencies, and the media" of the results of disciplinary proceedings. Finally, the APA gives both its Ethics Committee and Board of Directors some discretion in notifying others of the outcome of its cases. Where the committee has imposed probation or suspension or has stipulated resignation of a member, it may inform members and other individuals or organizations (several are specifically listed) in order to "maintain the highest level of ethical behavior by members or to protect the public." The APA board is required to "report annually and in confidence" to members the names of those who have been expelled or dropped from membership and the ethical principles involved. It is required to notify other parties if it "deems it necessary" to protect the public or to maintain the association's standards.

The IEEE's enforcement procedures explicitly offer assistance to members who strive to adhere to the institute's Code of Ethics, whose

livelihood is jeopardized by such efforts, or whose ability to discharge their professional responsibilities is compromised, or when the situation can be detrimental to the IEEE or to the engineering profession. The only type of assistance specifically offered in the documents reviewed is the submission of an *amicus curiae* brief in court proceedings. The IEEE Board of Directors may, at its discretion, publish findings or other comments in support of members and take whatever further action it deems appropriate. The APSA "promises to do all that it can within its resources to protect political scientists from unjustifiable abuses," relying on "persuasion and vigorous protest" as its primary means for supporting members.

Finally, the guidelines on research misconduct and conflict of interest issued by the AAMC and AAHC are accompanied by recommendations that mechanisms and procedures be established at research institutions to handle allegations of impropriety. The AAMC guidelines on conflict of interest suggest a process for disclosing and reviewing conflicts, and the framework for dealing with research misconduct offers lists of suggested sanctions and of parties that might be notified of the outcome of cases.

IMPROVING THE PROFESSIONAL SOCIETY RESPONSE

The scientific and engineering societies vary with respect to their history, their power and influence, their relationship to members, and their resources. Nevertheless, to some degree they all function as an important source of identity for individual members, and they are legitimate custodians of the disciplines' values and traditions. They are well positioned, then, to articulate ethical standards for professional conduct, and several sets of those standards were described earlier.

In almost every case the standards examined had been adopted within the past three to five years. They are an attempt to keep pace with recent changes in the practice of science that have permeated scientific research and publication and with changes in legal and regulatory requirements. They remain to be tested in the world of experience, but in principle they address critical issues facing scientists and engineers and offer prescriptions of what is expected of them.

But the adoption of such ethical standards does not guarantee their usefulness when caught in the cross-pressures of contemporary research. Such standards should be viewed as only one part, albeit an important one, of a larger system intended to promote responsible research conduct. One complementary strategy involves keeping the standards visible and relevant in the eyes of researchers. The societies can

accomplish this in a variety of ways, but the most common method employed is through discussions of research ethics at professional meetings and in the pages of their publications. While such efforts undoubtedly impart information, and perhaps insight as well, to members and ought to be encouraged, they are subject to the vagaries of editorial and program decisions about what ultimately reaches a larger audience. A useful complement to such activities would be a routine and systematic interpretative function.

The ethical prescriptions embodied in the standards are like blunt instruments; they must be sharpened by interpretation if they are to function as useful guides to responsible conduct. To accomplish this, the societies might publicize decisions rendered in cases of violations of their standards—a procedure now employed by only a few of the societies examined—with a detailed description of the reasoning used by the society in reaching its verdict. Published regularly, over time these decisions and commentaries will come to constitute a type of "case law" that breathes life into the society's ethical prescriptions and alerts members to the cumulative wisdom of the profession in applying the standards to various real-world dilemmas.

Another approach to interpretation would be to develop case materials—based on real or hypothetical incidents—designed for the education of practicing scientists as well as those in training. In pursuing this strategy for the latter group, the societies should work with their members based in colleges and universities in order to increase the likelihood that such materials will be developed.

Whether or not a society chooses to enforce its standards with a system to investigate and rule on allegations of misconduct and to levy sanctions is a decision that every society makes—either consciously or by default—as it considers the kind of relationship that it wants to develop with its members. But once committed to a system of enforcement, a society should mobilize the machinery necessary to carry out this function in an efficient and fair manner in order to earn the trust and respect of both members and outsiders. For members, this means designing a set of procedures that not only identifies violators but that also protects those who are falsely accused. For outsiders, the system must assure them that the society is prepared to acknowledge the possibility of scientific misconduct, to investigate allegations thoroughly, to hold researchers accountable, and to protect the public from the adverse consequences of improper research conduct. The ethical standards adopted by the societies not only define the boundaries of responsible research conduct; they also embody the virtues that researchers are expected to possess. Scientists and engineers are not only expected to act in a particular way; they are also expected to

exhibit a certain type of character. Hence, such standards reflect an ethics of character or virtue as well as an ethics of action. Recognizing such virtue in particular scientists and engineers offers the societies an opportunity to reward virtue, to call attention to the importance that the profession attaches to such character, and to publicly identify role models. The societies should seriously consider doing much more than is now done to confer recognition on scientists and engineers who exemplify the ideals of their discipline.

Finally, in considering how the scientific and engineering societies can more effectively promote responsible research conduct, one must keep in mind that such efforts incur costs in the form of time, energy, and resources committed to developing ethical standards, disseminating information, educating, registering disapproval, and conferring recognition. Consequently, the societies must be sensitive to what they can reasonably undertake at any particular point in time. This caution should not be interpreted as a prescription for inaction. Rather, it reflects a belief that costs, as well as more intellectual and professional factors, must be factored into the evaluation of alternative courses of action under consideration by the societies.

NOTES

1. Twenty societies representing diverse areas of research were contacted by the author for information on their policies/standards and activities related to research ethics. This draft includes information from the 13 societies that have responded. (See Appendix A for a complete listing of the societies contacted.) In addition, the sections reviewing professional societies' standards draw from materials describing standards adopted or drafted by several other societies. (See Appendix B for a list of all standards and guidelines referred to in the paper.)

2. Jennings, B., D. Callahan, and S. M. Wolf, 1987, "The professions: public interest and common good," *Hastings Center Report* 17(special supplement), p. 5.

3. Camenisch, P. F., 1983, *Grounding Professional Ethics in a Pluralistic Society*, Haven, New York, p. 48.

4. Pavalko, R. M., 1971, *Sociology of Occupations and Professions*, F. E. Peacock, Itasca, Ill., p. 25.

5. Tuohy, C. J., and A. D. Wolfson, 1977, "The political economy of professionalism: a perspective," in *Four Aspects of Professionalism*, Consumer Research Council, Ottawa, p. 67.

6. Association of American Medical Colleges (AAMC), 1982, *The Maintenance of High Ethical Standards in the Conduct of Research*, AAMC Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research, AAMC, Washington, D.C.

7. Association of American Medical Colleges (AAMC), 1989, *Framework for Institutional Policies and Procedures to Deal with Misconduct in Research*, AAMC, Washington, D.C.

8. Association of American Medical Colleges (AAMC), 1990, *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research*, AAMC, Washington, D.C.

9. See 1990, *Neuroscience Newsletter* 21 (March/April):1-2.

10. Adapted from Frankel, M. S., 1989, "Professional codes: why, how and with what impact?" *Journal of Business Ethics* 8:109-15.

11. Societies whose members conduct research with human or animal subjects have in many cases adopted rather detailed ethical guidelines. However, because of the research community's lengthy experience with these guidelines and the existence of parallel legal requirements, I have chosen not to include them here.

12. Institute of Medicine (IOM), 1989, *The Responsible Conduct of Research in the Health Sciences*, Committee on the Responsible Conduct of Research, National Academy Press, Washington, D.C., pp. 4-5.

13. National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), 1989, "Requirement for programs on the responsible conduct of research in National Research Service Award institutional training programs," *NIH Guide for Grants and Contracts* 18(December 22):1.

14. Sigma Xi, 1986, *Honor in Science*, Second Edition, Sigma Xi, New Haven, Conn.

15. American Chemical Society (ACS), 1981, *Trade Secrets ... Ethics and Law*, ACS, Washington, D.C.

16. National Academy of Sciences (NAS), 1989, *On Being a Scientist*, Committee on the Conduct of Science, National Academy Press, Washington, D.C.

APPENDIX A—SOCIETIES CONTACTED FOR DATA ON RESEARCH ETHICS ACTIVITIES

American Academy of Forensic Sciences (AAFS)
American Anthropological Association (AAA)
American Association for the Advancement of Science (AAAS)
American Chemical Society (ACS)
American Historical Association (AHA)
American Institute of Chemists (ACS)
American Institute of Professional Geologists (AIPG)
American Political Science Association (APSA)
American Psychological Association (APA)
American Society for Microbiology (ASM)
American Sociological Association (ASA)
Association of Academic Health Centers (AAHC)
Association of American Medical Colleges (AAMC)
Ecological Society of America (ESA)
Institute of Electrical and Electronics Engineers (IEEE)
International Epidemiological Association (IEA)
Society for Epidemiologic Research (SER)
Society for Neuroscience (SN)
Society of Professional Archaeologists (SOPA)
Society for the Scientific Study of Sex (SSSS)

APPENDIX B—SOCIETY STANDARDS AND GUIDELINES CONSULTED

American Anthropological Association
Principles of Professional Responsibility, 1990
American Association of University Professors
Statement on Plagiarism, July 1989
Statement on Multiple Authorship, June 1990
American Chemical Society
Academic Professional Guidelines (Draft), April 1990
Ethical Guidelines to Publication of Chemical Research, 1986
American Federation for Clinical Research
Guidelines for the Responsible Conduct of Research, 1989
American Historical Association
Statement on Interviewing for Historical Documentation, May 1989
Statement on Plagiarism, May 1986; amended May 1990
Statement on Standards of Professional Conduct, May 1987; amended May 1990
American Institute of Professional Geologists
Code of Ethics, December 1989
American Physical Society
Resolution on Freedom of Scientific Communication, November 1983
American Political Science Association
Rules of Conduct, 1968
Advisory Opinions of the Committee on Professional Ethics, Rights and Freedoms
American Psychological Association
Ethical Principles of Psychologists, 1981; amended June 1989
Ethical Principles Revised (Draft), June 1990
Publication Manual, Third Edition, May 1986
Guidelines for Ethical Conduct in the Care and Use of Animals
Guidelines for the Use of Drugs in Research by Psychologists
Ethical Issues in Psychological Research on AIDS
American Society for Microbiology
Code of Ethics, 1987; amended 1988
Instructions to Authors for All ASM Journals, 1990
American Sociological Association
Code of Ethics, August 1989
Association of Academic Health Centers
Conflicts of Interest in Academic Health Centers, 1990

Association of American Medical Colleges

Framework for Institutional Policies and Procedures to Deal with Misconduct in Research, March 1989

Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research, February 1990

The Maintenance of High Ethical Standards in the Conduct of Research, June 1982

Ecological Society of America

Code of Ethics, August 1990

Institute of Electrical and Electronics Engineers

Code of Ethics, August 1990

International Epidemiologic Association

Ethics Guidelines for Epidemiologists (Draft), 1990

Society for Epidemiologic Research

Statement on Ethical Issues Involving Conflicts of Interest for Epidemiologic Investigators (Draft), May 1989

Society for Neuroscience

Policy on Scientific Misconduct, 1989

Society of Professional Archaeologists

Code of Ethics

Standards of Research Performance, 1976

3

Mentorship and the Research Training Experience

David H. Guston

INTRODUCTION

Contemporary interest in the role of mentorship in the current research environment has two parts: one, there are concerns that, at a minimum, a trainee[1] is not abused or exploited during the mentorship experience; and two, there are desires to affirm the role of the mentor in transferring both the technical and ethical aspects of good research standards and practices. Abuse of trainees may, in its extreme, constitute a form of misconduct. The absence of sound training does not in itself constitute misconduct but, over time, it may lead to an erosion of research standards and thus compromise the integrity of the research process.

This paper describes the role of mentorship in the contemporary research environment and distinguishes it from other important relationships in the training of new researchers. The paper also discusses efforts by universities to improve mentorship practices.

Central to the research training experience is the duration of the training period. The period of training usually consists of graduate school and postdoctoral training, although many scientists now begin their research careers during undergraduate and sometimes even secondary education, and most continue to learn from their colleagues throughout their careers. The formal period of graduate and postdoctoral training varies considerably from one field of study to another. In 1988, the median time to doctorate for recipients of the Ph.D. was 6.5 years. The disciplinary median varied: 5.5 years in chemistry; 5.9 years in engineering; 7.1 years in health sciences and in earth, atmospheric, and marine sciences; and 9.0 years in anthropology

David H. Guston is a research fellow at the Center for Science and International Affairs at the John F. Kennedy School of Government at Harvard University. He was the research assistant for the Panel on Scientific Responsibility and the Conduct of Research.

and sociology. The length of time to the doctorate has increased for many disciplines in recent years.[2]

In some fields the duration of postdoctoral training has also increased. These increases reflect the increasing technical complexity of science and engineering and the continually expanding body of knowledge that the trainee must master. Other factors may include the lack of faculty positions and the need in laboratories for cheap labor.

Formal course work required for training also varies considerably among fields and institutions. Course work can involve from 1 to 3 or 4 years of formal courses. The duration of formal course work is important in that, in addition to instruction in a particular field of science or engineering, formal courses can address specific issues in the conduct of scientific research, such as statistics and research practices. Where course work includes formal classes in statistics and allows for discussion of the appropriate use of statistical methods, training reinforces good research practice through instilling concepts of research design, formal hypothesis testing, and the application of appropriate statistical analysis. Formal courses in the ethics of professional and research conduct are now quite common in law and medical schools and are becoming common in business schools. But formal course work can, at best, merely complement the actual substance of the trainee's work, for it is on the job—in the laboratory or the field—where most of research training takes place. To a great extent, research training depends on the mentor-trainee relationship discussed below, and it takes place in the context of the research work itself.

THE ROLE OF THE RESEARCH MENTOR

Defining the Mentoring Relationship

A mentor is defined as *that person directly responsible for the professional development of a research trainee*. Professional development includes both the explicit conduct of scientific research (e.g., instrument use, research design, observational technique, and theoretical or cognitive frameworks) and the implicit development of scientific standards (e.g., selection of research questions and data, authorship practices, and norms of communication, interpretation, and judgment). It applies to all levels of professional development, from undergraduate work to junior faculty positions, although the focus here is on graduate students and postdoctoral fellows.

It is important to realize what the mentor role is *not*. A mentor is not simply a patron who provides financial and other material support

(such as laboratory space and equipment, reagents, and so on), because the mentor should provide personal and professional support beyond patronage. Nor is a mentor simply an advisor who provides formal links between a student and the department or institution. The mentor is not just a supervisor who oversees the student's dissertation, because the mentor is responsible for professional development of the trainee in areas not immediately pertinent to the curriculum or dissertation. Furthermore, the mentor is not merely a role model, because the latter can influence a trainee indirectly, unknowingly, or from a distance.[3] Although trainees may frequently have mentors in their patrons, advisors, and supervisors (and sometimes one person fills all four roles), there is no necessary connection among them.

The Importance of the Mentor

The research literature generally supports the conventional wisdom that the mentoring relationship is a valuable one. Although the empirical evidence is ambiguous and contradictory in places, research studies on mentorship suggest that a mentor is an asset to the professional life of the young scientist or engineer.[4] For example, the productivity of graduate students with mentors may be greater than the productivity of those without mentors.[5] Scientists with mentors may be more "self-actualized" than those without.[6] Junior faculty with mentors may publish more books, receive more grants, and serve as leaders in more organizations than those without mentors. Academics who find mentors earlier in their careers tend to outperform their colleagues who find mentors later.[7] The prestige of mentors also influences the prestige of academic appointments for trainees,[8] but the mentors' teaching and promotion of the trainees are not as important as a record of collaboration.[9]

The potential contributions and harms of mentorship become clear when it is realized that mentoring is a replicative phenomenon; what happens in one relationship between mentor and trainee may be reproduced when that trainee becomes a mentor.[10]

Characterizing the Ideal Mentoring Relationship

The mentoring relationship is a unique and important one in academia, combining elements of other relationships, such as parenting, coaching, and guildmastering. One mentor has written that his "research group is like an extended family or small tribe, dependent on one

another, but led by the mentor, who acts as their consultant, critic, judge, advisor, and scientific father."[11] Another mentor speaks of trainees who have lost their mentors by death, job changes, or in other manners as "orphaned graduate students."[12] Others see "[g]raduate students … as apprentices [who] begin to work gradually over time … [and] become journeymen and eventually graduate and become masters themselves."[13]

Research studies on mentoring in science and engineering are sparse compared to those in professions that have a major social component, such as business, nursing, and education.[14] It is generally recognized that mentors transmit both technical and professional skills, regardless of their field.[15] The continuity and community of practice provided by mentoring is vital for good science, particularly in a profession whose authority is traditional and whose decision making is highly individualized.

The research mentor is believed to exercise a fundamental role in shaping the career development of the trainee. If the trainee shows promise of excellence, he or she may become a successful protege to the senior figure. If a trainee is struggling, the personal care of a mentor may rescue a productive scientific career that could otherwise have been lost.

Another generalized role for a mentor is to assure that work conducted under his or her supervision is completed not only in a sound and honest manner, but in a timely manner as well. This role is especially important if the supervised work is progressing toward a Ph.D. Given the trend of increasing time to the doctorate,[16] the role of the research mentor in assisting a trainee to select and complete a challenging yet manageable dissertation is among the most important a mentor can play.[17]

What is not certain, however, is the set of practices that distinguish good mentorship practices from those that are inappropriate or unacceptable. Because of the complexity and diversity of roles assigned to the mentor, some individuals may excel in providing certain kinds of guidance while neglecting others. For example, some mentors may be extremely resourceful in providing sources of patronage or assistance in securing professional opportunities while failing to maintain personal supervision or regular review of the work of their trainees. Others may provide more immediate guidance and be more accessible for their students, but are limited in their abilities to provide the economic resources or professional advancement that may be critical for young investigators.

Ideally, one would expect to have mentors who successfully perform in a variety of categories, and indeed many do. There are concerns,

however, about situations in which the mentor abuses a relationship with the trainee in a manner that violates fundamental standards of professional integrity, and situations that prevent the mentor from providing adequate training and guidance. These situations may result from personal factors such as emotional stresses, substance abuse, or discriminatory practices. Or they may result from environmental factors that foster a climate in which mentoring becomes a secondary or tertiary responsibility.

Whatever the source, damage can result from poor mentorship practices, whether abusive or neglectful. Such inappropriate practices need to be identified and corrected at the earliest possible moment, with a regard for the privacy of the involved parties. Institutional officers should make efforts to establish an appropriate climate within the research setting that encourages research collaboration and educational training and fosters ties between mentors and trainees that go beyond a formal employer-employee relationship. This climate should also encourage the identification of poor practices at an early stage. The climate fostered by the institution should also encourage a broader mentor-trainee environment that becomes important if some unanticipated event —such as the death of a mentor, or an instance of abuse or misconduct— disturbs the relationship. A broader environment would provide necessary support, both emotional and material, to the trainee under such circumstances from the resources of the department or institution.

Student descriptions of the characteristics of good mentors reinforce the idea of mentoring as a complex social relationship.[18] And mentors tend to confirm beliefs about the central importance of their social and personal characteristics.[19] Even with respect to practices within the laboratory, rather than within the departmental, professional, or extracurricular lives of their students, good mentors contribute to the personal, social, and creative decisions of their students. Snyder, for example, emphasizes the transmission of creativity in the laboratory in experimental design and choice of research direction— rather than experimental technique and instrument competence—as the primary focus of good mentoring.[20]

The ideal mentor will assist the trainee in pursuit of career goals and in the acquisition of the requisite technical, professional, and social skills for conducting research in a particular field. The ideal mentor challenges the trainee, spurring the trainee to higher scientific achievement. The ideal mentor helps the trainee navigate the difficult course of doctoral and postdoctoral education and helps socialize the trainee into the community of scientists, without taking advantage of a position of institutional superiority.

The ideal trainee reciprocates by adding continuity to the mentor's work and providing the creativity and impetus to learning inspired by the young mind. The ideal trainee performs in the laboratory and classroom, and labors to establish scientific credentials for the benefit of the mentor and the scientific community, as well as for him or herself. The ideal trainee does not abuse the extension of trust from the mentor and does not undermine the mentor's legitimate authority.

THE RESEARCH TRAINING EXPERIENCE

Despite the attractive qualities of good mentoring, the realities may not always incorporate the ideals. Mentoring is "a complicated relationship. … It can be very good or it cannot work so well"; the question is, "are the problems systemic or are the problemsidiosyncratic?"[21] This section addresses the research training experience and identifies points of conflict between ideal and real mentoring with a view to determining whether the problems are the result of systemic flaws or individual and idiosyncratic faults.

Market of Mentors

In the world of ideal mentorship, mentors and trainees might find each other through some open market in which each could select the other with an eye toward scientific merit, intellectual and personal compatibility, and other relevant criteria. An open market of mentorship would reduce the abuse of inequalities in the relationship, because trainees could reject unfair or exploitative mentors in favor of others available on the market. Likewise, mentors could select graduate students who best fulfill their obligations and perform their research.

Opinions vary over the extent to which the mentorship market actually works in science and engineering training. Perfect markets operate only under conditions including, among others, clear and available information and unconstrained expression of preference. Some observers believe students select mentors on the basis of informed choices. Others see the choice of mentors as a "random" event predicated on the difficulties of assessing faculty credentials, talents, and reputations in a new department.[22]

Expression of preferences may be constrained as well by access to information among the faculty. Faculty must usually choose from the pool of graduate students available in their department and therefore rely on their department's admissions criteria. Rivalry for graduate

positions, particularly research fellowships and assistantships, is highly competitive. Competition for postdoctoral positions is similar.

From the trainee's perspective, however, the situation may be more constrained. Students may be forced to choose a mentor very early in their professional training because of funding considerations. Thus, because the trainee is constrained by funding, he or she may choose to work with a faculty member solely on criteria of patronage. Because not all potential mentors have the resources to support graduate students or postdocs, the market for mentors may not be perfect. Furthermore, in departments or disciplines where faculty advisors are assigned to graduate students, there are often expectations that the advisor will be that student's mentor. Without careful consideration of common research interests and perhaps even personal characteristics in the assignment of advisors to trainees (or vice versa), and without clarifying the expectation among all parties that the advisor should do more than merely sign course schedules, the expectation that the formal advisor will also be a mentor may be dashed.

The financial and administrative factors that affect the mobility of graduate students and postdocs therefore become important issues.[23] One possible method to perfect the mentorship market is to increase the share of portable fellowships, assigned to students themselves, or training grants, assigned to departments, rather than research assistantships assigned to laboratories. Training grants may be preferable because they relieve junior graduate students of the burden of setting a research agenda and applying for funds, just at the time the student should be freer to consider research options. Such a recommendation does not necessarily mean increasing spending, but merely changing current funding practices to offset what has been a trend toward nonfungible support in the form of research assistantships.[24]

Conflict of Roles

A second issue in the reality of mentorship is the potential conflict of roles or disincentives for researchers to perform well in the mentoring role. Although the strength of the U.S. system in linking education and research has been recognized and admired for nearly three-quarters of a century,[25] the conflicts between teaching and performing research are becoming more apparent. In particular, faculty members at research universities that train most graduate students are usually not directly rewarded in their career advancement for their graduate teaching or training skills. They may receive indirect rewards from the contribution

of well-trained graduate students to their research and enhancement of reputation owing to their students excelling elsewhere in the system, but these rewards may not be significant in tenure or promotion decisions.

Another conflict of roles in mentoring may occur between the demands of maintaining a laboratory in the contemporary research environment and the need to provide appropriate attention to trainees. It has been suggested that the rise of "scientific managers" heading large laboratories and "riding the circuit" in order to fulfill other professional obligations and solicit necessary funding has fostered an environment where trainees may not receive the full benefit of experienced and personal mentorship at the laboratory bench. Although laboratory heads may fail to participate in the everyday workings of the laboratory for the most beneficent of reasons—finding funds to support graduate students, for example—their inattention or benign neglect may not serve their trainees' education. Sometimes non-faculty postdocs or researchers fill the hierarchical gap left by the faculty member's absence from the laboratory (a phenomenon described as "surrogate mentorship" or "mentor displacement"). This substitution may be problematic in that non-faculty, outside the tenure system and loosely connected with their institution, have even less incentive than faculty to address the educational and other aspects of mentoring not immediately connected to research productivity.

Size of Research Groups

The development of big science may create a laboratory atmosphere that requires more consistent attention to good mentorship practices. As the size of research laboratories expands, even for the beneficent cause of providing for trainees, the quality of the training environment may decline.[26] In the highly competitive contemporary environment, laboratory heads may be tempted to make research decisions for the good of the team, rather than for the best educational interests of the trainees, and to use trainees for the instrumental pursuit of a predetermined research goal. "The advisor does harm to the student if he uses him in the laboratory as a pair of hands on a fixed piece of equipment or as a computer algorithm for a theoretical thesis."[27] Under current circumstances, graduate students risk becoming "indentured servants."[28]

In experimental sciences such as high-energy physics, the research agenda has fostered an increasing size of research groups, with a concomitant impact on questions related to graduate student training. The same may be true of some aspects of biology, where broad,

interdisciplinary studies—occasionally involving large groups of 40 to 100 or more—are commonly carried out by collaborative arrangement under a single investigator. As only one member of a large team, working on a complex instrument, the graduate student's work may become ever more specialized. Such changes raise questions about expectations of appropriate doctoral research; for example, does machine design or improvement qualify as dissertation-level research? Size and specialization in the laboratory also raise such issues as how varied an experience mentors are obliged to provide their students, and other issues—such as who counts as an author and who is entitled to access to research data—that are especially sensitive where trainees are concerned.

It may even be possible for the research goals themselves to be in conflict with the best educational and training interests of the trainee. Graduate students and postdocs, although generally receptive to funding from industry, may recognize the risks involved to free and open communication of basic research. Although industrial ties for trainees may help them adapt to the realities of the contemporary research environment, such ties may bind them prematurely to an industrial culture not completely appropriate for an educational environment.

Personalities and Gender

Regardless of environmental pressures from big science, industrial science, or competitive science, mentorship is still a relationship between two individuals, and much relies on the personalities and compatibility of the two. Just as parent-child relationships can turn sour, so too can mentor-trainee relationships.

One way in which the mentoring relationship can turn bad is that instead of training an apprentice to be independent in the pursuit of a unique research question, a mentor may engage in "cloning," trying to reproduce an exact copy, in the scholarly sense, of the mentor in the trainee.[29] A mentor's attempts at cloning him or herself in the trainee can only serve to block the novelty and stifle the innovation that come from researchers entering a field of inquiry.

The scholarship on mentoring and sex differences emphasizes the personal and social factors that influence mentoring. There are disputes about whether women in academia receive the same attention and benefits as their male colleagues from a (traditionally male) mentor.[30] The most solid conclusion in the literature seems to be that male students avoid female mentors, while "female students neither gravitate toward nor avoid" them.[31]

Some serious problems do occur in opposite-sex mentoring relationships with sexual harassment, misunderstandings, or envy from coworkers or spouses, and with the lack of ability on the part of some male participants to treat the female mentor or trainee professionally.[32] Romantic liaisons between mentors and trainees, especially graduate students, are generally discouraged without being prohibited. It is not surprising that shared interests and close contact should foster such relationships. Some participants abuse these relationships, causing emotional stress as well as damaging careers. The power imbalance in such a relationship is a serious factor that deserves attention.

Power

Because mentorship involves a relationship between a senior and junior figure, the inequalities of power and institutional standing are important features to consider in seeking to foster responsible practices. Good mentorship requires a great deal of trust on behalf of both participants. Trainees and mentors share their vocations, their theories, their aspirations, and their reputations with each other. When the relationship is mutually rewarding and supportive, there are often no reasons to dispute the allocation of credit for new discoveries, even if the credit appears to be uneven.[33]

When conflicts arise, however, the expectations and assumptions that govern authorship practices, ownership of intellectual property, and references and recommendations are exposed for professional—and even legal—scrutiny. Mentorship and collaborative research practices rely heavily upon implicit standards and practices that have been shaped by customs and traditions over several decades. It is only recently that these standards and practices have been called into question by individuals who feel that they have been betrayed or wronged in their professional work. In some cases, these complaints reveal an individual's unwillingness to tolerate behaviors that others may have endured. Some cases may reflect a broader social trend toward litigation and relying on the courts to resolve interpersonal disputes. In others, mentors or trainees may have felt compelled to betray the other's trust in response to new competitive pressures in the research environment.

Whatever the cause, the inequalities between mentor and trainee can exacerbate ordinary conflicts such as the distribution of credit or blame for the quality of research.[34] Abuse of the relationship could even include the suppression of or retribution against whistle-blowing activities on the part of the trainee.[35] The mentor need not take overt action against a challenge from a trainee for basic inequalities of the

relationship to become apparent. Mentors have warned graduate students in no uncertain terms about the power politics of science when writing that "any suggestion of malpractice becomes immediately a most serious matter … [and] it is often expedient for the establishment to find a scapegoat, and the low person in the organizational hierarchy (who else but the graduate student?) is a prime candidate."[36]

If difficulty between a mentor and trainee occurs, then the institutionally insecure position of the trainee can become a great liability. The trainee often lacks the prestige and the ability to move about in the department, institution, or professional community that may mediate the difficulty. Trainees are dependent on mentors for research problems, laboratory space, and references. Although students and postdocs have some procedural rights (more at public institutions), their mentors, who are likely to be tenured faculty, are far more secure in the institution. Graduate students and postdoctoral fellows frequently exist in a netherworld in which institutional obligations are unclear or not forthcoming. At some institutions, the unionization of graduate students is indicative of this uncertain status.

Naturally, disjunctures exist between the ideal mentoring relationship and actual relationships. Because the relationship is exceedingly personal, many of the deviations from the ideal are liable to be of a personal and idiosyncratic nature. But because of the institutional settings common to most mentoring relationships, systemic problems may also occur. More intense scientific competition, a proliferation of roles for researchers in academia and industry, the instrumentation requirements for scientific education and research—these are all part of the new research environment and must be confronted in the training of every new researcher.

MAKING MENTORSHIP BETTER

Recognizing that there is a disjunction between the ideal mentorship experience and the reality of training in research, many groups and institutions have begun to encourage good mentorship practices. These efforts range from issuing training guidelines and definitions of responsibilities to establishing formal evaluation programs and course work. These efforts all acknowledge the importance of explicit guidance in the ethical and social aspects of training, in addition to the technical aspects.

Guidelines

Some universities have written guidelines for the supervision or mentorship of trainees as part of their institutional research policy guidelines.[37] Other groups or institutions have written "guidelines"[38] or "checklists,"[39] or have suggested "areas of concern" and "devices."[40] The Harvard University, University of Michigan, Institute of Medicine, and National Institutes of Health guidelines all affirm the need for regular, personal interaction between the mentor and the trainee. They indicate that mentors may need to limit the size of their laboratories so that they are able to interact directly and frequently with all of their trainees. Although there are many ways to ensure responsible mentorship, methods that provide "continuous feedback," whether through formal or informal mechanisms, are apt to be most successful.[41] Such practices as departmental mentorship awards (comparable to teaching or research prizes) can recognize, encourage, and enhance the mentoring relationship.

The principles outlined in the 1989 Institute of Medicine guidelines suggest "that the university has a responsibility to ensure that the size of a research unit does not outstrip the mentor's ability to maintain adequate supervision."[42] Three of these four guidelines are explicit about the mentors' responsibility to provide a research atmosphere conductive to responsible and fruitful research, to ensure that the trainee is not just a technical worker, to socialize the trainee into the appropriate standards of scientific research, and to offer appraisals, assistance, and advice on research strategies, problem choice, and career prospects. Two of the four specify that the mentor should accept responsibility for all work done under his or her supervision. One of the four emphasizes thoughtfulness in managing the complexity of matching mentors with trainees and considers conflicts of interest as a potential problem area in research training.

In a recent document on the role and nature of the dissertation, the Council of Graduate Schools makes several recommendations about the graduate training and the mentoring relationship, including reaching prior, written agreement about access to data and intellectual property rights in collaborative research between mentor and trainee; increasing the availability of information about other graduate students and their faculty advisors and mentors to new graduate students to aid in their selection process; preparing handbooks for faculty and students with guidelines to clarify expectations and mutual obligations in graduate education and dissertation research; and monitoring graduate student progress more closely by departments.[43]

Formal Programs and Requirements

Recognizing that the mentoring relationship is important for research training, some universities or departments have inaugurated formal educational efforts to promote good mentoring.[44] The National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration require that "all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program."[45] Already, such institutions as UCLA and the University of Chicago have established their responses to the new requirements.[46]

The UCLA Medical Science Training Program held a two-day retreat that included a total of four hours of discussions on scientific responsibility and good research practices. Students responded to questions about their experiences with regard to research conduct, listened to lectures on ethics in research, and examined case studies of questions in responsible research. The University of Chicago program presents a series of seven lectures and discussions during the course of the year addressing such topics as the government concerns over scientific integrity, human and animal subjects research, and the university's academic fraud procedures.

This review is not an exhaustive one of how institutions can and have encouraged good mentoring and the transfer of professional standards and practices from one generation of scientists to the next. But it does suggest that the closer one looks at graduate education and training in science and engineering, the more importance one attaches to the mentoring relationship. Although the relationship is a personal one between faculty and student, some institutional support is appropriate and necessary.

NOTES

1. This paper uses the term "trainee" to include both graduate students and postdoctoral trainees in their relationship to senior scientists, but makes distinctions where needed.

2. National Research Council (NRC), 1989, *Summary Report, 1988, Doctorate Recipients from United States Universities*, Office of Scientific and Engineering Personnel, National Academy Press, Washington, D.C. While the time to doctorate is increasing, there is some evidence that the magnitude of the increase may be affected by the organization of the cohort chosen for study. In the humanities, the increased time to doctorate is not as large if one chooses as an organizational base the year in which the baccalaureate was received by Ph.D. recipients, rather than the year in which the

Ph.D. was completed; see Bowen, W. G., G. Lord, and J. A. Sosa, 1991, "Measuring time to doctorate: reinterpretation of the evidence," *Proceedings of the National Academy of Sciences* 88 (February 1):713-17.

3. Cronan-Hillix, T., L. K. Gensheimer, W. A. Cronan-Hillix, and W. S. Davidson, 1986, "Students' views of mentors in psychology graduate training," *Teaching of Psychology* 13(3):123-27.

4. Hill, S., E. Kogler, M. H. Bahniuk, and J. Dobos, 1989, "The impact of mentoring and collegial support on faculty success: an analysis of support behavior, information adequacy, and communication apprehension," *Communication Education* 38(January):15-33.

5. Cronan-Hillix et al., "Students' views of mentors in psychology graduate training," 1986.

6. Rawles, B. A. 1980, *The Influence of a Mentor on the Level of Self-Actualization of American Scientists*, unpublished Ph.D. dissertation, Ohio State University.

7. Merriam, S. B., T. K. Thomas, and C. P. Zeph, 1987, "Mentoring in higher education: what we know," *The Review of Higher Education* 11(2):199-210.

8. Long, J. S., P. D. Allison, and R. McGinnis, 1979, "Entrance into the academic career," *American Sociological Review* 44(5):816-30.

9. Long, J. S., and R. McGinnis, 1985, "The effects of the mentor on the academic career," *Scientometrics* 7(3-6):255-280.

10. Rawles, *The Influence of a Mentor*, 1980.

11. Cram, D., 1989, "Commentary: Tribe and leader," *CGS Communicator* 22(April):1.

12. Sindermann, C. J., 1987, *Survival Strategies for New Scientists*, Plenum, New York.

13. John Brauman in Committee on Science, Engineering, and Public Policy (COSEPUP), 1990, "The mentor-student relationship," a printed transcript of the Scientific Conduct Seminar Series, July 10, Washington, D.C.

14. Gray and Gray, 1986, *Mentoring: A Comprehensive Annotated Bibliography*, International Association for Mentoring, Vancouver.

15. Cronan-Hillix et al., "Students' views of mentors in psychology graduate training," 1986; Smith, J. M., P. N. Chase, and J. J. Byrd, 1986, "A formalized mentor system in an educational setting," *Engineering Education* 76(4):216-18; Merriam et al., "Mentoring in higher education," 1987; Department of Health and Human Services (DHHS), 1990, *PHS Workshop: Education and Training of Scientists in the Responsible Conduct of Research*, March 8-9, Public Health Service, Washington, D.C.

16. Tuckman, H., S. Coyle, and Y. Bae, 1990, *On Time to the Doctorate: A Study of the Increased Time to Complete Doctorates in Science and Engineering*, Office of Scientific and Engineering Personnel, National Academy Press, Washington, D.C.

17. Council of Graduate Schools (CGS), 1990, *Research Student and Supervisor: An Approach to Good Supervisory Practice*, CGS, Washington, D.C.

18. Cronan-Hillix et al., "Students' views of mentors in psychology graduate training," 1986.

19. Ciervo, A. V., 1987, "Tinker, trainer, molder, spy," *Currents* 13(6):52-56; Cram, "Commentary: Tribe and leader," 1989.

20. Synder, S. H., 1989, *Brainstorming: The Science and Politics of Opiate Research*, Harvard University, Cambridge, Mass.

21. Jules LaPidus in COSEPUP, "The mentor-student relationship," 1990.

22. For the opposite perspective, see Amundson, N. R., 1987, "American university graduate work," *Chemical Engineering Education* 21(4):160-63.

23. "I should also say that having benefited … from … NSF fellowships when I was a graduate student and a postdoctoral, [I had] the flexibility to choose the people that I wanted … to work with" (remarks of John Brauman, in COSEPUP, "The mentor-student relationship," 1990). Also see recommendations for "portable" postdoctoral support in National Research Council (NRC), 1981, *Postdoctoral Appointments and Disappointments*, Committee on a Study of Postdoctorals in Science and Engineering in the United States, National Academy Press, Washington, D.C.

24. See appendix table 2-18 in National Science Foundation (NSF), 1989, *Science Indicators*, NSF, Washington, D.C.; see also, Institute of Medicine (IOM), 1990, *Funding Health Sciences Research: A Strategy to Restore the Balance*, Division of Health Sciences Policy, National Academy Press, Washington, D.C.

25. Weber, M., 1946 [1918], "Science as a vocation," Pp. 129-56 in *From Max Weber: Essays in Sociology*, edited by H. Gerth and C. W. Mills, Oxford University Press, New York.

26. Council of Graduate Schools (CGS), 1990, *The Doctor of Philosophy Degree: A Policy Statement*, Task Force on the Doctor of Philosophy Degree, CGS, Washington, D.C.

27. Amundson, "American university graduate work," 1987.

28. Maxine Singer in COSEPUP, "The mentor-student relationship," 1990.

29. See Baird, L. L., in press, "The melancholy of anatomy: the personal and professional development of graduate and professional school students," *Higher Education: Handbook of Theory and Research*, Agathon Press, New York.

30. Erkut, S., and J. R. Mokros, 1984, "Professors as models and mentors for college students," *American Educational Research Journal* 21(2):399-417; Cronan-Hillix et al., "Students' views of mentors in psychology graduate training," 1986; Merriam et al., "Mentoring in higher education," 1987.

31. See Erkut and Mokros, "Professors as models and mentors," 1984; and also Cronan-Hillix et al., "Students' views of mentors in psychology graduate training," 1986.

32. Rawles, *The Influence of a Mentor*, 1980.

33. National Academy of Sciences (NAS), 1989, *On Being a Scientist*, Committee on the Conduct of Science, National Academy Press, Washington, D.C.

34. NAS, *On Being a Scientist*, 1989.

35. Hollis, B. W., 1987, "I turned in my mentor," *The Scientist* 1(December 14):11.

36. Sindermann, *Survival Strategies for New Scientists*, 1987.

37. For examples, see Harvard University Faculty of Medicine, 1988, *Guidelines for Investigators in Scientific Research*, Harvard University, Cambridge, Mass.; and University of Michigan Medical School, 1989, *Guidelines for the Responsible Conduct of Research*, Medical School Committee to Develop Guidelines for the Responsible Conduct of Research, University of Michigan, Ann Arbor.

38. Institute of Medicine (IOM), 1989, *The Responsible Conduct of Research in the Health Sciences*, Committee on the Responsible Conduct of Research, Division of Health Sciences Policy, National Academy Press, Washington, D.C. Also, National Institutes of Health (NIH), 1990, *Guidelines for the Conduct of Research at the National Institutes of Health*, NIH, Bethesda, Md.

39. CGS, *Research Student and Supervisor*, 1990.

40. CGS, *The Doctor of Philosophy Degree*, 1990.

41. CGS, *Research Student and Supervisor*, 1990.

42. IOM, *The Responsible Conduct of Research*, 1989, p. 85.

43. Council of Graduate Schools (CGS), 1991, *The Role and Nature of the Doctoral Dissertation: A Policy Statement*, CGS, Washington, D.C.

44. The University of Southern California Graduate Association of Students in Psychology has implemented a system to evaluate faculty in their mentoring and advising roles (Cesa, I. L., and S. C. Fraser, 1989, "A method for encouraging the development of good mentor-protege relationships," *Teaching of Psychology* 16(3):125-28). The University of Missouri-Kansas City School of Medicine has a "docent" program for its 6-year, B.A.-M.D. students in which faculty physicians are assigned to "docent teams" of 3 students each from the last 4 years of training (for a total of 12 students per docent) (Calkins, E. V., L. M. Arnold, T. L. Willoughby, and S. C. Hamburger, 1986, "Docents' and students' perceptions of the ideal and actual role of the docent," *Journal of Medical Education* 61(September):743-48). West Virginia University has established a mentorship program for its undergraduates in industrial engineering, uniting sophomores with seniors and advising them both with a faculty member (Smith, J. M., P. N. Chase, and J. J. Byrd, 1986, "A formalized mentor system in an educational setting," *Engineering Education* 76(4):216-18).

45. National Institutes of Health (NIH) and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), 1989, "Requirement for programs on the responsible conduct of research in National Research Service Award institutional training programs," *NIH Guide for Grants and Contracts* 18(December 22):1.

46. Although the announced deadline for the requirements was July 1990, data on compliance and the range of programs implemented are not available because different training programs have different deadlines to submit their proposals and because those proposals submitted still have to be reviewed.

4

Reflections on the Current State of Data and Reagent Exchange Among Biomedical Researchers

Robert A. Weinberg

The following relates to the author's experiences in the biomedical research field over the past two decades. Accordingly, conventions and practices common in other specialized areas of research may not be reflected in what follows.

INTRODUCTION AND DEFINITION OF TERMS

Much of the popular and scholarly writing on the subject of storage and distribution of research data, results, and materials fails to distinguish between these entities. In practice, however, the ways in which primary data (i.e., raw data collected directly from experiments), derived results (conclusions, distillations, interpretations), and research reagents are handled are very distinct and governed by unrelated practices. The confounding of these various categories has led to great confusion and occasionally untenable conclusions.

Primary Data

There are two major types of data, each deriving from a distinct approach to doing science. For want of better terms, I will call these "survey" science and "manipulative" science, although more appropriate terms have undoubtedly already been coined by others. While these terms imply two very distinct ways of acquiring scientific information, it should be said that a multitude of intermediate strategies exist as well.

Robert A. Weinberg is a member of the Whitehead Institute for Biomedical Research and professor of biology at the Massachusetts Institute of Technology.

Survey Science and Derived Data

"Survey science" implies an experimental approach in which an experimental protocol is constructed that is followed repetitively on a number of occasions in order to accumulate a large corpus of data. Such a protocol is established prior to conducting experiments and collecting data, and is usually not altered during the course of the experiments in response to the data required. Collecting these data may involve dozens of iterations of a measurement or millions of such iterations, and the accumulated data may fill one laboratory notebook or many computer tapes.

Implicit in many such surveys and the protocols that guide them is the notion that a single, well-executed measurement will not suffice to produce unambiguous conclusions and that repetitive performance is required to achieve that end. This requirement for repetition may be necessitated by the heterogeneity or variability in the subjects of the study, unreliability in the measuring technique, lack of uniform competence amongst a large group of experimenters, and so forth.

The results of these measurements are commonly susceptible to statistical analysis, and more often than not, introduction into computerized data banks for storage, analysis, and retrieval. Examples of such "survey data" include clinical trials of drug regimens, DNA sequencing, epidemiological studies, other types of population studies, ecological surveys, and gathering of x-ray crystallographic data.

Manipulative Studies and Derived Data

A quite distinct method of doing science is to follow an experimental course in which a succession of distinct, unique manipulations is performed to reach the end result. Here, the precise experimental course cannot be laid out in advance, since, importantly, the outcome of an initial manipulation will determine the precise nature of those that immediately follow it; moreover, each of the steps in such a succession may itself be invested with an elaborate logical structure that determines the nature and interpretation of its outcomes.

While the design of each of the steps in such an experimental succession may be dictated by generally accepted technical practices and logical models, the precise nature and outcome of any given step is not predictable, since it will be determined by those steps preceding it. In contrast to survey-type experiments, in these manipulative experiments the protocol is constantly altered in response to the most recently obtained results. When compared with survey-type research, the logical

complexity of manipulative research is much denser per unit of data, and the data are usually not readily susceptible to statistical analysis, nor can they easily be introduced into a computerized data base for storage, retrieval, and analysis. Indeed, in many cases the time and expense required for such computerization would approach the time and expense invested initially in carrying out the experiments themselves. Examples of such manipulative experimentation include projects designed to clone a gene, develop a genetically complex organismic strain, or purify a protein and examine its mechanism of action.

Derived Results and Conclusions

Both survey and manipulative data serve as objects for distillation and interpretation, leading in turn to concepts and conclusions that may not be apparent upon cursory examination of the primary data. Invariably there are multiple alternative methods by which primary data can be analyzed through use of distinct conceptual models, statistical procedures, or deductive paths. Since such analytical and interpretative methods may differ strongly from one another, the choice of method may strongly affect the conclusions and interpretations attached to the data by the investigator. Consequently, the conclusions and/or interpretations may be the object of contention or special scrutiny even when the original primary data are clear, unambiguous, and above reproach. For this reason, the conclusions and results of a research project are often separable from the data that underlie them and are susceptible to separate critical scrutiny.

Derived Reagents

Conclusions should not be equated with derived reagents. As portrayed above, results and conclusions are pieces or bodies of information. In contrast, a reagent is a physical entity such as a purified protein, a mouse strain, a monoclonal antibody, a DNA clone, or a synthesized chemical that is created as a product of experimental work. In many instances, such reagents are, at least at the moment of their derivation, unique, and their availability empowers an investigator to perform further experiments that are not possible for those lacking such a reagent.

In some cases, the transfer of information can enable others to rapidly duplicate an initially unique reagent (e.g., a DNA sequence used by others to generate their own identical copies of a previously cloned

gene). In many other cases, information transfer does not itself enable others to duplicate the reagent, which duplication can only be achieved by a long, laborious repetition and completion of a complex experimental protocol used by others previously to create such a reagent (e.g., such reagents might include a monoclonal antibody, mouse strain, or complex synthetic chemical).

CURRENT PRACTICES FOR DATA DISSEMINATION AND STORAGE

Distribution of Primary Data

Primary data, whether of the survey or manipulative type, may on occasion be exchanged between researchers. The motivations for exchanging raw primary data can be of two sorts. The person requesting primary data may wish to use these data as a basis for extending or developing his/her own research project. Thus, provision of the data may obviate collection of similar data by the requester. Alternatively, the requester may be interested in critically examining the data of another scientist with the intent of determining whether the supplier of the raw data has collected it correctly and/or interpreted it properly in a published report or similar presentation of results. Here the motive is to subject the work of a peer to independent (and potentially adversarial) criticism.

1. Incorporation of another's raw data into one's own research is rarely useful in most areas of research. In particular, the primary manipulative data of one scientist are almost without exception useless to another since such primary data record a unique experimental path that would in general never be precisely retraced by another. In the case of survey data, there exist certain possibilities for constructive use of the raw data of others. For example use of "meta-analysis" may allow a researcher to incorporate the raw data of a number of independent clinical trials, generating conclusions that would not be tenable from analysis of a single trial. But more often than not, most types of survey data are not useful to peers in a research field because they have been collected with a focus or address a particular question that is not of immediate concern to others.

2. Raw data are even less frequently exchanged for the purpose of critically examining the interpretations and conclusions of another, independent researcher. The very act of requesting such data could be

viewed as a challenge to the scientific competence and/or integrity of the provider. Accordingly, such a request is not undertaken lightly.

Moreover, the raw data themselves commonly do not provide the clearest test of the validity of another researcher's conclusions. In the case of primary data of the manipulative type, such data may be extremely difficult to interpret, even when collected and recorded in a most methodical and thorough fashion. More importantly, the validity of another's experiments and derived conclusions are best tested by attempts at independent reproduction of the key results that led to those conclusions.

Failure to independently reproduce the work of another may initially be attributed to a failure to replicate faithfully all the conditions of the earlier experiment. But repeated failures of such attempts at replication gradually erode the credibility of the initial experiment. Conversely a single, cleanly performed, successful independent replication represents a stunning vindication of the earlier experiment. It would seem that critical examination of a peer's raw data might frequently reveal instances in which primary data have been misinterpreted in the course of deriving conclusions. In practice this almost never occurs when examining manipulative data and only infrequently occurs during the (rare) examination of survey data of others.

3. The above descriptions of data exchange pertain exclusively to exchange and communication between independent, potentially competing research groups. Entirely different dynamics and rules govern the exchange of data within a research group that functions under the supervision of a single principle investigator. Here, practices that enhance cooperation, effective mentorship, and the productivity of the group as a whole will come into play. Accordingly, raw data of one researcher will frequently be examined by others within the group as a means of constructive criticism, quality control, and education in research practices. In some groups, such raw data will be examined with frequency only by the research supervisor. A far better, though hardly universal, practice is for the workers and trainees within the group to frequently examine and critique each other's data, either informally or in the setting of regularly scheduled research group meetings. Such examination of data within a group can usually be carried out in the spirit of mutual education and improvement, and need not be encumbered by the tensions arising when one scientist asks to see the data of a competitor.

Storage of Primary Data

Most primary data are stored in the individual laboratories in which they were initially derived, generally as hard copy in laboratory notebooks, data sheets, and so on. Few conventions exist at present concerning the storage of research data.

In many laboratories, there is a vaguely articulated notion that primary data should be stored for a period of 3 to 5 years after initial collection. Practices also vary as to where the data should be stored and by whom. Part of this ambiguity stems from questions attached to the value of such stored data and its ownership, as discussed in a subsequent section. In some laboratories, the data and databooks become the property of the laboratory under the stewardship of its principal investigator. In others, those that collected the data, often in the course of their own research training, retain possession of the databooks and keep them after leaving the laboratory.

The suggestions by some commentators that many types of scientific data should be incorporated into computerized data banks and subjected to periodic auditing seem to be dramatically out of touch with the realities of scientific data collection, storage, and evaluation. Raw data of the manipulative sort are, with rare exception, not susceptible to formatting and storage in computerized data bases. Moreover, the auditing of manipulative data, stored in a laboratory archive of data notebooks, can usually be done effectively only by members of a small cadre of peers in the same subspecialty. Even with such expertise, effective data auditing is extremely labor-intensive.

The results and conclusions of certain types of experiments (e.g., protein and DNA sequences) are, in contrast to primary data, readily stored in computer banks and can indeed be subjected to highly effective computerized analysis. But these particular cases are not illustrative of the general problem of raw data storage and analysis because (1) they are in fact results generated by the processing of raw data, and thus not raw data at all; and (2) they are representative of only a small fraction of the information generated in biomedical research, especially research of the manipulative sort.

Data storage practices have received increased attention in recent years because of the ever more frequent attempts to patent certain concepts and reagents flowing out of biomedical research. Primary data are often required to document patent claims and precedents for discovery, and this has provided incentive for some laboratories to improve their data storage practices. A secondary motivation for improving storage practices is the spectra of increasing auditing of

primary data by parties from outside the laboratory. This latter motivation has to date proven far weaker than the first.

Some universities have begun to discuss whether they, as universities, should create central repositories for storage of all the primary data collected in their research laboratories. This would seem to be an unworkable solution for a number of reasons: (1) the output of bench workers, each of whom may generate 0.25 to 1.0 shelf-feet of databooks per year, necessitating enormous amounts of dedicated central storage space; (2) the enormous logistical problems of cataloguing, retrieval, systematic accessioning, and periodic deaccessioning of databooks; (3) the reluctance of those who generated the data to entrust them to a nonexpert with associated loss of control and possible irretrievability from a poorly managed archive; (4) unresolved questions concerning legal ownership of the data; and (5) dubious benefit from establishment of a centralized archive.

PRACTICES INFLUENCING THE DISTRIBUTION OF RESEARCH REAGENTS

Factors that influence the distribution of research reagents, as defined above, differ dramatically among different subspecialties of biomedical research. These dramatic differences can be ascribed to differences in the culture of each of these subspecialties which become deeply ingrained early in the history of the subspecialty, often because of the strong influences of its founders and/or most prominent practitioners. For example, yeast genetics is a subspecialty having a long tradition of rapid, free exchange of research materials, (e.g., special yeast strains), whereas human genetics as a field has not been blessed with such openness (with notable exceptions in the recent past). While some might rationalize these cultural differences in terms of the logistical and functional demands of the various research subspecialties, such functional pressures have proven far less important than the precedents established by the leaders of each field, each acting on the basis of what he/she has perceived to be acceptable and desirable standards of professional behavior.

Granting the above cultural differences, it is nonetheless worthwhile to enumerate the countervailing pressures that influence their establishment. Militating against the distribution of reagents are several factors. A laboratory may often work for a decade to derive a unique reagent (e.g., a cloned gene). Having created such a reagent, this laboratory would like to derive direct benefit from its creation. Moreover, whether or not the creation of the reagent entailed great

effort, the creators of the reagent may wish to limit its distribution in order to disadvantage peers whom they see as competitors or even adversaries.

The culture of modern biomedical science encourages individual laboratories to devote effort focused on the systematic development of a single research problem over a number of years. The end goal of such research is not a compendium of random bits of data in the particular research area, but rather the construction of a coherent, logically developed narrative about a discrete scientific issue. Good scientists strive to tell "a good story" rather than a series of disconnected anecdotes. Such a coherent development of a research problem often entails the creation of a series of unique reagents, each used to catalyze a new series of experiments and the creation of yet other, second-generation reagents. As such, the development of each reagent is not an end goal in itself, but only a means of opening a new chapter in the investigator's research agenda.

Because of this, the creation of a reagent may be seen as a long-term investment required to seed work for many years to come. Having invested great effort in establishing a preeminent position in solving the first parts of a particular problem, an investigator may be reluctant to dissipate this initial advantage by making reagents rapidly available to all interested parties, including those competitors who, though benefiting greatly from the availability of such a reagent, have devoted no effort to its creation.

For these reasons, rules that some might propose that would rigidly dictate the rapid distribution of all research reagents following their creation may act to seriously reduce the motivations of those who have created these reagents as vital precursors to subsequent steps of their own planned research program. If no special advantage accrues from creating such a reagent, the great effort invested in its creation may become much less attractive. Some may argue that receiving credit for the development of a reagent should be sufficient reward for its development, but this overlooks the facts that (1) development of the reagent may itself not attract wide attention and approval of peers or the public in spite of its great intrinsic utility, and (2) for many scientists, the receipt of credit from peers at one or another point in their career may be far less important than their own continuing ability to move forward in fulfilling a long-term, self-imposed strategic plan for reaching certain research goals.

Another set of factors works, in contrast, to facilitate the rapid distribution of research materials. The most fundamental of these is the simple fact that the progress of many scientific disciplines is greatly accelerated when research reagents are exchanged freely. Thousands of

examples in contemporary science bear witness to this. The second factor derives from the fact that the research underlying the development of a reagent may have been supported by public funds and the derived conclusion that the reagent should be placed in the public domain (or at least the open arena of peers) following its derivation. Related to this is the notion that the public has the right to expect the most efficient use of research monies, and that the efficiency of the entire publicly supported research enterprise can be greatly enhanced if reagents are made rapidly available to all those who could benefit from them. Traditions prevailing in a field may be strong and unambiguous in encouraging practitioners within the field to freely communicate and exchange reagents. Those deviating from this become known to their peers and may suffer subtle forms of professional isolation as a consequence of their repeated infraction of these generally accepted rules. Research reagents may often be given out as gestures of goodwill with the hope that reciprocity will be practiced by the recipient on some future occasion.

Finally, several research journals now require that reagents described in research reports published in their journal be made available to other qualified investigators following publication. This practice is not universally shared among all journals. Those that do stipulate reagent sharing have not been explicit as to how rapidly such reagents should be distributed following publication. At least one journal editor has threatened to refuse publication rights to any author who refuses to make reagents freely available, whether or not such reagents have been described in the journal managed by this editor. Some authors intentionally publish in journals that do not have a distribution-of-reagents requirement in order to evade this obligation. There is, moreover, the suspicion that some journals have refrained from imposing such a rule in order to attract the papers of those authors who do not wish to live under such constraints. Although these rules have been in effect for several years, it is not yet clear what effect they have had on real practices and whether violations of these rules have come to the attention of the journal editors.

These rules have been established ostensibly to facilitate the independent reproduction of an already published result, but it is important to note that those scientists receiving reagents as a direct consequence of adherence to these rules are usually not confined to using these reagents for the exclusive purpose of independent reproduction of an already published result. More often than not, these reagents are distributed with few if any stipulations attached to their ultimate use. Accordingly, these journal-imposed rules should be seen

as subserving the second, unrelated goal of facilitating progress in the field as a whole.

The above discussion analyzes the factors influencing reagent distribution. It is worthwhile to examine, if only cursorily, actual practice in this area. In the field of molecular biology (i.e., all those areas of biomedical research that utilize and are affected by the gene-cloning technology and ancillary techniques), the conventions of sharing vary somewhat. Nonetheless, all center on the standard that reagents and results should be made available to the general community of researchers within a reasonable period after they are obtained, usually several months.

In certain cases, the product of a research project is a unique reagent (e.g., virus or mouse strain, monoclonal antibody) that has been obtained through either serendipity or an extremely laborious procedure and is, in any case, not readily replicated independently by others, even those having great expertise and extensive descriptions of its derivation. Such a unique reagent becomes a valuable commodity.

In some cases, such a reagent is given out freely by those who have created it with no stipulations attached. In other cases, it may be given out as part of a collaborative agreement in which the recipient agrees to use it for clearly stated applications and to compensate the donor with a coauthorship on a published report that may result from its use. This is generally viewed as a reasonable request on the part of the donor if such stipulations are made during a short period (e.g., 6 to 18 months) after initial derivation of the reagent. They are seen as a just reward for having produced this unique reagent, since other rewards (e.g., recognition received because of the initial report of its isolation) may in certain cases be rather minimal. However, after this grace period, current conventions dictate that the reagent be given out freely to all who request it.

Some donors inquire of the recipient as to intended use of the reagent, stipulating that the donated reagent not be used for applications that are already being pursued by the donor and his/her coterie of collaborators.

Because of increasing pressure from journal editors, many such unique reagents are becoming freely available within weeks or several months of their description in the published literature (see above).

Donors of such unique reagents frequently stipulate that the donated reagent not be passed on to third parties without prior authorization. Since there is no statute of limitations attached to such a stipulation, the original donor may receive requests from a recipient for authorization to pass the reagent on to third parties years after this reagent has lost its unique character and the interest of the original donor.

In certain cases, such unique reagents have been hoarded for years, a practice that is viewed with great distaste by many. In one instance, a virus strain was hoarded and studied for more than a decade by a single investigator. Ironically, it soon became a valueless commodity as other investigators, unable to study it and compare its properties with known reagents, lost interest in it and the reports describing it.

Many such reagents have been produced by industry (i.e., biotechnology companies) over the past decade. Industry has proven surprisingly willing to distribute reagents to the general research community. Such distributions are often encumbered by stipulations that the reagent be used only for an agreed-upon application and/or for noncommercial purposes. In many cases, this generosity is seen as a gesture of goodwill on the part of a company that is anxious to maintain good and close ties with a research community that serves as a wellspring of research of great benefit to the company.

Alternatively, a company may benefit in direct and immediate ways from distribution of a reagent. Thus, it may demand and receive the right for prepublication review of a report describing the results that have depended on use of the donated reagent. All patentable results or processes deriving from use of the reagent may also be claimed by the donating company. In some cases, the company or its investigator employees may demand to be included as coauthors on any published report deriving from use of the reagent. Yet other companies may demand nondisclosure of any results in any form until the company's representatives have had an opportunity to review these results to determine patentability.

Some researchers build their careers on a practice of developing a unique reagent and then insisting on coauthorship as a quid pro quo of its distribution, even if the donor of the reagent does not contribute in any substantive way to the research that utilizes the donated reagent. Although this is viewed with distaste by most, it has proven an effective means for a small number of researchers to build substantial bibliographies and reasonable reputations. The effectiveness of this stratagem stems from the fact that once the donor becomes a collaborator with the recipient, the donor is entitled to appear as a coauthor on reports and to include any results in his/her own lectures. In these cases, it is often difficult for other peers to sort out the donor's contributions to the project from those of the recipient who actually carried out the work.

Given recently developed cloning, sequencing, and antibody generation techniques, the proportion of research reagents that remain unique (i.e., not readily replicated independently by others) for extended periods of time is steadily shrinking. For example, a DNA clone may

now be replicated within days or weeks by others possessing only fragmentary sequence information. Thus, any stipulations placed on the distribution of reagents are becoming unenforceable and unreasonable. Here, even though phrases like "collaboration" may be interspersed in the initial conversations preceding exchange of the reagent, a real collaboration rarely ensues since both parties realize that a full-fledged collaboration would be an unreasonable quid pro quo for a reagent that has only minimal intrinsic value by virtue of its easy replicability. Consequently, the donor of such a reagent is usually recognized in the "acknowledgments" coda of a paper rather than as a coauthor at the beginning.

DATA OWNERSHIP AND RETENTION

The concept of data ownership, which is deeply embedded in the culture of social scientists, carries little weight among researchers in basic biomedical research, especially among those engaged in manipulative research. Part of this stems from the utility of the data to those who possess it. In the case of a scientist performing manipulative (rather than survey) experimentation, the data generated represent only an historical record of logical steps that led to one or another endpoint conclusion. Such data are generally only useful to those very few who would retrace these steps in an attempt to strengthen or strike down the initially reached conclusion. Even this use of the data of others is rarely resorted to, since as argued above, the independent replication of experiments is the most common and usually most effective method of critically assessing the results of others. This use of independent replication will with great likelihood remain the favored method of assessing the work of others, even in a period when declining research budgets would seem to discourage duplication of experiments.

Equally important, in a rapidly moving basic research field, research priorities change frequently. Consequently, both the initially obtained research data and the derived results or endpoints soon become historical relics—footnotes to those working 3 or 4 years later in the same area. Such data become valueless, and the concept of ownership of research data has at best marginal meaning. Primary data are often saved only for sentimental purposes or in response to a perceived but rarely realized need to refer to the primary data years later for the purposes of fending off critical peers or buttressing a patent application.

The above should serve to explain why in a manipulative field like molecular biology, the current practices regarding primary data ownership are nonuniform and haphazard—why should elaborate rituals

be attached to a commodity that is essentially valueless? As discussed above, the data notebooks of a researcher may be kept by him/her upon departure from a lab; in other laboratories, they are kept as property of the laboratory and placed in a common archive. In a molecular biology laboratory, these archival databooks may on very rare occasion be perused to determine the origin and derivation of a reagent in current use (e.g., a gene clone).

Because of all this, it seems clear that any convention that may eventually be promulgated in order to impose standardized data ownership and/or storage practices will not arise because of operational requirements of the research itself, but because of extra-scientific considerations such as the need to make all research programs easily accessible to those interested in auditing them, or to document patent claims that may derive from such research.

SUMMARY AND CONCLUSION

The long-term trends governing these practices are undoubtedly moving toward increased distribution of reagents and certain classes of results. It is still unclear to what extent these standards will be widely imposed by journals and/or granting agencies. Within limits, these changes will have a salutary effect on the progress of science as a whole. Care must be taken, however, to avoid extreme and rigid rules that will work inadvertently to reduce the motivations of individual researchers to carry out certain types of research or to hamper their flexibility to strike up advantageous collaborations with peers to whom they have given special access to unique reagents. In a larger sense, one must be careful not to hobble a research enterprise that over the past two decades has proven among the most productive, creative, and cost-effective in the history of science.

5

Factors Enhancing Acceptance of Federal Regulation of Research

Barbara Mishkin

INTRODUCTION

This paper analyzes factors important for gaining general acceptance of federal regulations governing the conduct of research. The regulations requiring prior review of research with human subjects by an institutional review board (IRB) provide a good model because their development is well documented and they are now generally accepted. Moreover, the difficulties encountered in applying the IRB model to activities unaccustomed to such requirements demonstrate the importance of preparation, patience, and goodwill in developing new regulations.

This paper focuses primarily on the factors in the development of the IRB regulations that affected their acceptance: (1) adequate time frame, (2) constituent participation in policy making, and (3) public access to the deliberative process. Attention to these factors greatly enhanced acceptance of the regulations by the biomedical research community and increased public confidence in their reasonableness and effectiveness. By contrast, inadequate preparation and a lack of constituent participation resulted in initial resistance on the part of many social, education, and behavioral scientists to the extension of IRB requirements to activities not previously covered by such regulations.

ADEQUATE TIME FRAME

As described elsewhere, the IRB regulations were developed incrementally over approximately 10 years.[1] Interdisciplinary attention to the protection of human subjects was reflected both in the lay press and in scientific journals between 1955 and 1965, heightening public awareness of the issues. For example, in 1960, the National Institutes

Barbara Mishkin is an attorney with the firm Hogan and Hartson in Washington, D.C.

of Health (NIH) awarded a grant to the Law-Medicine Institute of Boston University to study the legal and ethical aspects of conducting research with human subjects. The resulting report, published in 1963, suggested (among other things) "group consideration" or prior review of such research.[2] In 1966, the surgeon general adopted that recommendation by requiring NIH grantees to provide prior review of research with human subjects by an institutional committee.[3] A year later, Pappworth published a compendium, drawn from reputable journals, of experiments in which people were subjected to a variety of highly risky procedures and suffered a disquieting number of serious adverse effects (including meningitis, shock, liver damage, cardiac arrest, and punctures of main arteries or major organs).[4] Pappworth concluded that because self-regulation was clearly ineffective, legislative remedies—including prior review by "Medical Research Committees"—were required.[5]

Concurrently, legal scholars turned their attention to issues of liability, and some suggested prior review of research as a method of limiting the risk to which subjects would be exposed (thereby limiting potential liability).[6] Possibly in response to multidisciplinary pressures, the Public Health Service modified its policies in 1971 to require the broader composition of institutional review committees:

> The committee must be composed of sufficient members with varying backgrounds to assure complete and adequate review of projects. … The committee should be able to determine acceptability of the proposal in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes.[7]

The revised Department of Health, Education, and Welfare (DHEW) policy, familiarly known as the "Yellow Book," thus imposed additional requirements designed to avoid conflicts of interest in the review process. Scientists initially protested that nonscientists on the review committees would unreasonably impede the conduct of research; however, the public pressures and scholarly recommendations were such that the new requirements withstood the negative pressure from academic administrators and clinical investigators.[8]

In sum, the IRB system was developed by the Public Health Service incrementally over a period of years and was supported by articles in respected scientific and medical journals, as well as by scholarly writings of experts in law and ethics. At the same time, public pressure for reform appeared in the lay press, and NIH administrators recognized both the need for change and the importance of an interdisciplinary approach to the development of new policies.

CONSTITUENT PARTICIPATION IN POLICY MAKING

From 1974 to 1983, the HEW policies were further refined by the National Commission for the Protection of Human Subjects and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereafter referred to as the National Commission and the President's Commission, respectively). Important aspects of the work of these two commissions were (1) the interdisciplinary composition of their members, staff, and consultants; (2) their openness to the public; and (3) their consideration of the views of all interested parties (including government officials, university administrators, research scientists, public interest groups, and members of the general public).

The National Commission set the standard of public accessibility, as required by its enabling legislation and the newly enacted "Government in the Sunshine" laws.[9] When the commission held hearings, as it did on each major topic of concern, everyone who requested an opportunity to be heard was permitted to testify. Those who could not appear in person were invited to submit comments in writing. The result was that all constituents correctly felt that they had access to the commission's attention and could participate in a meaningful way in its deliberations.

Scientists and academic administrators had equal access, as did federal officials. So, too, did research subjects. The commission made site visits to various institutions at which commission members and staff had an opportunity to inspect the facilities and talk with both research scientists and their subjects. The commission also held hearings on the role and operation of IRBs at various sites around the country, to afford researchers and administrators an opportunity to present their views.

PUBLIC ACCESS TO THE DELIBERATIVE PROCESS

All of the National Commission's meetings were open to the public and were announced in advance. Copies of all meeting materials distributed to commissioners (including draft documents) were available to anyone who asked, and all correspondence addressed to the commission was photocopied and distributed to each commissioner. (This policy was followed scrupulously, even when the commission received dozens of duplicate postcards from around the country on matters such as fetal research.) In addition, the commission sent regular mailings of meeting agendas and summary minutes to a mailing list of

several hundred individuals and organizations. The President's Commission followed the same policies and procedures.

RESISTANCE FROM THE NEWLY REGULATED

Considerable consternation arose in 1974 from the conversion of the NIH grants administration policies to formal HEW regulations, in an attempt to avoid impending congressional legislation. The problem was the sudden applicability of rules, designed with medical research in mind, to activities of a very different nature (such as social science research, demonstration projects of the "welfare" component of HEW, and behavioral science methodologies such as participant observation and deception). The imposition of the "medical model" to such diverse activities provoked cries of anguish and calls for revision from social and behavioral scientists, suddenly confronted with an entire set of regulations that were both unfamiliar and (they firmly believed) destructive. The education components of HEW held fast to their authority to promulgate their own regulations and refused to adopt the department's new version.[10]

The National Commission's procedural remedy was to invite social and behavioral scientists to explain the nature of their activities and their concerns, and to encourage them to propose revisions to the regulations that would alleviate the perceived problems without compromising the basic system of IRB review. Some of the most vigorous debates among commissioners and staff revolved around issues such as how to adapt informed consent provisions to research in which disclosure of the methodology and purpose would utterly defeat the exercise (for example, deception research and covert or participant observation). Everyone (witnesses, commissioners, and staff) learned from the exchanges, and ultimately, a consensus emerged that satisfied the social and behavioral scientists without leaving the biomedical scientists and research administrators feeling that they had "sold out."

A review of the witnesses who testified at the commission's IRB hearings demonstrates the breadth of concern among behavioral and social scientists. Among the 44 witnesses were 16 behavioral or social scientists, whose testimony focused largely on the difficulty of applying rules derived from a biomedical model to research involving participant observation, survey questionnaires, covert observation, and administration of standardized psychological or educational tests. They emphasized that "informed consent" has no meaning in many of these contexts and could be counterproductive in others. Moreover, a signed consent form could present greater risk to subjects than their

participation in certain research (for example, in research concerning illegal activities).

Constructive suggestions were offered for clarifying definitions (of such terms as "human subject," "research," and "risk"), for excluding certain categories of research from IRB review, and for modifying the consent requirements under certain conditions. They also suggested that IRBs contain members familiar with the kind(s) of research under review. These suggestions were included in the commission's recommendations and ultimately adopted by the Department of Health and Human Services (DHHS) as amendments to the IRB regulations.[11]

Biomedical researchers described their own problems with the existing system. For example, they pointed out that very little risk to human subjects is presented by research utilizing tissues and organs removed for diagnostic or therapeutic purposes, unless the tissues are personally identified and sensitive information is involved. They also reported that a large proportion of IRB time was being spent reviewing such secondary uses of discarded tissue. Similar points were made about retrospective reviews of medical records. Their recommendations for further refinement of the definition of risk, and for expedited review of certain categories of research activities, were endorsed by the commission and subsequently adopted by DHHS.[12]

In short, the deliberative process worked well, due in large part to the clear willingness of the commission to receive and respond positively to the complaints and suggestions of all concerned. In addition, the statutory requirement that DHHS accept and implement the commission's recommendations (or explain in the *Federal Register* why it could not) reinforced the department's inclination to adopt the commission's recommendations. Goodwill on the part of virtually all concerned further enhanced the process.

EVIDENCE CONCERNING IRB PERFORMANCE

Both the National Commission and the President's Commission undertook studies of IRBs. The National Commission's study focused on their composition, administration, and operating procedures. Masses of data were collected on IRB membership, structure, and authority; voting and operating procedures; record keeping; administrative support; time spent on specific tasks; relation between the level of risk presented and the amount of time spent reviewing a protocol; number of times that protocols and consent forms were revised; and the reading level of approved consent forms. These data yielded useful (and sometimes surprising) findings. For example, it was discovered that the number of

times consent forms were revised bore no relation to the extent to which the final (approved) version met all regulatory requirements.[13] Nor did it improve the readability of the forms.[14]

The National Commission's study also surveyed the attitudes of IRB members and the researchers who submitted protocols to the IRB. The survey results were generally consistent with the testimony of witnesses at the hearings, in that behavioral scientists expressed frustration and disappointment about IRB members' lack of familiarity with the traditional methods of behavioral sciences, while the biomedical scientists complained about the disproportionate amount of time spent in preparing and reviewing protocols presenting no discernible risk to subjects (as in research involving by-products, such as body fluids and tissues, obtained from a diagnostic intervention).[15] Interestingly, however, most researchers believed that the IRB system improved research more than it impeded it, and they were generally supportive of the IRB system overall.[16]

The President's Commission, like its predecessor, evaluated the performance of IRBs. Rather than relying on surveys, however, the President's Commission conducted site visits to observe IRBs in action. Critics had suggested that NIH should have a better system for monitoring IRB performance than reliance on annual promises to comply with the regulations. Those who had been subjected to inspections by the Food and Drug Administration (FDA), however, complained about the difficulties encountered when inspectors, totally unfamiliar with biomedical research, undertook to evaluate IRB performance.[17] The shortcomings of the FDA inspections were demonstrated in the commission's study by comparing FDA inspection reports with evaluations of the same IRBs performed by experienced IRB members of the site visit teams.[18]

The peer site visits also revealed that there was room for further improvement in IRB performance. For example, site visitors found that some IRBs did not provide full IRB review of proposals, others lacked "a clear understanding of their role and responsibility," and there were occasional lapses in commitment to the protection of human subjects.[19] In addition, experienced IRB members often could suggest procedural modifications to eliminate problems, increase efficiency, and improve relations between the IRB and the scientists. Clearly, IRBs responded better to site visits by peers than to inspections conducted by personnel unfamiliar with research policies and procedures.

PATIENCE, PERSEVERANCE, AND GOODWILL

The resolution of policy differences between the Public Health Service (predominantly NIH) and the education and social services component of DHHS was not easy. The prolonged process illustrates what happens when regulatory constraints are applied without warning to activities not previously subject to regulation.

As previously noted, problems arose when Public Health Service policies, developed with biomedical research in mind, were converted to DHHS regulations applicable to all "research, development, and related activities" conducted or supported by the department. With one stroke, activities such as Head Start and medical assistance demonstration programs became "research with human subjects" for which IRB review and informed consent would be required.

Efforts to incorporate the commission's recommendations into amendments to the IRB regulations became mired in an intramural conflict between officials at NIH (representing the Public Health Service's interests) and staff of the DHHS assistant secretary for planning and evaluation (ASPE), representing the education and social security arms of the department. Draft upon draft of revisions proposed by NIH were unacceptable to the ASPE.

The sticking point was the requirement for informed consent (and the right to withdraw at any time) for "demonstration projects" designed to test new ways of delivering public assistance. New benefit programs—or modifications of existing programs—normally include a mandatory evaluation component. As a result, the receipt of public benefits in a demonstration program is normally conditioned upon the beneficiaries' willingness to cooperate with the evaluation of the program (e.g., by responding to survey questionnaires or by permitting follow up tests of educational progress). The requirement to assure the subjects of evaluation research that they could receive benefits to which they were entitled, whether or not they agreed to participate in the research, and that they could withdraw from the research at any time and without penalty, threatened to destroy the department's ability to assess new benefit programs such as Medicare copayment requirements.

The proposed amendments to the IRB regulations were nearing adoption when the President's Commission was established, and the commission proposed modifying the exemptions to the IRB and consent requirements. In a letter to then-Secretary Patricia R. Harris, the commission recommended that there be three categories of research normally exempt from IRB review:

> (a) Research involving questionnaires, interviews, or standard education or psychological tests, in which the agreement of the subjects to participate is already an implicit or explicit part of a research process which itself will involve little or no risk; (b) research in which consent is not typically obtained because the gathering of information involves merely observation of behavior in public places (for which there is no reasonable expectation of privacy), review of publicly available information, or analysis of data containing no personally identifiable information; and (c) social, economic, or health service research conducted under governmental aegis (such as HEW Medicare copayment experiments or the OEO negative income tax experiment) in which consent of "subjects" may or may not be warranted by statute.[20]

The commission's first two categories of proposed exemptions were adopted in the final rules published in January 1981; however, the third category was not specifically listed as an exemption. Instead, a provision was added permitting the DHHS secretary to waive applicability of the IRB and consent requirements "to specific research activities or classes of research activities otherwise covered by these regulations" providing the secretary published notices of such waivers in the *Federal Register.*[21]

Pursuant to the waiver provision, DHHS Secretary Richard Schweiker subsequently published a notice waiving IRB review and consent requirements for demonstration projects designed to test cost-sharing requirements in the Medicaid program.[22] Shortly thereafter, the secretary published a proposal to exempt from IRB review "research and demonstration projects conducted under the Social Security Act and other Federal statutory authority and designed to study certain public benefit or service programs, the procedures for obtaining benefits or services under those programs, and possible changes or alternatives to those programs or procedures, including changes in methods or levels of payment."[23]

Although the President's Commission urged that the exemption be drawn more narrowly,[24] the department rejected the commission's proposed modifications and exempted research and demonstration projects designed to evaluate programs under the Social Security Act and other public benefit or service programs, as originally proposed.[25] In addition, the regulations were amended to permit IRBs to waive informed consent requirements for similar studies conducted under the auspices of state or local governments.

Controversy over IRB review of public assistance demonstration projects continues, even today. The effort to establish uniform federal policies for the protection of human subjects, first suggested by the National Commission in 1978, was reiterated by the President's Commission in 1982.[26] It was not until June 1986 that proposed uniform policies were published for public comment, and it was more

than 2 years later that proposed uniform regulations were published.[27] Final rules were published on June 18, 1991.[28] A major factor in the delay has been (as before) the applicability of the IRB and consent requirements to education research and to demonstration projects designed to evaluate public benefit programs.[29]

LESSONS FOR THE FUTURE

The development of IRBs as a regulatory mechanism for protecting human subjects demonstrates that time, collegial interaction, and goodwill are important ingredients for successful rulemaking. When policy conflicts arise, participation in the deliberations by all who wish to be heard not only improves the substantive regulations, but also increases the likelihood of their acceptance and enhances public confidence in the process. In short, the success and credibility of the process are directly related to the extent to which all interested parties are afforded an opportunity to participate.

The hazards of proceeding unilaterally were demonstrated recently by the unsuccessful attempt of the NIH to establish "guidelines" for dealing with conflicts of interest, without affording adequate opportunity to comment. The research community felt it had been blindsided. Responses reflected outrage, a sense of betrayal, and frustration.[30] A much fuller airing of the concerns of all interested parties, as well as a public deliberative process, would more likely produce a broadly accepted set of rules. Such an approach also would enhance public confidence in the process and substance of the rulemaking. In the absence of a more thoughtful development of rules, mistrust and resistance probably will continue.

NOTES

1. See, for example, Jonsen, A., 1984, "Public policy and human research," pp. 3-19 in *Biomedical Ethics Reviews*, Humber, J. M. and R. T. Almeder (eds.). Humana, Clifton, N.J.

2. For a brief history of early antecedents, see President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982, *Compensating for Research Injuries*, U.S. Government Printing Office, Washington, D.C., p. 30.

3. See President's Commission, *Compensating for Research Injuries*, 1982, pp. 30-33.

4. Pappworth, M. H., 1967, *Human Guinea Pigs*, Beacon, Boston.

5. Pappworth, *Human Guinea Pigs*, 1967, pp. 209-10; see also, President's Commission, *Compensating for Research Injuries*, 1982, pp. 32-33.

6. See, for example, Calabresi, G., 1969, "Reflections on medical experimentation in humans," *Daedalus* (Spring):387-405.

7. Department of Health, Education, and Welfare (DHEW), 1972, *The Institutional Guide to DHEW Policy on Protection of Human Subjects*, DHEW, Washington, D.C., p. 4; see also, President's Commission, *Compensating for Research Injuries*, 1982, pp. 35-36.

8. Department of Health, Education, and Welfare (DHEW), 1973, *Final Report of the Tuskeegee Syphilis Study Ad Hoc Advisory Panel*, DHEW, Washington, D.C., p. 38.

9. Public Law 94-348, Title III (88 Stat. 342 [1974]).

10. See National Commission for the Protection of Human Subjects, 1978, "Institutional review boards: report and recommendations," *Federal Register* 43(November 30):56174, 56184-85.

11. Department of Health and Human Services (DHHS), 1981, "Final regulations amending basic HHS policy for the protection of human subjects," *Federal Register* 46(January 26):8366-92 (45 C.F.R. Part 46).

12. DHHS, "Final regulations … for the protection of human subjects," 1981.

13. National Commission, "Institutional review boards," 1978, pp. 56174, 56189-90; see also, National Commission, 1978, *IRB Report, Appendix to Report and Recommendations: Institutional Review Boards*, p. 1-26.

14. National Commission, "Institutional review boards," 1978.

15. National Commission, *IRB Report, Appendix*, 1978, pp. 1-95 through 1-101.

16. National Commission, *IRB Report, Appendix*, 1978, p. 1-42.

17. Some referred to the inspectors as "rat inspectors," emphasizing the fact that their training was predominantly in such matters as counting the number of rat droppings at food and drug manufacturing plants.

18. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983, *Implementing Human Research Regulations*, U.S. Government Printing Office, Washington, D.C., pp. 105-14.

19. President's Commission, *Implementing Human Research Regulations*, 1983, pp. 76-97.

20. Letter from Morris B. Abram to Patricia Roberts Harris (September 18, 1980), reprinted in the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1981, *Protecting Human Subjects, First Biennial Report*, U.S. Government Printing Office, Washington, D.C., pp. 166-167 (Appendix D: Correspondence with HHS on Regulations).

21. 45 C.F.R. Section 46.101(e), as published in DHHS, "Final regulations … for the protection of human subjects," 1981, p. 8386.

22. Department of Health and Human Services (DHHS), 1982, "Waiver of requirements as applied to Medicaid demonstration projects involving cost-sharing (copayments, deductibles, coinsurance)," *Federal Register* 47(March 4):9208.

23. Department of Health and Human Services (DHHS), 1982, "Exemption of certain research and demonstration projects from regulations for protection of human subjects: proposed rule," *Federal Register* 47(March 22):12276.

24. President's Commission, *Implementing Human Research Regulations*, 1983, Appendix D, pp. 177-180.

25. Department of Health and Human Services (DHHS), 1983, "Exemption of certain research and demonstration projects from regulations for protection of human subjects: final rule," *Federal Register* 48(March 4):9269.

26. President's Commission, 1982, *First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and Their Implementation for the Protection of Human Subjects in Biomedical and Behavioral Research*, as reprinted in *Federal Register* 47(March 29):13272; see especially, Part D, Conclusions, pp. 13282-83.

27. Executive Office of the President (EOP), Office of Science and Technology Policy (OSTP) (with 15 affected departments/agencies), 1986, "Proposed model federal policy for protection of human subjects," *Federal Register* 51(June 3):20204; Executive Office of the President (EOP), Office of Science and Technology Policy (OSTP) (with 15 affected departments/agencies), 1988, "Federal policy for the protection of human subjects: notices and rules," *Federal Register* 53 (November 10):45660-82.

28. Executive Office of the President (EOP), Office of Science and Technology Policy (OSTP) (with 15 affected departments/agencies), 1991, "Federal policy for the protection of human subjects: notices and rules," *Federal Register* 56(June 18):28003-32.

29. Personal communication, Alicia Dustira, Executive Office of the President, Office of Science and Technology Policy, November 11, 1990.

30. See Palca, J., 1990, "NIH conflicts of interest guidelines shot down," *Science* 247(January 12):154, and related articles.

6

Congressional Activities Regarding Misconduct and Integrity in Science

Barry D. Gold

INTRODUCTION

In 1980, four cases of alleged fraud and misconduct in science involving scientists at top research centers, all in the area of biomedical research, captured headlines in the scientific and popular press. The cases included Elias Alsabti, an Iraqi who fabricated his medical and research credentials and who was alleged to have plagiarized almost 60 scientific papers in cancer immunology while working at a half-dozen research centers in the United States;[1] Marc Strauss, an oncologist at Boston University, alleged to have falsified patient records to make patients eligible for clinical trials;[2] Vijay Soman, an endocrinologist at Yale Medical School, alleged to have fudged and fabricated data and plagiarized a rival's paper;[3] and John Long, a cancer researcher at Massachusetts General Hospital, alleged to have fabricated and falsified data and mislabeled the cell line he was studying.[4]

These cases raised concerns over the capability of existing mechanisms to handle allegations of misconduct in science and maintain integrity in the research environment. Concerns about misconduct in science persisted throughout the 1980s as more allegations were made public and as reports of poor handling of allegations continued to surface. Most of the congressional attention on this subject focused on the role of the National Institutes of Health (NIH) and the National Science Foundation (NSF) to ensure that allegations of misconduct are handled properly and that the integrity of federally funded research is maintained.

Barry D. Gold is a professional staff member for the Subcommittee on Science of the Committee on Science, Space, and Technology of the U.S. House of Representatives. He was the staff officer for the Panel on Scientific Responsibility and the Conduct of Research.

EARLY OVERSIGHT

House Science and Technology Committee

In 1981, then Representative Albert Gore, Jr. (D-TN), chairman of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held oversight hearings entitled "Fraud in Biomedical Research."[5] The hearings were motivated by the four widely publicized cases mentioned above, the issuing by NIH of disbarment regulations, and the interest of Representative Gore in ethical issues in science.[6] The witnesses were primarily senior spokesmen for science (e.g., Philip Handler, president, National Academy of Sciences [NAS]), but also included one researcher (John Long, Massachusetts General Hospital) who had admitted to having fabricated data on the size of the Hodgkin's immune complex and one scientist (Philip Felig, Yale University) whose career had been affected by a case of alleged misconduct concerning one of his students (Vijay Soman).

These hearings were a subset of ongoing congressional activities designed to examine ethical and institutional issues in science, primarily biomedical research. Other hearings focused on ethical issues surrounding recombinant DNA research.

Most of the witnesses at the Gore hearing held that the problem of fraud in scientific research was not significant and that adequate mechanisms existed within the scientific community to handle these cases. For example, NAS President Handler testified that misconduct in science was "grossly exaggerated" by the press and that it is not a problem when it does happen because "it occurs in a system that operates in an effective, democratic, and self-correcting mode" that makes detection inevitable.[7]

According to journalists Broad and Wade,[8] the scientists who had been called as witnesses and the congressmen presiding at the hearing held strongly divergent views about the nature and seriousness of the problem. They reported that "Gore and his fellow Congressmen were moved to visible amazement and then anger at the attitudes of the senior scientists they had called as witnesses." Representative Gore typified the perspective of his colleagues when he said that "one reason for the persistence of this type of problem is the reluctance of people high in the science field to take these matters very seriously." Jim Jensen, formerly a professional staff member for the committee, stated that committee members expressed concern that the universities and responsible federal agencies were not prepared to handle these cases. In addition, some committee members suggested that scientists convicted

of fraud or misconduct in science should be treated like any other criminal and be put in jail and/or asked to repay public funds.[9]

In discussing the divergent views between the congressmen and senior spokesmen of science, Broad and Wade identified what they considered to be contributing factors: (1) Congress had been forced into its own self-examination by the Abscam bribery case, (2) the congressmen viewed the scientists as a "fellow group of professionals who apparently preferred to deny a problem existed rather than face up to it," and (3) the congressmen understood that "no matter how small the percentage of scientists who might be fakers of data, it required only one case to surface every few months or so for the public credibility of science to be severely damaged."

The House Science and Technology Committee, while feeling that the scientific community had to do a better job on this issue, decided to adopt a "wait and see" attitude. This decision was due in part to the testimony given by William Raub of NIH regarding actions then being initiated, in part to the fact that the House Science and Technology Committee has no real legislative jurisdiction over NIH, and in part to the concentration of cases in biomedical research.[10] It would be eight years before the oversight subcommittee would hold a second set of hearings. In the intervening years the committee and its staff played a role in the development and passage of the Health Research Extension Act and participated in investigations of individual cases and their resolution, Representative Gore was elected to the Senate, and many of the original staff members assumed other positions.[11]

Senate Labor and Human Resources Committee

Congressional activity in 1981 was not confined to the House of Representatives. The Senate Labor and Human Resources Committee held oversight hearings on the National Cancer Institute (NCI). During these hearings, Chairman Orrin Hatch (R-UT) asked why the NCI had failed to place a hold on federal funds to a researcher alleged to have falsified data. The issue that emerged at the hearings was whether or not to suspend the funding of a researcher accused of fraud or misconduct in science while the investigation of the charge was pending.[12] [Note: There are now regulations in place that require suspensions under certain conditions.[13]]

EARLY LEGISLATIVE AND REGULATORY EFFORTS

The first attempt by Congress to address fraud and misconduct in science was the Health Research Extension Act of 1983. Section 485 of this act included language aimed at ensuring that allegations of fraud and misconduct in science were handled effectively.[14] The bill containing these provisions was passed by Congress but was vetoed by President Reagan in 1984.

Essentially the same language was included in P.L. 99-158, the Health Research Extension Act of 1985.[15] Section 493 states:

> (a) The Secretary shall by regulation require that each entity … submit … assurances satisfactory to the Secretary that such entity—(1) has established (in accordance with regulations that the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and or behavioral research at or sponsored by such entity; and (2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

This bill was passed but the president vetoed it, stating that the bill "manifest[ed] an effort to exert undue political control over decisions regarding scientific research."[16] Congress passed the bill over the president's veto in November 1985. It represents the first time Congress formally directed any federal agency to require that universities and other recipients of NIH research funds have systems in place for handling allegations of misconduct and to report the outcomes of these deliberations to NIH in a timely fashion. This statute required the promulgation of regulations that assign the primary responsibility for responding to allegations of fraud and misconduct in science to the local institution and required a general oversight role for NIH. The institutional assurances requirement draws heavily on the model established in the 1970s with the creation of Institutional Review Boards (IRBs) at local institutions.

Institutional Review Boards were created in response to a series of widely publicized cases of abuses in human subjects research. The Congress adopted legislation in the early 1970s that contained new requirements for grantee institutions sponsoring federally funded human subjects research. Under the terms of this legislation, research institutions must certify to the funding agency that they have established a local IRB that monitors and approves the protocol for human subjects research and that operates in a manner that is consistent with federal guidelines in this area.

The IRB experience appears to have reconciled the needs of local institutions for maintaining flexibility and some autonomy within a

general framework of government standards. Institutional assurances on animal welfare were also implemented in 1986 by the Public Health Service (PHS). These two experiences with research regulation seem to have influenced the early stages of legislative deliberations in establishing guidelines for handling cases of misconduct in science.

The regulations required by the Health Research Extension Act of 1985 were first listed as part of NIH's regulatory agenda in April 1986. Preliminary guidelines were issued in the *NIH Guide for Grants and Contracts* in July 1986, and the notice of proposed rulemaking was issued in September 1988. The final rule was promulgated on August 8, 1989. Although NIH officials testified in hearings about why it took so long to produce this rule, the length of time contributed to the congressional perception that NIH was not seriously addressing the issue of misconduct in science. Another regulatory step by NIH was the improvement of the ALERT system, a computer-assisted system for tracking individuals who are under investigation or who have been sanctioned for misconduct. Initiated by NIH in 1981, the ALERT system was improved and expanded to include all PHS activities.[17]

THE NEXT ROUND

House Judiciary Committee

On February 26, 1986, the Subcommittee on Civil and Constitutional Rights of the House Judiciary Committee held hearings to examine the role of libel laws in discouraging publication of reports or allegations of misconduct in science.[18] Walter Stewart and Ned Feder of NIH testified before the subcommittee that the threat of libel against journal editors was a major factor in preventing publication of their article on misconduct in science and the quality of the scientific literature. The article resulted from an analysis of papers coauthored by John Darsee, which included 18 scientific papers, 88 abstracts, and three book chapters.[19] The Darsee case received wide press coverage in 1983 and involved the fabrication of data while he was a cardiology researcher at both Emory University and Harvard University. Stewart and Feder's study examined the extent to which Darsee's coauthors, journal editors, and referees could have known, or should have known, that his reported research findings were fabricated and inaccurate. Stewart and Feder contended that Darsee was able to publish fabricated material because his coauthors and the peer review system failed to provide appropriate vigilance in examining the data.

The much-disputed conclusions of the Stewart and Feder article are that misconduct among biomedical scientists may be more prevalent than commonly believed and that traditional quality control mechanisms may not work as well as expected. In discussing reviewers' comments on the article, Benjamin Lewin, editor of *Cell*, stated, "Although they [the reviewers] had criticisms of the article, the overwhelming consensus was that the article says something important about the way science is done, and that it would be in the public interest to have it published."[20]

House Committee on Science and Technology Task Force on Science Policy

A few months later, on May 14, 1986, Stewart and Feder were among a series of witnesses at hearings on research and publication practices convened by the Task Force on Science Policy of the House Committee on Science and Technology.[21] Witnesses at the hearing addressed two issues: (1) "whether current policies allow for the most efficient expenditure of resources for biomedical research" and (2) "the way scientific research is currently conducted and communicated in America."

Stewart and Feder submitted a draft of their still unpublished paper for the hearing record. (Their paper was widely circulated prior to publication, and a revised version of the paper was published in *Nature* on January 15, 1987.) In describing their study, they said it was an attempt "to measure the frequency of misconduct in a large sample of scientists." They then went on to describe the study and their findings regarding types and prevalence of misconduct among this sample, possible causes, implications for the larger scientific community, the difficulties they encountered in getting their work published, and a recommendation that the science community "start considering solutions to the problem" of the validity of published research and the accuracy of the scientific literature.

In their testimony, Stewart and Feder expressed their belief that these problems had existed for a long time, and they questioned the adequacy of existing institutional mechanisms for preventing and/or responding to the types of alleged misconduct described in their paper. They reported that, on the basis of discussions with other scientists, (1) their estimate of the prevalence of misconduct was not widely off base; (2) pressure to publish may be a contributing factor to the occurrence of the alleged abuses; (3) many research papers are likely never to be read; and (4) they had not investigated what the costs to science might be of researchers trying to replicate or build on falsified results. The other

witnesses testifying at the hearing were Sandra Panem on the efficient use of biomedical research funds and Patricia Woolf, who had been asked to discuss the issues raised by Stewart and Feder.

During her testimony, Woolf stated that Stewart and Feder had raised serious questions concerning misconduct in science. She voiced strong concerns that the normal process of peer review of their paper had been circumvented by threats of libel. In discussing the paper itself, she indicated that it did not answer the question of the prevalence of fraud and misconduct in science, but that the scientific community had in any event "set itself the task of examining and improving its quality assurance programs."[22] She suggested that many scientists view publication as a device primarily for professional advancement (i.e., promotion and tenure and successful grantsmanship), as opposed to the communication of results.

Woolf supported the view that the appropriate strategy for maintaining quality in science is to strengthen existing internal review mechanisms in science rather than developing governmental regulations. She indicated that while the peer review system works reasonably well, there is room for improvement and that some efforts are under way to improve it. One suggestion she offered was to provide professional recognition or credit to scientists for the amount of time spent reviewing manuscripts.

INTEREST BROADENS IN THE HOUSE

In 1987, five cases of fraud and misconduct in science, primarily in biomedical research, were reported in the scientific and popular press, and in one instance the supervisor of the individual charged with misconduct committed suicide. With increasing reports that a number of universities and NIH had stumbled in handling allegations of fraud and misconduct, congressional interest reached a new high. Three separate hearings were convened during 1988, two by the House Committee on Government Operations and one by the House Committee on Energy and Commerce, which has legislative and authorizing jurisdiction for NIH.

Witnesses and congressional members participating in the hearings suggested that the science community, in spite of claims to the contrary, had not demonstrated an ability to handle this issue through existing self-regulatory mechanisms, and that government regulation may be necessary. As a result of these hearings, Congress delivered a strong message of displeasure to the scientific community concerning its handling of allegations of fraud and misconduct in science.

House Committee on Government Operations

On April 11, 1988, the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Operations, chaired by Representative Ted Weiss (D-NY), held oversight hearings titled "Scientific Fraud and Misconduct and the Federal Response."[23] This subcommittee has oversight jurisdiction and investigatory authority, but no legislative authority, over the Department of Health and Human Services (DHHS) and other executive branch agencies. The hearings focused on the experience of NIH in handling allegations of fraud and misconduct in science, the treatment of whistle-blowers, and public health and safety concerns that could arise as a result of the publication of fraudulent research data.

During these hearings, Representative John Conyers, Jr. (D-MI), in discussing misconduct in science in the context of white-collar crime, suggested that a federal statute could make fraud or misconduct in science a criminal offense. Witnesses, including two whistle-blowers, dismissed this suggestion as overly harsh and having the potential to "create a damaging climate of fear among scientists."[24] Representative Weiss expressed his view that the scientific community, including NIH, the universities, and the professional societies, had shown a general unwillingness to guard against fraud and misconduct in science.

House Committee on Energy and Commerce

The next day, on April 12, 1988, the Committee on Energy and Commerce, chaired by Representative John Dingell, Jr. (D-MI), held oversight hearings titled "Fraud in NIH Grant Programs."[25] These hearings called into question NIH performance in handling allegations of fraud and misconduct in science. Representative Dingell contended that NIH had inadequately addressed due process rights and the protection of whistle-blowers in these cases. The hearings focused on the NIH investigation of misconduct charges involving a 1986 *Cell* paper coauthored by David Weaver, Thereza Imanishi-Kari, David Baltimore, and others.

Stewart and Feder were the first witnesses at the hearing. They presented an analysis of five cases of misconduct in science, including allegations concerning the data in the *Cell* paper. Stewart and Feder subsequently became advisors to the subcommittee in June 1988 regarding the *Cell* paper and other cases of alleged misconduct. Margot O'Toole, who raised the initial allegations concerning the *Cell* paper, testified at the hearings not only about the substance of these allegations

and the process by which they were examined, but also about the subsequent difficulties she faced in securing a research position. One issue raised in the Dingell hearings was whether this case represented misconduct in the reporting of experimental results or a professional disagreement in interpreting data that were breaking new ground.

Also at issue, and of prime importance to Representative Dingell and the subcommittee, was the fate suffered by young scientists who act as whistle-blowers. Dingell's committee had previously drafted the Whistle-blower Protection Act, designed to protect federal employees who disclose waste, fraud, and abuse in government programs. This act was signed into law in 1989.

Although the Whistle-blower Protection Act would not have applied to O'Toole, two witnesses in a June 1989 hearing held by Representative Weiss (see below) suggested that Congress should extend the Whistle-blower Protection Act to university faculty and research staff who are federal grantees. In responding to a letter from Weiss following these hearings, NIH Acting Director Raub wrote that although constrained by the administration's position, "we are very sympathetic toward efforts that would provide appropriate protection to whistle-blowers. The applicability of the provisions of this [Whistle-blower Protection] Act to the scientific/academic community certainly warrants careful consideration."[26]

The subcommittee members were displeased with the investigations by Massachusetts Institute of Technology, Tufts University, and NIH of the allegations of error in the *Cell* paper. University officials testified that since O'Toole's initial allegation did not include charges of misconduct, they relied on informal methods of resolving professional disagreements. They indicated that, had a charge of misconduct been made, a more formal investigation would have been provided under a different set of policies and procedures. This distinction drew the interest of the subcommittee. The institutional representatives commented that while the procedures for conducting investigations could use some fine-tuning, they were learning from each case they handled.

House Committee on Government Operations

On September 29, 1988, Representative Weiss held another set of hearings before the Committee on Government Operations to explore (1) the issue of conflict of interest in U.S. academic research, (2) the effectiveness of local institutions in preventing and investigating instances of fraud and misconduct in science, and (3) whether or not NIH needs to do more to prevent and investigate instances of fraud and

misconduct in science. The hearing focused on conflict of interest issues involving commercial ties by university scientists. In one case it was suggested that commercial incentives may be an important factor motivating scientists to engage in research misconduct.[27]

On the topic of criminal penalties for scientists found guilty of allegations of fraud and misconduct in science brought up at the earlier Government Operations Committee hearing, Representative Conyers stated that he had "received 2,500 letters from those who supported criminal penalties since our hearings some months ago [April 11, 1988] for withholding information, falsification, [and] misleading research."[28]

During these hearings, the Office of Inspector General (OIG) of the Department of Health and Human Services presented a draft report on misconduct in scientific research.[29] The OIG report included the results of its recent study of (1) the extent to which NIH and its grantee institutions have developed policies and procedures to prevent, detect, and handle scientific misconduct cases and (2) what selected grantee institutions have learned and what changes they have made as a result of their experience in conducting investigations of allegations in misconduct. The OIG report was based on a telephone survey of a random sample of FY 1986 NIH grantee institutions and site visits to nine grantee institutions that had experience with cases of misconduct in science.

DHHS Inspector General Richard Kusserow noted the lack of a central locus of responsibility at NIH for matters of misconduct in science. He stated that 93 percent of the grantee institutions with 100 or more awards have policies and procedures in place to handle allegations of misconduct in science, but that overall only 22 percent of PHS grantee institutions have adopted such policies. [Note: NIH later pointed out that the 22 percent of PHS grantee institutions with policies in place account for 88 per cent of all PHS award dollars.] He identified weaknesses in the misconduct procedures that are in place, often including a failure by research institutions to notify NIH and keep sponsoring officials fully informed of the status or results of a misconduct investigation.

On the question of prevalence, the OIG report contained a strong disclaimer against using their figures as an estimate of the actual prevalence of misconduct in science. The report stated that 36 percent (17 of 47) of the grantee institutions with established procedures reported allegations of misconduct that required their use. Sixteen of the 34 cases (47 percent) investigated by these institutions were substantiated. Based on these figures, the OIG estimated that 95 cases of misconduct in science (47 substantiated and 48 unsubstantiated) had been addressed by PHS grantee institutions. The report was not explicit

regarding the time period over which these cases occurred, but it would appear to be from 1982 to 1988. The OIG report identified an interest among grantee institutions in receiving guidance in developing guidelines for preventing misconduct in science.

Based on these findings, the DHHS inspector general recommended that the secretary of DHHS establish investigatory and oversight functions independent of the research funding agencies and develop a more formal process to deal with cases of alleged misconduct in science. Other recommendations included additional notification requirements for the awardee institutions and the development of alternative methods of detecting possible misconduct, including spot audits of scientific data and specific reviews by editors of scientific journals.

The OIG report also noted that there was no central locus of responsibility or accountability for scientific misconduct within DHHS. While OIG has responsibility to prevent and detect fraud and abuse in DHHS programs and operations, such as Medicare and Medicaid payments, the responsibility for handling reports of misconduct in research programs resided within different components of the Public Health Service. The OIG report recommended that the secretary of DHHS develop a formal centralized process to deal with scientific misconduct.

In his testimony, James Wyngaarden, director, NIH, noted that he had not had an opportunity to review the draft OIG report prior to its release at the hearing. He departed from his prepared testimony to comment critically on the confrontational nature of the OIG report. He indicated that NIH had assumed an active role in addressing issues of misconduct in science. He strongly opposed the recommendation that a body outside of NIH be established to conduct investigations of allegations of misconduct in science.

Rumors of Legislative Activity

Following these hearings, rumors of legislative action abounded. One draft bill was prepared and circulated by Representatives Dingell and Henry Waxman (D-CA) as an amendment to the NIH reauthorization bill, but it was never formally introduced. The amendment would have established a new office of scientific integrity in DHHS. The office would have been responsible for coordinating investigations of allegations of fraud and misconduct involving PHS funds and would have transferred the current monitoring activity from NIH to the OIG or the assistant secretary for health. In addition, the office would have been authorized to conduct random audits, develop

standards of research conduct, and develop retraction guidelines for scientific journals.

In describing this proposed bill, Robert Rosenzweig, president of the Association of American Universities (AAU), said, "To put it bluntly, its passage would have been a calamity for the science community."[30] He went on to state, "The powers of this new directorate would substantially reverse the presumption of the 1985 legislation, which recognized an institution's responsibility for the conduct of its members and placed the government in a monitoring role. If enacted as proposed, the new office would have been empowered to receive allegations of misconduct and, if it chose, to investigate them independently of institutional processes."

On March 16, 1989, Assistant Secretary for Health James Mason established two new offices: the Office of Scientific Integrity (OSI) in NIH and the Office of Scientific Integrity Review (OSIR) in his office.[31]

FEDERAL AGENCIES TAKE ACTION

Public Health Service

In 1987, the PHS drafted a notice of proposed rulemaking (NPRM) on misconduct in science. Following the 1988 hearing held by Representative Dingell, DHHS officials negotiated changes in the NPRM with the Office of Management and Budget (OMB), and a final rule dealing with misconduct in science was published on August 8, 1989.[32] The final rule required each institution applying for PHS research funds to certify by January 1, 1990, that it had adopted satisfactory misconduct procedures. The applicant institutions are required to keep these policies current and to provide copies to authorized DHHS officials upon request.

Under the final rule, universities and other research institutions have the primary responsibility for preventing, investigating, reporting, and resolving allegations of scientific misconduct. The new rule does not address issues of the responsible conduct of research and fostering integrity in science (i.e., data sharing and retention, authorship practices, and so on). These issues were addressed in a separate advance notice of proposed rulemaking (ANPRM) issued September 19, 1988, to solicit comments. The ANPRM is a mechanism that a government agency can use to solicit comments and ideas regarding a possible rule without committing to producing final regulations. Some items contained in the ANPRM have subsequently been adopted by DHHS administrative actions.

National Science Foundation

On February 10, 1987, the National Science Foundation published proposed rules for handling allegations of fraud and misconduct in science.[33] These rules were subsequently revised and issued as final regulations in July 1987.[34] NSF based these regulations on informal policies that had been developed to deal with previous allegations and the 1986 policy guidelines of the NIH. The NSF final rule addresses the definition of fraud and misconduct, roles and responsibilities and procedures for detecting, investigating, and adjudicating allegations of misconduct, remedies and sanctions, and due process rights of the individuals and institutions involved in misconduct cases. The awardee institutions bear the primary responsibility for handling allegations of misconduct.

RECENT HEARINGS

House Committee on Energy and Commerce

On May 4th and 9th, 1989, Representative Dingell held additional hearings on scientific misconduct before the Committee on Energy and Commerce.[35] These hearings reopened questions about the NIH investigation of charges of misconduct stemming from the paper published in *Cell* by Weaver, Imanishi-Kari, Baltimore, and others. Two panels of witnesses appeared during the first day of hearings. The first panel represented the NIH institutional officers who had conducted the investigation into allegations of wrongdoing, members of the NIH investigatory panel, and Secret Service forensics experts who had examined the laboratory notebooks of Imanishi-Kari. The Secret Service forensics experts presented testimony claiming that pages of Imanishi-Kari's data were prepared out of noted chronological order. Although these data were not cited in the published paper, some of them—including data that the Secret Service experts claimed were produced after publication—were cited in the NIH investigation. Her colleagues largely dismissed the charge as "sloppiness." Noting the potential usefulness of forensic evidence in this case, NIH Director Wyngaarden promised to have a forensics expert included in each NIH investigation.

The second panel was composed of the coauthors of the disputed paper. The hearings were antagonistic, concluding with a series of charges and countercharges between Dingell and Baltimore. O'Toole's

conduct as a whistle-blower became an issue. Baltimore characterized her actions as initially "rational and appropriate." Baltimore was surprised, however, that "having failed to get the desired outcome from two peer reviews, O'Toole would continue to press her case in additional and less conventional forums." O'Toole stated that the "thing is not that the mistake happened, the thing that astonished me was the universal attitude that it didn't have to be corrected." In his summary remarks, Representative Dingell highlighted the whistle-blower's plight, suggesting that it was too "daunting" for a young investigator to allege fraud and reminding the committee that O'Toole found making allegations dangerous, even if she only alleged error.

During the second day of hearings the subcommittee heard from three panels of witnesses. The first panel consisted solely of O'Toole. She asserted that a number of experiments reported in the disputed paper had not been conducted or had been reported incorrectly. The second panel represented the committee from Tufts that had conducted an investigation of the charges by O'Toole and that had found no evidence of misconduct by Imanishi-Kari. The witnesses indicated that they viewed the dispute as involving differing interpretations of data and not misconduct. The third panel represented the committee from MIT that had investigated the allegations and also had concluded that the allegations were the result of normal disagreements over the interpretation of data.

House Committee on Government Operations

On June 13, 1989, Representative Weiss held additional oversight hearings before a subcommittee of the Committee on Government Operations, entitled "Is Science for Sale? Conflicts of Interest vs. the Public Interest."[36] Representative Weiss's concerns at this hearing were twofold: first, the possibility that supplementing federal research funding with private (i.e., industry) funding could unduly influence the results of that research; and second, whether or not universities that "sold" the results of federally funded research to both domestic and foreign industries were acting in the public interest. There was general agreement that the conflict of interest issue needs to be looked at more closely and that guidelines may be needed. The issue of university-industry relationships was much more contentious, with some witnesses considering these relationships essential and some questioning whether too much was being given away, especially when taxpayer-supported research was sold to foreign companies.

House Committee on Science, Space, and Technology

On June 28, 1989, Representative Robert Roe (D-NJ) held hearings before the Committee on Science, Space, and Technology, entitled "Maintaining the Integrity of Scientific Research."[37] Unlike the adversarial climate in the other hearings described above, these hearings were more cooperative in nature and comprehensive in scope. Witnesses representing the federal agencies (DHHS, NIH, and NSF), working scientists, the institutions and their administrators, journal editors, and individuals who had been involved with cases of alleged misconduct either as whistle-blowers or as investigators testified at the hearings.

In his opening remarks, Representative Roe expressed his belief that the responsibility for maintaining integrity in science belonged primarily to the science community, that it must effectively deal with issues of fraud and misconduct in science, and that Congress had a legitimate concern to see that these issues were resolved because the federal government was funding science at increasing levels. His views were shared by other members of the subcommittee who stated that they hoped the scientific community would effectively deal with issues of fraud and misconduct in science without governmental intervention.

The witnesses were organized into four panels. The first panel reviewed actions taken by the PHS and NSF to establish oversight mechanisms for misconduct in science and the NSF and NIH definitions of scientific misconduct, noting the distinction between fraud and the honest errors that often occur in the scientific research process. The second panel examined the environment within which research is conducted, stating that pressure to publish is cited as one of the leading factors contributing to misconduct in science. The panel also addressed the ways in which ethics and values are taught to students, commenting that this is not a formal process. The panel also reviewed key findings of the Institute of Medicine report *The Responsible Conduct of Research in the Health Sciences* (National Academy Press, Washington, D.C., 1989), which concluded that "in the long run, the quality of the research environment may be more damaged by sloppy or careless research practices and apathy [lack of attention to traditional monitoring approaches] than by incidents of research fraud or other serious scientific misconduct" (p. 21).[38]

The third panel addressed institutional responses to incidents of scientific misconduct and commented on the development of institutional policies and procedures for handling allegations of misconduct, experience with implementing these procedures, and the need to improve them. During these hearings one witness suggested that the

effectiveness of these procedures could be improved by providing limited immunity to those who conduct investigations of misconduct and to those who report the findings of misconduct. The fourth panel focused on the role of scientific journals and journal editors in fostering integrity in research. The panel discussed the role of the peer review process in ensuring integrity in research, the limitation of that process in uncovering fraud, and possible changes in authorship practices that might be explored. An experimental audit of papers approved for publication, to develop a better estimate of the prevalence of misconduct, was also discussed.

House Committee on Energy and Commerce

On Monday April 30, 1990, the Subcommittee on Oversight and Investigations, chaired by Representative Dingell, held hearings on allegations of financial conflicts of interest.[39] The case in question involved Syed Zaki Salahuddin, a scientist in the laboratory of Robert Gallo, and Pan-Data, a Bethesda-based biomedical company that performed work for Gallo's laboratory. Salahuddin was alleged to have played a role in creating Pan-Data, to have used his position at NIH to bring business to the firm, and to have benefited financially from this arrangement, while not disclosing his relationship with the firm to officials at NIH, including Gallo. According to Dingell, of concern to the subcommittee was "whether monetary interests are undermining the academic integrity and impairing the ability of scientists to carry out health research for which they are supposedly being paid" and to see "that NIH is able to function efficiently, well, honorably and competently in the public interest."

On Monday May 14, 1990, the Subcommittee on Oversight and Investigations, chaired by Representative Dingell, held a fourth hearing on allegations of fraud and misconduct stemming from the paper published in *Cell* by Weaver, Imanishi-Kari, and Baltimore, among others. Two panels of witnesses presented testimony.[40] The first was composed of two forensic experts from the Secret Service, and the second panel consisted solely of Suzanne Hadley, deputy director of the NIH Office of Scientific Integrity. Imanishi-Kari was invited to testify as well but declined. Four days prior to the hearing, Imanishi-Kari held a press conference, charging that the committee had failed to provide her with information about the results of the forensics examination or the purpose for the new hearings.[41]

The hearings sought to establish the authenticity of the dates for the counter tapes in Imanishi-Kari's notebooks. Secret Service investigators

reported that along with a subcommittee staff member they had traveled to MIT in 1990 to identify the gamma counters used by Imanishi-Kari during 1984 and 1985 and to obtain samples of counter tapes from the laboratory notebooks of other investigators who used these same machines during the period of time in question. They then developed an identity relating the counter number to the date of use of the machine and established a relationship between the fading of type density prior to ribbon replacement. Based on these identities they reviewed the counter tapes in Imanishi-Kari's notebooks and concluded that up to one-third of the counter tapes in the I-1 notebook had not been produced on the dates claimed. As Imanishi-Kari did not testify and as there was no one asking questions of the Secret Service investigators on her behalf, the forensic evidence was not challenged.

The second panel consisted solely of Hadley, who had no prepared statement and simply responded to questions from Representatives Ron Wyden (D-OR) and Dingell. In response to questioning from Wyden, Hadley affirmed that NIH possessed a mounting body of evidence over and above the evidence gathered by the Secret Service and the subcommittee regarding the authenticity of key sets of data associated with the paper in question. She also indicated that one research grant to Imanishi-Kari had been terminated and that NIH lacked the authority to suspend a second because it was in the middle of its funding cycle.

At the conclusion of these hearings, Representative Dingell indicated that the material gathered by the subcommittee would be referred to the OIG at DHHS and to the Office of the U.S. Attorney in Baltimore for possible criminal proceedings.

OTHER SIGNS OF LEGISLATIVE INTEREST

In addition to the hearings described above, the Congress has from time to time provided formal guidance to research agencies through quasi-legislative language included in committee reports. For example, in 1981 Senator Lawton Chiles asked NIH Director Wyngaarden to prepare a report describing NIH's handling of allegations of fraud and misconduct in science.[42]

The Senate Appropriations Committee also included language in the 1989 report accompanying the FY 1990 appropriations bill for DHHS. Under the heading "Misconduct in Research," the committee wrote that it "is concerned about the effects on research that may result from recent investigations into allegations of misconduct in the biosciences."[43] The report went on to say, "The Committee deplores those instances where scientists have been guilty of fabrication or falsification of data, or of

plagiarism, but believes the vast majority of America's biomedical researchers are honest, dedicated, and hardworking individuals of the highest integrity." After mentioning the possibility for honest error, the self-correcting nature of science, and the tension between free inquiry and regulation, the report concluded: "Thus, the Committee will closely monitor the work of the new NIH Office of Scientific Integrity and the DHHS Office of Scientific Integrity Review to make certain that these agencies carry out their proper roles, but do not take actions that thwart or interfere with the continued creativity and excellence that are the hallmarks of biomedical research in this country."

In commenting on the funds provided to establish the NIH Office of Scientific Integrity (OSI), the language in the 1989 Senate Appropriations Committee report states that the mission of OSI is "to promulgate policies and procedures designed to safeguard the integrity of research conducted and supported by the NIH."[44] However, the federal notice announcing the establishment of OSI and OSIR states that OSIR has responsibility for "propos [ing] policies and procedures for preventing, detecting, reporting, and handling instances of alleged or suspected misconduct in science and present[ing] such policies to the Assistant Secretary of Health for approval."[45]

INTERESTED COMMITTEES

The majority of the hearings to date have been held in the House of Representatives. The committees most interested in this issue are:

- House Committee on Science, Space, and Technology, chaired by Representative Roe until 1991 and currently chaired by Representative George Brown (D-CA); Subcommittee on Investigations and Oversight, also chaired by Roe until 1991 and currently chaired by Representative Howard Wolpe (D-MI). The Science, Space, and Technology Committee has legislative and authorizing jurisdiction over a number of federal research agencies, including NSF and NASA.
- House Committee on Energy and Commerce, chaired by Representative Dingell; Subcommittee on Oversight and Investigations, also chaired by Dingell. The Energy and Commerce Committee has legislative and authorizing jurisdiction over DHHS, as well as aspects of federal research in the Department of Defense and Department of Energy.
- House Committee on Government Operations, chaired by Representative Conyers; Subcommittee on Human Resources and Intergovernmental Relations, chaired by Representative Weiss. The

Government Operations Committee has oversight jurisdiction and investigatory authority over all aspects of government. The Weiss subcommittee has jurisdiction over DHHS, among other executive branch agencies. The Government Operations Committee has no legislative authority.

Since the 1981 Hatch hearings, no Senate committee has undertaken formal activities in this area. The Senate Labor and Human Resources Committee, chaired by Senator Edward Kennedy (D-MA), has expressed concern over the regulatory reforms discussed in the House and the way institutions have been handling allegations of fraud and misconduct in science.

FUTURE ACTIVITIES

In December 1989, Representative Dingell inquired about the status of the NIH's investigation of allegations concerning Robert Gallo's discovery of the AIDS virus.[46] This resulted from an extensive 16-page investigative report by John Crewdson of the *Chicago Tribune*.[47] In that article, Crewdson suggests that NIH did not do an adequate job in investigating concerns about Gallo's discovery of the AIDS virus and that there may be substance to some of the allegations. As of February 1990, NIH had requested that the NAS and the IOM nominate a panel of qualified independent experts "to verify the independence and thoroughness of the NIH's own investigation."[48] It is expected to be a number of months before this review is complete.

The Subcommittee on Human Resources and Intergovernmental Affairs of the House Committee on Government Operations, chaired by Representative Weiss, released a committee report on misconduct in science based on hearings convened by the subcommittee over the past few years.[49] The report addresses conflict of interest issues, questions concerning substandard research practices and their relevance to misconduct, and the role and plight of whistle-blowers, among other issues. The findings were critical of the existing systems within government and universities for handling these issues, and the committee made the following recommendations: (1) to restrict by statute or regulation "honoraria, consulting fees, stocks/equity, and other conflicts of interest for Federal health research grantees"; (2) that NIH should more carefully enforce its guidelines and regulations on disclosure of nonfederal funding sources; (3) that "NIH should implement and enforce data-sharing requirements"; and (4) that "Congress should initiate

legislation to protect whistle-blowers and introduce penalties for grantees who cover up misconduct."

In May 1990, Representative Roe solicited comments on a draft bill that would provide limited immunity to institutions and individuals that conduct investigations of alleged misconduct and to the journals and editors that report the findings of these investigations. The bill was not formally introduced.

In the 102nd Congress, the National Institutes of Health Revitalization Amendments of 1991 (HR 2507) contain a subtitle dealing with scientific integrity. The bill would provide legislative authority for the Office of Scientific Integrity (OSI) within NIH; direct the secretary of DHHS to establish guidelines for whistle-blower protection; define scientific misconduct as seriously deviating from "standards of conduct that are recognized within the scientific community … includ[ing] fabrication, and plagiarism"; direct the General Accounting Office (GAO) to study the effectiveness of OSI; and direct the secretary of DHHS to establish guidelines for journals listed in the National Library of Medicine referencing systems for retractions and corrections. As of fall 1991, the bill had been approved by the House and was awaiting action in the Senate. Its prospects of becoming law, however, may be tied to two controversial subtitles on the bill not directly related to scientific integrity, the moratorium on fetal tissue research and federal reimbursement for university indirect costs.

ACTIVITIES OF CONGRESSIONAL SUPPORT AGENCIES

Congressional Budget Office

To the best of our knowledge, the Congressional Budget Office has conducted no studies in this area.

Congressional Research Service

In response to a request from the House Committee on Science, Space, and Technology, the Congressional Research Service (CRS) prepared a report entitled *Scientific Misconduct in Academia: Efforts to Address the Issue.*[50] In the report, the authors review responses by the PHS, NIH, NSF, professional societies, universities and colleges, and journals to the issue of fraud and misconduct in science. They evaluate the adequacy of these efforts, discuss additional options, and describe the policy issues facing Congress as "(1) assessing the effectiveness and

efficiency of recommendations and actions and (2) considering incentives to motivate the appropriate parties to adopt and implement the most effective recommendations."

CRS has also completed a study addressing the current status of activities and efforts to address the issues of misconduct in science across all relevant federal agencies. This report, which includes a survey of federal activity in this area, has not yet been released.

General Accounting Office

The General Accounting Office (GAO) has not conducted any studies on fraud or misconduct in science. From time to time, in response to congressional requests, GAO has conducted studies of the peer review system and the distribution of federal research funds.[51] As noted above, legislation pending in the House would direct GAO to study the Office of Scientific Integrity to determine its effectiveness in investigating and preventing scientific misconduct and report by the end of fiscal year 1992 to the House Energy and Commerce and the Senate Labor and Human Resources Committees.

Office of Technology Assessment

In response to a request from the Task Force on Science Policy, of the House Committee on Science and Technology, the Office of Technology Assessment (OTA) prepared a report in 1986 entitled *The Regulatory Environment for Science*.[52] The report examines the social and legal forces acting to restrict or regulate scientific research from the postwar period to the present. The report discusses regulatory actions implemented in the 1960s and 1970s "that began to constrain not just what topics scientists should pursue, but also how they should be pursued and the results disseminated." The roles of institutions, professional societies, citizen groups, and the government, and the mechanisms they use in controlling research, are reviewed and discussed.

OTA has recently completed a study entitled *Federally Funded Research: Decisions for a Decade*, examining the U.S. system for supporting basic research.[53] The report "analyzes what OTA identifies as four pressing challenges for the research system in the 1990s: setting priorities in funding, understanding trends in research expenditures, preparing human resources for the future research work force, and supplying appropriate data for ongoing research decisions" (p. iii). The

report signifies an interest and capacity of the Congress for addressing the contextual issues of the research system and not focusing merely on smaller segments of research policy such as misconduct.

GENERAL OBSERVATIONS

This review of congressional activities concerning misconduct in science is characterized by the divergence in perspective between the Congress and the science community regarding the prevalence of misconduct, the competency of the science community versus Congress to judge instances of misconduct, the effectiveness of the institutions of science to implement oversight and investigative mechanisms (i.e., the ability to be self-policing), and the legitimacy of questions concerning the use and misuse of public funds.

Representatives from the research community have indicated that cases of research misconduct are extremely rare and that they usually involve isolated acts by psychologically disturbed individuals. Some witnesses have suggested that these actions may be encouraged by career advancement incentives within the research enterprise and that systemic pressures such as "pressure to publish" may require attention. Several members of Congress have expressed views that challenge these findings. It has been suggested in congressional testimony that the incidence of research misconduct is higher than has been publicly reported. It has also been suggested that whistle-blowers who expose wrongdoing in the research environment experience reprisals that subsequently inhibit the disclosure of cases of misconduct.

Representatives of the research community have indicated that since many misconduct cases involve disputes about the significance of reported research findings, individuals with scientific credentials are needed to distinguish error from misconduct and to determine appropriate research practices. While recognizing mistakes and inexperience in the early stages of institutional investigations of these cases, many witnesses have stated repeatedly that local institutions are capable of handling misconduct investigations in an appropriate manner. Based on the procedural delays, and the informality that has often accompanied local investigations, some congressional members and staff have concluded that the research community does not currently have an adequate system of safeguards to ensure against the waste of federal research funds. Congressional observers have commented that misconduct investigations conducted by research institutions do not follow basic standards of other investigations into waste, fraud, and abuse involving government funds. They have suggested that more

formal policies and procedures are needed and that such investigations require certain standards of evidence to support claims by individuals accused of misconduct.

Over the past decade exchanges between the scientific community and the Congress over questions of misconduct in science have been marked by tension over the legitimate roles and responsibilities of each group to address these issues. Similar tension has characterized other discussions of congressional oversight or regulation of scientific research.

Throughout these discussions Congress and its committees have affirmed their belief in the veracity of scientific research and the importance of the contributions of the research community to the nation. In fact, more often than not congressional committees have argued that they are supporters of science and that they have an obligation and an interest to see that the enterprise remains healthy.

Many authors have noted the role of the media in disclosing accounts of research misconduct as a key factor in bringing the misconduct issue to the attention of Congress. Another factor in the legislative review process is the growth in staff and oversight responsibilities that occurred in the Congress in the mid to late 1970s. A third factor is reports by congressional staff that they receive a constant, if somewhat low-level, stream of complaints from scientists who believe there is something wrong with the system. As long as these allegations have substance and are not seriously addressed by the institutions of science, it is likely that Congress will remain interested in the issue of misconduct. Furthermore, misconduct in science is one of several issues on the congressional agenda with regard to universities and the academic research enterprise that include indirect cost payments, facilities maintenance, conflicts of interest, and education, all of which will continue to receive increased attention.

NOTES

1. Broad, W. J., 1980, "Would-be academician pirates papers," *Science* 208(June 27):1438-40.

2. Broad, W. J., 1981, "Fraud and the structure of science," *Science* 212(April 10):137-41; Sun, M., 1981, "Hatch batters NCI with Straus case …," *Science* 212(June 19):1366-67.

3. Broad, W. J., 1980, "Imbroglio at Yale (II): A top job lost," *Science* 210(October 10):171-73.

4. Wade, N., 1981, "A diversion of the quest for truth," *Science* 211(March 6):1022-25.

5. U.S. Congress, 1981, *Fraud in Biomedical Research*, House of Representatives, Committee on Science and Technology, Subcommittee on Investigations and Oversight, 97th Cong., 1st sess., March 31 and April 1, U.S. Government Printing Office, Washington, D.C.

6. Private communication, Jim Jensen, 1990.

7. Broad, W. J., and N. Wade, 1982, *Betrayers of the Truth: Fraud and Deceit in the Halls of Science*, Simon and Schuster, New York.

8. Broad and Wade, *Betrayers of the Truth*, 1982.

9. Private communication, Jensen, 1990.

10. Private communication, Jensen, 1990.

11. Private communication, Jensen, 1990.

12. Broad, "Fraud and the structure of science," 1981; Sun, "Hatch batters NCI," 1981; and Woolf, P., 1981, "Fraud in science: How much, how serious?" *Hastings Center Report* 11(October):9-14.

13. Department of Health and Human Services (DHHS), 1989, "Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science: final rule," *Federal Register* 54(August 8):32446-32451.

14. U.S. Congress, 1983, Health Research Extension Act of 1983, House of Representatives, HR 2350, Part F, section 485.

15. U.S. Congress, 1985, Health Research Extension Act of 1985, House of Representatives, Report 99-309 to accompany HR 2409.

16. National Archives and Records Administration (NARA), 1988, *Public Papers of the Presidents of the United States—Ronald Reagan, 1983*, Volume 2, NARA Washington, D.C.

17. Littlejohn, M. J., and C. M. Matthews, 1989, *Scientific Misconduct in Academia: Efforts to Address the Issue*, 89-392 SPR, Congressional Research Service, Washington, D.C.

18. U.S. Congress, 1986, *Current American Libel Law and Alternative*, House of Representatives, Judiciary Committee, Subcommittee on Civil and Constitutional Rights, February 26, U.S. Government Printing Office, Washington, D.C.

19. Stewart, W., and N. Feder, 1987. "The integrity of the scientific literature," *Nature* 325(January 15):207-14.

20. Boffey, P. M., 1986, "Major study points to faulty research at two universities," *New York Times* (April 22):C1.

21. U.S. Congress, 1986, *Research and Publication Practices*, House of Representatives, Committee on Science and Technology, Task Force on Science Policy, 99th Cong., 2nd sess., May 14.

22. U.S. Congress, *Research and Publication Practices*, 1986.

23. U.S. Congress, 1988, *Scientific Fraud and Misconduct and the Federal Response*, House of Representatives, Committee on Government Operations, Subcommittee on Human Resources and Intergovernmental Relations, 100th Cong., 2nd sess., April 11, U.S. Government Printing Office, Washington, D.C.

24. U.S. Congress, *Scientific Fraud and Misconduct*, 1988.

25. U.S. Congress, 1989, *Fraud in NIH Grant Programs*, House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 100th Cong., 2nd sess., April 12, Serial No. 100-189, U.S. Government Printing Office, Washington, D.C.

26. U.S. Congress, 1989, *Is Science for Sale? Conflicts of Interest vs. the Public Interest*, House of Representatives, Committee on Government Operations, Subcommittee on Human Resources and Intergovernmental Relations, 101st Cong., 1st sess., June 13, 20-969, U.S. Government Printing Office, Washington, D.C.

27. U.S. Congress, 1989, *Federal Response to Misconduct in Science: Are Conflicts of Interest Hazardous to Our Health*? House of Representatives, Committee on Government Operations, Subcommittee on Human Resources and Intergovernmental Relations, 100th Cong., 2nd sess., September 29, U.S. Government Printing Office, Washington, D.C.

28. U.S. Congress, *Federal Response to Misconduct in Science*, 1989.

29. Department of Health and Human Services (DHHS), 1988, *Misconduct in Scientific Research*, Office of the Inspector General, OAI-88-07-420, Draft.

30. Rosenzweig, R. M., 1988, "Preventing fraud is a task for scientists, not Congress," *The Scientist* 2(December 12).

31. Department of Health and Human Services (DHHS), 1989, "Statement of organizations, functions, and delegations of authority," *Federal Register* 54(March 16):11080-81.

32. DHHS, "Responsibilities of PHS awardee and applicant institutions," 1989.

33. National Science Foundation (NSF), 1987, "Misconduct in science and engineering research: proposed regulations," *Federal Register* 52(February 10):4158-61.

34. National Science Foundation (NSF), 1987, "Misconduct in science and engineering research: final regulations," *Federal Register* 52(July 1):24466-70.

35. U.S. Congress, 1989, *Scientific Fraud*, House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 101st Cong., 1st sess., May 4, 9, Serial No. 101-64, U.S. Government Printing Office, Washington, D.C.

36. U.S. Congress, *Is Science for Sale*?, 1989.

37. U.S. Congress, 1990, *Maintaining the Integrity of Scientific Research*, House of Representatives, Committee on Science, Space, and Technology, Subcommittee on Investigations and Oversight, 101st Cong., 1st sess., June 28, No. 73, U.S. Government Printing Office, Washington, D.C.

38. U.S. Congress, *Maintaining the Integrity of Scientific Research*, 1990.

39. U.S. Congress, 1990, *Scientific Fraud, Part 2*, House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 101st Cong., 1st sess., April 30 and May 14, U.S. Government Printing Office, Washington, D.C.

40. U.S. Congress, *Scientific Fraud, Part 2*, 1990.

41. Mervis, J., 1990, "NIH cuts research funding of scientist under investigation for Cell paper," *The Scientist* 4:9.

42. Chalk, R., 1988, "Survey of current work on scientific misconduct," a background paper prepared for COSEPUP, December.

43. U.S. Congress, 1989, *Report on Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 1990*, Senate, Report 101-127, September 13.

44. U.S. Congress, *Report on Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 1990*, 1989.

45. DHHS, "Statement of organizations," 1989.

46. Greenberg, D. S., 1990, "Prodded by Dingell, NIH studying Gallo AIDS role," *Science and Government Report* (January 15):4.

47. Crewdson, J., 1989, "The great AIDS quest," *Chicago Tribune*, special report (November 19):V1-16.

48. Culliton, B. J., 1990, "NIH misconduct probe draws legal complaints," *Science* 249(July 20):240-43.

49. U.S. Congress, 1990, *Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health*? House of Representatives, Committee on Government Operations, 101st Cong., 2d sess. H. Rpt. 101-688, U.S. Government Printing Office, Washington, D.C.

50. Littlejohn and Matthews, *Scientific Misconduct in Academia*, 1989.

51. In response to a 1985 request by Senator Mark Hatfield (R-OR), ranking minority member of the Appropriations Committee, GAO undertook an examination of the systems and procedures used by federal agencies to distribute federal research monies. Of special concern were the "fairness and effectiveness" of the peer review process. In 1987, GAO issued a report on the distribution of federal research funds and a fact sheet on peer review at NIH and NSF. The fact sheet concluded that no data exist to provide conclusive evidence that the peer review system in either NIH or NSF is unfair (biased), but that chance does play some role in determining who gets funding.

52. Office of Technology Assessment (OTA), 1986, *The Regulatory Environment for Science*, Technical memorandum, OTA, Washington, D.C.

53. Office of Technology Assessment (OTA), 1991, *Federally Funded Research: Decisions for a Decade*, OTA-SET-490, U.S. Government Printing Office, Washington, D.C.

Part B

Selected Guidelines for the Conduct of Research

7

Guidelines for the Conduct of Research at the National Institutes of Health

National Institutes of Health

INTRODUCTION

Scientists in the Intramural Research Program of the National Institutes of Health generally are responsible for conducting original research consonant with the goals of their individual Institutes, Centers, and Divisions.

NIH scientists, as all scientists, should be committed to the responsible use of the process known as the scientific method to seek new knowledge. While the general principles of the scientific method—formulation and testing of hypotheses, controlled observations or experiments, analysis and interpretation of data, and oral and written presentation of all of these components to scientific colleagues for discussion and further conclusions—are universal, their detailed application may differ in different scientific disciplines and varying circumstances. It is clear, however, that only by adherence to the highest standards of intellectual honesty in formulating, conducting and presenting research does science advance and do scientists fulfill their contract with the community at large.

These Guidelines state general principles that NIH scientists are expected to follow in their research activities with regard to supervision of trainees, data management, publication practices, authorship, peer review and use of privileged information, and clinical investigations in order to promote the uniform application of the highest ethical standards to the conduct of all scientific research. It is the responsibility of each Laboratory or Branch Chief, and successive levels of supervisory individuals (especially Institute, Center, and Division Intramural Research Directors), to insure that each NIH scientists is cognizant of these Guidelines and to resolve issues that may arise in their implementation.

NOTE: Issued in 1990; reprinted courtesy of the National Institutes of Health, Bethesda, Md.

These Guidelines supplement existing NIH policies on the conduct of research. In particular, those policies concerning Institutional Review Board oversight of clinical research protocols; animal use; radiation, chemical and other safety issues; and other aspects of the Standards of Conduct for all federal employees remain parts of the canon of conduct for each scientist.

The formulation of these Guidelines is not meant to codify a set of rules, but rather to make explicit patterns of scientific practice that have been developed over many years and are followed by the vast majority of scientists, and to provide benchmarks when problems arise. Although no set of guidelines, or even explicit rules, can prevent willful scientific misconduct, it is hoped that formation of these Guidelines will contribute to the continued clarification of the application of the scientific method in changing circumstances.

The community will ultimately judge the NIH by its adherence to these intellectual and ethical standards, as well as by its development and application of important new knowledge through scientific creativity.

SUPERVISION OF TRAINEES

Research training is a complex process, the central aspect of which is an extended period of research carried out under the supervision of an experienced scientific mentor. This supervised research represents not merely performance of tasks assigned by the supervisor but rather a process wherein the trainee takes on an increasingly independent role in the choice of research projects, development of hypotheses and the performance of the work. Indeed, if training is to prepare a young scientist for a successful career as a research investigator, it must be geared toward providing the trainee with the aforementioned skills and experiences. It is particularly critical that the mentor recognize that the trainee is not simply an additional laboratory worker.

Each trainee should have a designated primary scientific mentor. It is the responsibility of this mentor to provide a training environment in which the trainee has the opportunity to acquire both the conceptual and technical skills of the field. In this setting, the trainee should undertake a significant piece of research, chosen usually as the result of discussions between the mentor and the trainee, which has the potential to yield new knowledge of importance in that field. The mentor has the responsibility to supervise the trainee's progress closely and to interact

personally with the trainee on a regular basis in such a way as to make the training experience a meaningful one. Styles of research differ, both among fields and among investigators in a given field, so that no specific rules should be made about the number of trainees that is appropriate for a single mentor to supervise. Nonetheless, mentors should limit the number of trainees in their laboratory to the number for whom they can provide an appropriate research experience.

There are certain specific aspects of the mentor-trainee relationship that deserve emphasis. First, mentors must be particularly diligent in avoiding the involvement of trainees in research activities that do not provide meaningful training experiences but which are designed mainly to further research or development activities in which the mentor has a potential monetary or other compelling interest. Second, training must impart to the trainee appropriate standards of scientific conduct. The mentor conveys these standards by instruction and by example. Third, mentors have a responsibility to provide trainees with realistic appraisals of their performance and with advice about career development and opportunities.

DATA MANAGEMENT

Research data, including detailed experimental protocols, primary data from laboratory instruments, and procedures of reduction and analysis of primary data, are the essential components of scientific progress. Scientific integrity is inseparable from meticulous attention to the acquisition and maintenance of these research data.

It is expected that the results of research will be carefully recorded in a form that will allow continuous access for analysis and review. Attention should be given to annotation and indexing of notebooks to facilitate detailed review of data. All data, even from observations and experiments not directly leading to publication, should be treated comparably. Research data should always be immediately available to scientific collaborators and supervisors for review. In collaborative projects involving different units, all investigators should know the status of all contributing data and have direct access to them.

Research data, including the primary experimental results, should be retained for a sufficient period to allow analysis and repetition by others of published material from those data. In some fields, five or seven years are specified as the minimum period of retention but this may vary under different circumstances.

PUBLICATION PRACTICES

Publication of experimental results is an integral and essential component of research. Other than presentation at scientific meetings, publications in a scientific journal should normally be the mechanism for the first public disclosure of new findings. Although appropriately considered the end point of a particular research project, publication is also the beginning of a process in which the scientific community at large can substantiate, correct and further develop a particular set of results.

Timely publication of new and significant results is important for the progress of science, but fragmentary publication of the results of a scientific investigation or multiple publications of the same or similar data are inappropriate. Each publication should make a unique and substantial contribution to its field. As a corollary to this principle, tenure appointments and promotions should be based on the importance of the scientific accomplishments and not on the number of publications in which those accomplishments were reported.

Therefore, each paper should contain all the information that would be necessary for the scientific peers of the authors to repeat the experiments. This principle requires that any unique materials (e.g., monoclonal antibodies, bacterial strains, mutant cell lines), analytical amounts of scare reagents and unpublished data (e.g., protein or nucleic acid sequences) that are essential for repetition of the published experiments be made available to other qualified scientists. It is not necessary to provide materials (such as proteins) that others can prepare by published procedures, or large quantities of materials (such as polyclonal antisera) that may be in limited supply, although it is desirable to do so.

AUTHORSHIP

Authorship refers to the listing of names of participants in all communications, oral and written, of experimental results and their interpretation to scientific colleagues. Authorship is the fulfillment of the responsibility to communicate research results to the scientific community for external evaluation.

Authorship is also the primary mechanism for determining the allocation of credit for scientific advances and thus the primary basis for assessing a scientist's contributions to developing new knowledge. As

such, it potentially conveys great benefit, as well as responsibility. For each individual the privilege of authorship should be based on a significant contribution to the conceptualization, design, execution, and/or interpretation of the research study, as well as a willingness to take responsibility for the defense of the study should the need arise. In contrast, other individuals who participate in part of a study may more appropriately be acknowledged as having contributed certain advice, reagents, analyses, patient material, support, etc., but not be listed as authors. It is expected that such distinctions will be increasingly important in the future and should be explicitly considered more frequently now.

In recent years, there has been a rapid increase in the average number of authors per communication. In part, this increase is due to the needs of modern research projects for contributions from many individuals, frequently those with different specialized skills. While multi-authorship is not a problem in itself, it raises many issues such as criteria for inclusion as an author, ability of each author to evaluate and defend all aspects of a study, sequence of listing of authors, and separation of various experimental results to increase numbers of communications and authorship citations. To clarify some of these concerns, consideration should be given in interdisciplinary studies to preparing brief statements of the exact contribution of each author to the work described in each communication.

Because of the variation in detailed practices among disciplines, no universal set of standards can be easily formulated. It is expected, however, that each research group and Laboratory or Branch will freely discuss and resolve questions of authorship before and during the course of a study. Further, each author should review fully material that is to be presented in public forums or submitted (originally or in revision) for publication. Each author should be willing to support the general conclusions of the study and be willing to defend the study.

The submitting author should be considered the primary author with the additional responsibility of coordinating the completion and submission of the work, satisfying pertinent rules of submission, and coordinating responses of the group to inquiries or challenges. The submitting author should assure that the contributions of all collaborators are appropriately recognized and must be able to certify that each author has reviewed and authorized the submission of the manuscript. The recent practice of some journals in requiring approval signatures from each author before publication is felt to be a useful step in regard to fulfilling the above.

PEER REVIEW AND PRIVILEGED INFORMATION

Peer review can be defined as expert critique of either a scientific treatise, such as an article prepared or submitted for publication, a research grant proposal, a clinical research protocol, or of an investigator's research program, as in a site visit. Peer review is an essential component of the conduct of science. Decisions on the funding of research proposals and on the publication of experimental results must be based on thorough, fair and objective evaluations by recognized experts. Therefore, although it is often difficult and time-consuming, scientists have an obligation to participate in the peer review process and, in doing so, they make an important contribution to science.

Peer review requires that the reviewer be expert in the subject under review. The reviewer, however, should avoid any real or perceived conflict of interest that might arise because of a direct competitive, collaborative or other close relationship with one or more of the authors of the material under review. Normally, such a conflict of interest would require a decision not to participate in the review process and to return any material unread.

The review must be objective. It should be based solely on scientific evaluation of the material under review within the context of published information and should not be influenced by scientific information not publicly available.

All material under review is privileged information. It should not be used to the benefit of the reviewer unless it previously has been made public. It should not be shared with anyone unless necessary to the review process, in which case the names of those with whom the information is shared should be made known to those managing the review process. Material under review should not be used in any manner by the reviewer unless specifically permitted by the journal or reviewing organization and the author.

CLINICAL RESEARCH

Clinical research, for the purposes of these Guidelines, is defined as research performed on human subjects as part of human experimentation. All of the topics covered in the Guidelines also apply to the conduct of clinical research; clinical research, however, entails further responsibilities for investigators.

The preparation of a written research protocol ("Clinical Research Protocol") according to existing guidelines prior to commencing studies is almost always required. By virtue of its various sections governing background; patient eligibility and confidentiality; data to be collected; mechanism of data storage, retrieval, statistical analysis and reporting; and identification of the principal and associate investigators, the Clinical Research Protocol provides a highly codified mechanism covering most of the topics covered elsewhere in the Guidelines. The Clinical Research Protocol is generally widely circulated for comment, review and approval. It should be scrupulously adhered to in the conduct of the research. The ideas of the investigators who prepared the protocol should be protected by all who review the document.

Clinical investigators are responsible for assuring that the proposed clinical research will be conducted only if the Clinical Center, or other clinical facilities, has the appropriate capability and support structure to insure that the research can be done safely and efficiently. The principal investigator should be familiar with the functioning of the clinical unit and should allow the investigation to continue only if the unit can provide adequate clinical care.

Investigators who are neither clinicians nor trained in clinical research may perform laboratory research on material derived from humans. To conform to the requirement of working under approved human experimentation guidelines, they should ordinarily be advised by or collaborate with trained clinical investigators.

The supervision of trainees in the conduct of clinical investigation is complex. Often the trainees are in fellowship training programs leading to specialty or subspeciality certifications as well as in research training programs. Thus, they should be educated in general and specific medical management issues as well as in the conduct of research. The process of data gathering, storage, and retention can also be complex in clinical research and sometimes not easily subject to repetition. The principal investigator is responsible for the quality and maintenance of the records and for the training and oversight of all personnel involved in data collection.

CONCLUDING STATEMENT

These Guidelines are not intended to address issues of misconduct, i.e., fabrication, falsification, plagiarism or other practices motivated by intent to deceive. Rather, their purpose is to provide a framework for the fair and open conduct of research without inhibiting scientific freedom and creativity.

8

Guidelines for Investigators in Scientific Research

Harvard University Faculty of Medicine

I. INTRODUCTION

These guidelines describe practices generally accepted by members of the Faculty of Medicine and already in effect in their laboratories. The primary intent of codifying them is to bring them to the attention of those beginning their careers in scientific research. These recommendations are not intended as rules, but rather as guidelines from which each group of investigators can formulate its own set of specific procedures to ensure the quality and integrity of its research.

II. SUPERVISION OF RESEARCH TRAINEES

Careful supervision of new investigators by their preceptors is in the best interest of the institution, the preceptor, the trainee, and the scientific community. The complexity of scientific methods, the necessity for caution in interpreting possibly ambiguous data, and the need for advanced statistical analysis all require an active role for the preceptor in the guidance of new investigators. This is particularly true in the not uncommon circumstance of a trainee who arrives in a research unit without substantial experience in laboratory science.

RECOMMENDATIONS

1. The responsibility for supervision of each junior investigator should be specifically assigned to some faculty member in each research unit.

NOTE: Dated February 16, 1988; reprinted with permission from Harvard University School of Medicine, Cambridge, Mass.

2. The ratio of trainees to preceptors should be small enough that close interaction is possible for scientific interchange as well as oversight of the research at all stages.
3. The preceptor should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting, and storing data. (A preceptor who limits his/her role to the editing of manuscripts does not provide adequate supervision.)
4. Collegial discussions among all preceptors and trainees constituting a research unit should be held regularly both to contribute to the scientific efforts of the members of the group and to provide informal peer review.
5. The preceptor should provide each new investigator (whether student, postdoctoral fellow, or junior faculty) with applicable governmental and institutional requirements for conduct of studies involving healthy volunteers or patients, animals, radioactive or other hazardous substances, and recombinant DNA.

III. DATA GATHERING, STORAGE, RETENTION:

A common denominator in most cases of alleged scientific misconduct has been the absence of a complete set of verifiable data. The retention of accurately recorded and retrievable results is of utmost importance for the progress of scientific inquiry. A scientist must have access to his/her original results in order to respond to questions including, but not limited to, those that may arise without any implication of impropriety. Moreover, errors may be mistaken for misconduct when the primary experimental results are unavailable. In addition, when statistical analysis is required in the interpretation of data, it should be used in the design of studies as well as in the evaluation of results.

RECOMMENDATIONS:

1. Custody of all original primary laboratory data must be retained by the unit in which they are generated. An investigator may make copies of the primary data for his/her own use.
2. Original experimental results should be recorded, when possible, in bound books with numbered pages. An index should be maintained to facilitate access to data.
3. Machine print-outs should be affixed to, or referenced from, the laboratory notebook.

4. Primary data should remain in the laboratory at all times and should be preserved as long as there is any reasonable need to refer to them. The chief of each research unit must decide whether to preserve such primary data for a given number of years or for the life of the unit. In no instance, however, should primary data be destroyed while investigators, colleagues, or readers of published results may raise questions answerable only by reference to such data.

IV. AUTHORSHIP:

A gradual diffusion of responsibility for multi-authored or collaborative studies has led in recent years to the publication of papers for which no single author was prepared to take full responsibility. Two critical safeguards in the publication of accurate, scientific reports are the active participation of each coauthor in verifying that part of a manuscript that falls within his/her specialty area and the designation of one author who is responsible for the validity of the entire manuscript.

RECOMMENDATIONS:

1. Criteria for authorship of a manuscript should be determined and announced by each department or research unit. The committee considers the only reasonable criterion to be that the coauthor has made a significant intellectual or practical contribution. The concept of "honorary authorship" is deplorable.
2. The first author should assure the head of each research unit or department chairperson that s/he has reviewed all the primary data on which the report is based and provide a brief description of the role of each coauthor. (In multi-institutional collaborations, the senior investigator in each institution should prepare such statements.)
3. Appended to the final draft of the manuscript should be a signed statement from each coauthor indicating that s/he has reviewed and approved the manuscript to the extent possible, given individual expertise.

V. PUBLICATION PRACTICES:

The committee has observed certain practices that make it difficult for reviewer and reader to follow a complete experimental sequence: the rapid publication of data without adequate tests of reproducibility

or assessment of significance, the publication of fragments of a study, and the submission of multiple similar abstracts or manuscripts differing only slightly in content. In such circumstances, if any of the work is questioned, it is difficult to determine whether the research was done inaccurately, the methods were described imperfectly, the statistical analyses were flawed, or inappropriate conclusions were drawn. Investigators should review each proposed manuscript with these principles in mind.

RECOMMENDATIONS:

1. The number of publications to be reviewed at the time of faculty appointment or promotion should be limited in order to encourage and reward bibliographies containing fewer but more substantive publications rather than those including many insubstantial or fragmented reports. (It has been suggested, for example, that no more than 5 papers be reviewed for appointment as assistant professor, nor more than 7 for associate professor, and no more than 10 for professor.)
2. Simultaneous submission of multiple similar abstracts or manuscripts to journals is improper.

VI. LABORATORY GUIDELINES:

Because each research unit addresses different scientific problems with different methods, each unit should develop its own specific guidelines to identify practices that seem most likely to enhance the quality of research conducted by its members. Those guidelines should be provided to the new investigator upon starting work.

9

Rules and Guidelines for Responsible Conduct of Research

Johns Hopkins University School of Medicine

The distinction this School of Medicine has achieved as a center for research in the biomedical sciences is the result of dedication throughout the institution to the highest standards of professional conduct. In a time-honored system, the ethics of science are transmitted, along with practical and theoretical knowledge, to junior researchers by their senior colleagues. The atmosphere of truthfulness, accountability, and free exchange of ideas characteristic of this School has been considered sufficient to ensure responsible conduct of research. However, growth of the School and the greater complexity of regulations governing research make it increasingly likely that some researchers may not be fully aware of established norms. The purpose of this document is (1) to set forth principles and practices generally known and followed by researchers in the School of Medicine, (2) to ensure that all researchers in the School of Medicine are informed of institutional and governmental regulations that affect their work, and (3) to establish procedures designed to protect against fraudulent research, or unjustified charges thereof, with the least possible hindrance to scientific investigation.

This document is addressed to all faculty, postdoctoral fellows, students, and other research personnel in the School of Medicine. Everyone engaged in research in the School of Medicine should become familiar with its contents.

I. ORIENTATION AND GUIDANCE FOR FACULTY

General expectations for the academic conduct of faculty members and many specific requirements governing the conduct of research are set forth in the following documents:

NOTE: Issued in 1990; reprinted with permission from Johns Hopkins University, Baltimore, Md.

- Policies and Guidelines Governing Appointments, Promotions, & Professional Activities of Faculty Members of The Johns Hopkins University School of Medicine
- The Sponsored Projects Handbook
- The Faculty Handbook of The Johns Hopkins University School of Medicine
- Guidelines of the Joint Committee on Clinical Investigation
- Use of Experimental Animals at the Johns Hopkins Medical Institutions and University
- Policy on Conflict of Commitment and Conflict of Interest
- Rules and Guidelines for Responsible Conduct of Research
- Procedures for Dealing with Issues of Professional Misconduct
- Grievance Procedure for Faculty, Fellows, and the Student Body

All faculty members should have copies of these documents and should be familiar with their contents.[1]

As teachers and researchers, faculty should be informed about ethical issues in research. Because these issues have rarely been part of their formal training, both current and new faculty should devote some effort and time to their study. They will thus be better able to inculcate in their trainees a clear understanding of the principles of academic integrity. Faculty also serve as role models, and the manner in which they conduct their own research must be above reproach. Discussion of research ethics should be a regular part of department and division meetings.

A. RULE

1. The Office of the Registrar of the School of Medicine will distribute to each new faculty member the documents listed above and the booklet *Honor in Science* published by Sigma Xi. Faculty will be required to sign an acknowledgment of receipt of the above at the time they respond to their initial letter of appointment from the dean.

II. SUPERVISION OF STUDENTS, POSTDOCTORAL FELLOWS, AND OTHER RESEARCH PERSONNEL

Preceptors are responsible for the careful supervision of their trainees and other research personnel. The complexity of scientific methods and the need for careful experimental design, caution in

interpreting possibly ambiguous data, and advanced statistical analysis all require that the preceptor assume an active role of guidance and supervision. Preceptors should be prepared to give additional attention to a trainee or an employee who arrives in a research unit without substantial experience in laboratory science.

A. RULES

1. Responsibility for supervision of each student, fellow, or other (non-faculty) member of a research unit must be assigned to a specific faculty preceptor. For particular research projects, supervision should be carried out by the responsible investigator; overall supervision of each student or fellow must be assigned to a faculty advisor.
2. As a part of their orientation the Office of the Registrar of the School of Medicine must provide each new medical student and graduate student with a copy of this statement and also *Procedures for Dealing with Issues of Professional Misconduct* and the booklet *Honor in Science* published by Sigma Xi. At the time of registration these documents must also be given to all postdoctoral fellows, whose written acknowledgment of receipt of the documents will be kept on file in the Office of the Registrar. Preceptors should familiarize trainees and other research personnel with relevant governmental and institutional requirements for conduct of studies involving healthy volunteers or patients, animals, radioactive or other hazardous substances, and recombinant DNA.

B. RECOMMENDATIONS

1. The ratio of trainees to faculty members should be small enough that close interaction is possible for scientific interchange as well as supervision of the research at all stages.
2. The degree of supervision by the preceptors should take into account the experience and skill of trainees. A preceptor should help the trainee develop not only good research practices and technical expertise, but also good research ethics.
3. The preceptor should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting, and storing data. The editing of manuscripts alone does not constitute adequate supervision by the preceptor.

4. Preceptors should have realistic expectations regarding the performance of trainees and other research personnel and should inform them of these expectations.
5. Collegial discussions among all preceptors and trainees constituting a research unit should be held regularly both to contribute to the scientific efforts of the members of the group and to provide informal peer review.
6. Preceptors should be alert to behavioral changes in trainees or other research personnel that may indicate inordinate personal or academic stress or substance abuse. Stresses are particularly likely to occur at times of transition or as deadlines approach. Since the care with which research activities are conducted may be adversely affected by stress, a trainee or employee may need closer supervision at such times.

III. DATA GATHERING, STORAGE, RETENTION

The retention of accurately recorded results is of utmost importance for the progress of scientific research. Original laboratory data[2] must be retrievable not only to answer scientific questions but also to respond to questions that may arise about the propriety of research conduct. Errors may be mistakenly characterized as misconduct when the primary experimental results are unavailable. Moreover, a common denominator in most cases of alleged research fraud has been the absence of a complete set of verifiable data. The rules and recommendations in this section are designed to ensure that all research data are recorded appropriately and that access to them will be available when necessary.

The University is aware that scientific investigation may be impeded if undue conditions are placed on the ability of departing investigators to retain custody of original data generated in the course of work performed here. Nevertheless, there are pragmatic reasons for preserving the University's ready access to original data. For example, access to original data may be necessary if the University is to render the most effective assistance in rebutting unjustified claims of fraud made against its researchers. Then, too, the University is responsible for promoting the collective reputation for integrity of its researchers with public and private granting agencies. The inability to produce original data is always considered the best evidence for purposes of avoiding questions of admissibility in administrative or judicial proceedings.

A. RULES

1. Custody of all original data must be retained by the unit in which they are generated. When hospital records, which cannot be kept in the research unit, are used in research projects, summaries must be maintained by the investigator. An investigator who moves to another institution must submit to the department director a written request to remove original data from the University. This request must contain an itemized description of the data and must specify where the data will be located in the future. In granting such requests, the department director must remind the researchers that legally the data are the property of the University, that any inventions made here must be disclosed to the appropriate patent office of The Johns Hopkins University, and that original data must be made available for review if questions of scientific misconduct should arise. If the department director does not approve the removal of data, an appeal may be made to the dean.
2. To date, no governmental regulations prescribe the length of time researchers must maintain original data. Until governmental regulations appear on this issue, the School will require that original data be retained for at least five years from the date of publication. Beyond that, where questions have been raised regarding the validity of published data, investigators must preserve original data until such questions have been resolved to the satisfaction of the School and any involved government agencies. The chief of each research unit must decide whether to preserve original data for a given number of additional years or for the life of the unit.

B. RECOMMENDATIONS

1. Original experimental results should be kept in an orderly fashion in such a way that they are accessible and can be easily reviewed by peers. Records should identify when experiments were done and by whom.
2. Machine print-outs or other primary data (e.g., an autoradiogram) should be affixed to or referenced from the laboratory notebook.

IV. AUTHORSHIP

Two critical safeguards in the publication of accurate scientific reports are the active participation of each coauthor in verifying any part

of a manuscript that falls within his or her specialty area and the designation of one author who is responsible for obtaining coauthor verification. A gradual diffusion of responsibility for multi-authored or collaborative studies has led in recent years to the publication of papers for which no single author was prepared to take full responsibility.

A. RULES

1. One author from within the School of Medicine must be designated as responsible for obtaining coauthor verification for any manuscript submitted for publication by a faculty member, fellow, or student as part of his or her activity at the School of Medicine. The designated author must give to the director of an appropriate department or division a copy of the title page of the manuscript, upon which a statement is added to the effect that everyone listed as an author has contributed to the paper significantly, has reviewed the manuscript, and stands behind the parts within his or her own area of expertise. Each listed author must sign this statement. These statements must be kept in the permanent files of the department or division.
2. Any faculty member, fellow, or student who submits an abstract must ensure that all named authors have consented to authorship prior to submission of the abstract. Each named author must be given a copy of the abstract.

B. RECOMMENDATIONS

1. Criteria for authorship of a manuscript should be determined and announced by each department or research unit. Authorship should be given generously, but only to those who have contributed significantly to the research, are prepared to stand behind their findings, and have reviewed the entire manuscript. The referral of patients included in a clinical study does not, in and of itself, constitute a significant contribution warranting coauthorship status. The practice of permitting "honorary authorship" is unacceptable and should be actively discouraged by primary investigators and heads of departments and research units.
2. All publications should credit research findings appropriately by citing relevant observations of others, as well as by recognizing the work and input of all contributors in their own environments.

V. PUBLICATION PRACTICES

Certain practices make it difficult for reviewer and reader to follow a complete experimental sequence. Among these are the premature publication of data without adequate tests of reproducibility or assessments of significance, the publication of fragments of a study, and the submission of multiple similar abstracts or manuscripts differing only slightly in content. In such circumstances, if any of the work is questioned, it is difficult to determine whether the research was done accurately, the methods were described properly, the statistical analyses were adequate, or appropriate conclusions were drawn. Investigators should review each proposed manuscript with these principles in mind.

A. RECOMMENDATIONS

1. The number of publications to be reviewed at times of faculty appointment or promotion should be limited in order to encourage and reward bibliographies containing substantive publications rather than those including a large number of insubstantial or fragmented reports.
2. Published papers should credit sponsors of the work, and any acknowledgment requirements in grant and contract documents should be adhered to scrupulously since they are contractual obligations. Moreover, it is important that reviewers and readers be informed of the sponsorship of research projects in order that they may be alert to possible bias in the research arising from a sponsor's financial interest in the results.

VI. LABORATORY GUIDELINES

Because each research unit addresses different scientific problems with different methods, particular units may need to develop their own specific rules or guidelines regarding the prevention of academic misconduct. Such rules or guidelines should be provided to all new investigators when they start work in the unit.

VII. REPORTING ACADEMIC MISCONDUCT

The trust and good faith traditionally associated with The Johns Hopkins University School of Medicine will flourish only if every member of this community bears responsibility for upholding the highest

standards of integrity. Should academic misconduct occur, early identification and intervention are in the best interests of everyone. Steps to be taken by anyone who suspects that another's research conduct has been improper are detailed in *Procedures for Dealing with Issues of Professional Misconduct*. The institution recognizes the risks to persons who report apparent scientific misconduct and has made every effort to protect them as well as those who might be accused in error.

A. RULE

1. It is a professional obligation of faculty, students, or fellows to inform superiors if they have reservations about the integrity of the work of another member of this academic community.

NOTES

1. Copies are available from the Office of the Registrar of the School of Medicine.

2. While what constitutes "original" or "primary" data may differ from laboratory to laboratory depending on the technology used, in every instance an investigator is expected to maintain an accurate record of experimental data that is as close to the original form of the data as is practical. When the "original" data are so voluminous or are collected and/or modified in atypical ways (for example, in the case of data collected by computer), individual investigators should seek concurrence of their division or department head in deciding what aspect of their research will constitute primary data, bearing in mind the possible future need to support reported findings.

Acknowledgment: "Guidelines for Investigators in Scientific Research," the report of the Committee on Professional Misconduct of Harvard Medical School, was very helpful in the preparation of this statement.

10

Guidelines for the Responsible Conduct of Research

University of Michigan Medical School

INTRODUCTION

This document represents the work of a Medical School ad hoc committee that was charged with the task of developing a set of guidelines for the conduct of research that would promote adherence to the highest scientific and ethical standards. The committee consisted of senior and junior members of both the clinical and basic science faculties and included a postdoctoral trainee. There are two important points to highlight from the charge to the committee. First, this document is meant to serve as a useful *guideline* for the conduct of research. It is neither a specific policy statement with legal ramifications nor a rulebook with an attached set of punishments. The document is meant merely to structure and reiterate the collective wisdom of a representative group of faculty members of the Medical School regarding scholarly practices directed at maintaining the highest aspirations of the medical academic profession. The second feature of this document that is worthy of note is its intention to promote the highest scientific and ethical standards. Although it is undeniable that the recent national focus of attention on misconduct in research influenced the decision to form this committee, the committee was not charged with the negative goal of preventing or prosecuting unacceptable behavior in the biomedical sciences. Ours is a profession that is constructed with intrinsic safeguards against misconduct. The extensive system of peer review that begins within our own laboratories or institutions and intensifies upon application for grant funding or following submission of a manuscript for publication, limits the viability of a biomedical scientist who does not adhere strictly to open and honest practices. In the final analysis, the veracity of the work of a biomedical scientist is judged by

NOTE: Dated March 1989; reprinted with permission from the University of Michigan, Ann Arbor.

the test of time. Against this background, it is clear that no external review committee, however menacing or powerful, could function better than the mechanisms by which we biomedical scientists already police ourselves. The presumption of the committee, therefore, was that the biomedical scientific enterprise is basically healthy, sound, and honest. Thus, the task at hand was to provide useful suggestions on maintaining and promoting the prevailing spirit of integrity.

A previous report prepared by the University of Michigan Joint Task Force on Integrity in Scholarship in 1984 (Steneck Report) already has addressed many important areas pertaining to the ethical conduct of research (see Appendix I [of that report]). It defined the ethical obligations of a scholar and the pressures that can discourage integrity in scholarship. Moreover, it articulated specific procedures to be followed when misconduct is alleged. In this document, we have chosen to focus our attention on promoting the best qualities of the scientific environment so as to discourage misconduct at its source. Since the essentials of appropriate conduct in science should be taught by the mentor to his pupils, we begin our report by identifying the responsibilities of mentorship and then continue with a discussion of the appropriate handling of data. Authorship defines our output as scholars; thus this important subject, as well as the related area of peer review, is covered in considerable detail. A consideration of the rules of proper conduct in the general discussion of the academic environment, the responsibilities of the institution to its faculty members, and guidelines for academic advancement are presented.

RESPONSIBILITIES OF A MENTOR

1. *Initial Stages of Training*
   a. Make certain that the mentor's particular laboratory is appropriate for the trainee and his[1] goals.
   b. Make an effort to provide sufficient funding, instrumentation, and space for the conduct of the trainee's research.
   c. Have a plan for the overall training of the fellow/student as well as an outline for a research project.

[1] The pronoun "his" is understood throughout this document to stand for "his or her."

d. Make certain that the trainee is educated in all matters of laboratory safety, humane treatment of animals, and safe conduct of human research.
e. Inform the trainee of the publication policies of the laboratory.
f. Identify a responsibility/supervisory structure in the laboratory.

2. *Ongoing Responsibilities*

a. Maintain an environment for the free and open discussion of data.
b. Hold regularly scheduled meetings for the critical evaluation of the laboratory's output.
c. Meet individually with the trainee on a regular basis.
d. Make certain that all data are properly recorded and stored.
e. Accept responsibility for all of the trainee's work.
f. Limit the laboratory group to a size that can be managed educationally, intellectually, and financially by the mentor.
g. Treat the trainee with respect as a colleague.

3. *Preparing for Departure*

a. Assist in career counseling and job placement for the trainee.
b. Assist postdoctoral trainees in defining independent areas of research to pursue.
c. Assist the postdoctoral trainee in obtaining independent funding.

The essence of biomedical science, whether clinical or basic in nature, is learning and teaching, as exemplified best in the relationship between the trainee and the mentor. The process of learning the meaning of quality and integrity in science begins early in a trainee's scientific life and continues on a daily basis. As in any aspect of life, good habits last a lifetime and bad habits are perpetually difficult to overcome. Thus, the conduct, expectations, goals, and aspirations of a mentor are reflected, often forever, in his trainees. For this reason, no other aspect of biomedical science is quite as crucial for its healthy future as the trainee-mentor relationship. The responsibilities of a trainee to his mentor are simple; to learn, to carry on research, and to create. Those of a mentor are somewhat more mundane but require thoughtful planning. The needs of a trainee vary depending on the stage of his evolution; thus the responsibilities of a mentor can be divided into the early, middle, and late stages of the trainee's stay under his care.

When a trainee seeks to pursue his education in a particular laboratory, it is usually viewed as a blessing by the mentor. The trainee

represents a companion, a scientific colleagues with whom to exchange ideas, and a source of inspiration and new ideas, not to mention an additional pair of willing hands. It is not surprising that the temptation is to accept the trainee without too much deliberation. However, it is of critical importance that the mentor consider several important issues before taking this step. First, he must carefully evaluate whether the scientific capabilities, directions, and goals of the laboratory are appropriate for the trainee in light of his own aspirations. Secondly, the mentor must have sufficient resources, including salary funding, instrumentation, and space, with which to support the trainee and his work. Finally, the mentor must have a well-considered plan for the overall education of this trainee, including a general outline for a research project. Inability to fulfill any one of these three important responsibilities should steer the mentor away from acceptance of the trainee in question. After a trainee is accepted into the laboratory, it is important to identify a supervisory structure into which the trainee can fit so that he is able to obtain assistance when it is needed and so that the lines of responsibility are understood. To avoid any future disagreements, it is essential that the publications policies of the laboratory are openly discussed at the onset (see "Guidelines for Authorship" section below). Before the research efforts of the trainee commence, the mentor must take special care to educate him in all matters related to laboratory safety, humane treatment of animals, and safe conduct of human research.

The responsibilities of a mentor during the bulk of the trainee's time with him relate to the general maintenance of high standards of laboratory research. It is understood that the mentor will treat the trainee with respect as a colleague, rather than as a simple technician. Furthermore, the mentor must assume responsibility for all of the trainee's work, keeping in mind that the trainee's contributions to any laboratory effort should be credited appropriately. It is of critical importance to maintain in the laboratory an environment that is conducive to the free and open discussion of data so that the trainee can benefit from the experience and wisdom of the others that work with him. Toward this end, regularly scheduled meetings should be held so that the laboratory's output, and more specifically the trainee's efforts, can be evaluated critically. The mentor's contacts with the trainee should not be limited to these laboratory meetings. Less formal interactions between the mentor and his trainee to discuss research are of great importance, although the frequency of these meetings may vary with the seniority and experience of the trainee. Through direct contact, the mentor should strive to maintain quality control over the trainee's efforts, with a special emphasis on the proper recording and storage of

all data obtained. In order to ensure this level of supervision over his trainees, the mentor should make every effort to limit the size of his laboratory group to one that he can manage comfortably in meeting its educational, intellectual, and financial needs.

The role of the mentor changes as the trainee prepares to depart from the laboratory. The mentor is often judged by the later performance of his former trainees; thus he may find that his responsibilities to them last a lifetime. It is of equal importance, then, to both mentor and trainee that the former provide career counseling and assist with appropriate job placement for the latter. A potential problem with departing postdoctoral trainees can be avoided if the mentor and trainee together define independent areas of research that the trainee can pursue. In this regard, it should be noted that the intellectual "property" of a laboratory group normally stays with the laboratory unless the mentor willingly parts with some aspect of it by ceding it openly to a trainee. A final and most important level of instruction that should be offered by the mentor to his trainee is assistance in obtaining independent funding. Success in this endeavor will provide the ultimate evidence as to the effectiveness of the training offered in the mentor's laboratory.

DATA COLLECTION AND MANAGEMENT

1. *Collection of Data*
   a. Make certain that all laboratory staff are appropriately trained for the experimental procedures being utilized.
   b. Clearly outline the responsibilities of each participant in the collection of data.
   c. Make certain that all staff are aware of any calibration or routine maintenance procedures associated with experimental instrumentation.
   d. Detailed documentation of all experimental protocols should be maintained.
   e. All data should be recorded in a consistent format established by the investigators.
   f. Where appropriate, laboratory notebooks should be kept in sequence by date.

2. *Data Analysis*
   a. The statistical analyses utilized should be clearly documented for all experiments.
   b. Inclusion or exclusion of data in the analysis should be noted.
   c. When necessary, strong consideration should be given to seeking statistical consultation.
3. *Data Storage*
   a. Stored documentation should allow investigators to easily reconstruct experiments.
   b. Investigators should determine the quantity and time of raw data storage. (The NIH has suggested at least five years.)

Two major processes govern biomedical research: discovery and dissemination. In order to adequately sustain these tasks, the method and manner in which data are collected and analyzed must be considered carefully. The issues related to data collection and analysis are divided into three major categories: collection of data, data analysis, and data storage. It is important to recognize that the specific methodology and format of data collection and analysis are a function of the scientific discipline as well as of the types of experiments being performed. Common to all experimentation, however, is the need for well-organized and well-documented procedures, results, and analyses. It should be recognized that all scientific efforts, in the final analysis, are judged by the interpretation and results expressed in published or presented documents. Careful attention to both the organization and the details of data collection, analysis, and storage will assist in the maintenance of the highest quality and quantity of research to be disseminated.

It is of critical importance to establish the responsibility of technicians, collaborators, graduate students, and fellows involved in the collection of research data. Inherent in those responsibilities is the necessity for adequate training in all techniques and procedures for which they are well- trained within the expectation of the principal investigator. Since the quality of data may correlate with the expertise of the involved technicians, consistency in task assignment is recommended. The principal investigator must assume the ultimate responsibility for establishing the level of expertise required of all individuals involved in the performance of scientific study.

Frequently, research necessitates the use of sophisticated systems or instruments in the collection of routine data. It is important that all laboratory personnel involved in the utilization of these systems be

aware of any calibration or routine maintenance or procedures associated with proper use of the instrumentation. Some instrumentation requires frequent calibration or validation procedures to be performed. Documentation of these procedures as part of the experimental protocol in the laboratory notebooks is suggested.

Experiments usually begin with an experimental design. A protocol of the experimental design should be available for all personnel involved and become part of the scientific notebook. Many issues may arise, however, during the conduct of an experiment requiring revision of the protocol or an evolution of the experimental design. The rationale for any protocol revision and how and when it occurs should be documented clearly.

All aspects of scientific study should be recorded carefully and consistently in laboratory notebooks. The format of this documentation is dependent on the character of the research being performed. Maintenance of a journal is recommended for appropriate documentation of procedures and results on a daily basis. Although bound notebooks with numbered pages may be most appropriate for many types of laboratory experiments, others necessitate dependence on output from specialized instruments and computer systems which cannot be stored conveniently in bound format. It is recommended that all investigators carefully consider the appropriate format for their data and develop a consistent documentation system which will enable well-organized, long-term recording of their scientific pursuits. The organization of the notebook should be such that it would permit the investigators to reconstruct the experiments or procedures that have been performed.

Once the experimental data have been collected, the interpretation and statistical analysis of these data are important aspects of the scientific study. Since any data set can be interpreted and statistically analyzed in a variety of ways, it is very important that the specific procedures, analysis methods, and criteria for significance be well documented and described. In particular, the criteria and/or rationale for inclusion or exclusion of data from the analyses should be noted. When necessary, strong consideration should be given to seeking statistical consultation for final analysis and interpretation.

It is important that all research data be stored after the conclusion of the study. According to the most recent guidelines put forth by the National Institutes of Health, it is suggested that raw data be stored for at least five years. The medium on which the data are stored is much less important than maintaining effective documentation. All investigators should determine the quantity of data required for storage to enable the reconstruction of the experiments.

RIGHTS AND RESPONSIBILITIES OF PEER REVIEW

1. *Rights*
   a. Anonymity should be guaranteed to the reviewer.
2. *Responsibilities*
   a. Accept material for review only if qualified to do so.
   b. Preserve the integrity of the review process.
   c. Maintain confidentiality at all times.
   d. Insure impartiality by identifying any potential conflicts of interest.
   e. Document the basis for negative evaluations.
   f. Strive to be reasonable and fair, particularly in requesting additional data.
   g. Submit reviews in timely fashion.

The process of peer review is of vital importance in maintaining the quality and integrity of the biomedical sciences. Indeed, it is on the basis of this time-honored process that the field has been self-policed. By living up to the responsibilities of peer review, it is possible to advance any field of scientific study while at the same time preventing faulty or fraudulent research from achieving the impetus of recognition. Indeed, it is only through effective peer review that scientists and scholars can guarantee the highest standards of their profession.

The peer review system, both in the process of deciding on awards of research grants and in the review of scientific manuscripts, relies on the unpaid and voluntary efforts, often very time-consuming, of fellow scientists. In order for this system to work optimally, the reviewer should be a recognized authority on the subject under review. If the reviewer feels that he is not sufficiently knowledgeable to review the subject in an expert fashion, he should not accept the manuscript or grant application for review. In many instances he will know the applicant; it is, therefore, an obvious right and an obligation that he remain anonymous before and after publication.

Above all, the reviewer has the responsibility for preserving the integrity of the review process. In receiving a manuscript or a grant proposal, he is entrusted with privileged information that is unavailable to anyone outside the laboratory of the submitting scientist(s). It is of obvious importance for the reviewer not to make use of information gained in the review for his own purposes until it is published or, prior to that, only by consent of the author. A closely related responsibility

of the reviewer is to maintain the confidentiality of the review process. The contents of a work under review should not be distributed to other colleagues. There are certain exceptions to this general rule, however. For example, it should be permissible to discuss parts or even all of a submitted work with trusted colleagues to obtain a second opinion in instances when the reviewer is unfamiliar with the methodology or considers the author to be mistaken. Under these circumstances, it is appropriate for the reviewer to identify to the overseer of the review (e.g., editor or study section) the various colleagues who assisted with the review.

It is the responsibility of the reviewer to give a fair and impartial consideration of the material under review. If he feels that he has a conflict of interest, he should identify it immediately and return the grant application or manuscript. Conflicts of interest under these circumstances might include situations in which the reviewer is a direct competitor or a mentor of the party submitting work for review or, alternatively, if the reviewer may derive a direct personal benefit from the review. If, on the other hand, the reviewer is convinced that he can provide an unbiased opinion of the submitted material and the overseer of the review (e.g., editor or study section) concurs, then it would be appropriate for the opinion to be provided with full disclosure of the potential conflict of interest.

In providing a review, whether positive or negative, it is important for the reviewer to document the reasons for the opinions. It is inappropriate for a reviewer to provide a negative opinion of a submitted work without demonstrating the logic for the conclusion so that the submitting party can respond with appropriate revisions or a reasonable rebuttal. In most instances, the reviewer should be able to provide direct evidence, either by citation from the published literature or from his own research efforts, to support his conclusions. It is the duty of the reviewer to be reasonable in the evaluation and judgment of a submitted work. If he thinks that the manuscript or grant proposal would be improved substantially by more experimental evidence, it is obviously fair to suggest such experiments. However, if such extra evidence would only add marginally to an already strong case, or would be beyond the scope of the project or the facilities available to the investigator, it would be unreasonable for the reviewer to request or demand such extra evidence. Finally, the reviewer has the responsibility of carrying out his review in timely fashion. If he knows that he will not be able to meet the deadline set by the director or grant agency, he should return the manuscript or proposal.

GUIDELINES FOR AUTHORSHIP

1. *Individuals should be considered for inclusion as authors on work submitted for publication if they have provided:*
   a. Significant contributions affecting the direction, scope, or depth of research;
   b. Long-term guidance and development of the project;
   c. Creative contributions to the project with clear understanding of its goals;
   d. Development of methodologies necessary for timely completion of the project;
   e. Data analysis or interpretation vital to conclusions of the project.
2. *Individuals should not be included as authors for contributions strictly limited to:*
   a. Providing lab space or use of instrumentation;
   b. Providing funding:
   c. Services, consulting, or materials provided for a fee, or reimbursement;
   d. Involvement in patient care or providing patient sample;
   e. Routine technical work (as provided by any individual in the lab);
   f. Status as supervisor, section head, or department chairperson;
   g. Proofreading or editing of manuscripts;
   h. Advice given to solve problems that are narrowly defined or unrelated to the project objective.
3. *Responsibilities*
   a. Primary author:
      i. Inform all authors and contributors as to how their contributions will be acknowledged.
      ii. Be able to identify the specific contribution of each author.
      iii. Understand the general principles of all work included in the paper.
      iv. Be willing to share openly the data obtained and methodology utilized in the investigation.

b. All authors:
   i. Be able to defend the methodology and data pertinent to their specific contributions to the project.
   ii. Agree with the general conclusions and interpretations of the paper.

4. *Content*
   a. All manuscripts should serve to represent an accurate and complete reflection of the methods utilized and the data obtained in the investigative effort.
   b. In a publication, all data pertinent to the project should be reported, whether supportive or unsupportive of the thesis or conclusions.
   c. Except for review articles, publishing the same material in more than one paper should be avoided.
   d. Unnecessary fragmentation of a complete body of work into separate publications should be avoided.
   e. When ideas, concepts, or the text of others are used, appropriate citations should be made.
   f. Prior work in the field should be referenced appropriately.
   g. The source of funding should be identified when a work is published.

Authorship is the ultimate recognition of the contribution of an investigator to a completed body of scientific work. Authorship is objective evidence of an academician's scholarly activity. There is prestige attached not only to authorship per se but also to the order in which authors appear on a publication. For these reasons, decisions regarding the inclusion and exclusion of authors are of utmost importance and must be made with great care and consideration. It is of importance that the contributions of those who have contributed significantly to a project be appropriately acknowledged in some fashion, if not by authorship itself. In order to avoid conflicts or misunderstanding, the publication policy of each laboratory should be discussed openly, and, whenever possible, the principal author should apprise all contributors to a project of the manner in which their input will be recognized before commencing with their efforts.

Individuals should be included as authors on a work submitted for publication if they have provided significant contributions affecting its direction, scope, or depth. These contributions may take many different forms. Generally, the principal author will have designed many of the

experiments, performed much of the work, analyzed most of the data, and written the manuscript. In some cases, a senior author or mentor may have provided much of the work involved in the development of a project and, after it was initiated, provided long-term guidance to its completion. Other advisors may have provided the creative spark or the idea that was carried forward in the work. Some mentors may have developed and performed methodologies without which the project may not have reached a timely completion. It is imperative, as noted below, that this methodological input extend beyond the performance of routine assays by a technician, sometimes for a prearranged fee. The contribution of other authors to a manuscript may be in the analysis or interpretation of the data. The conclusions of some projects might not have been reached without this vital input.

While it may be difficult in some instances to decide whether specific contributions warrant authorship, there are clear circumstances under which individuals should not be included as authors. The simple provision of resources such as laboratory space, instrumentation, or even research funding without direct involvement in a project should not of itself be grounds for authorship. If a "collaborator" provides services, consulting, or materials for a fee or reimbursement under a contractual arrangement, he might not be considered as an author on a scientific project. This principle should also extend to the provision of routine technical work, as may be provided by any paid technician in a laboratory, without significant input into the design or conduct of a study. In clinical areas, contributions limited to involvement in the care of a patient or to the provision of specimens from a patient should not be grounds for inclusion as an author on a manuscript. Occasionally, supervisors, section heads, or departmental chairpersons insist upon inclusion as authors simply in recognition of their status, but this is inappropriate unless there are other grounds that warrant such recognition. Simple proofreading or editing of manuscripts should provide no basis for inclusion as an author. Occasionally, a principal investigator on a project may seek advice on narrowly defined problems or on problems unrelated to the project's objective. Provision of such advice should not provide grounds for authorship.

In addition to the benefits of prestige, authorship carries with it the burdens of certain responsibilities. The responsibilities of authorship should apply not only to written and published documents but also to verbal communications in public forums including the press. The principal author must be responsible for establishing the list and order of authors. He must be able to identify the specific contributions of each author and understand the significance of each contribution to the conclusion of the project. The principal author, representing all of the

authors, must be willing to share details of the methodologies and data used in the course of investigation. Currently, it is the policy of many journals that publication also implies a willingness to share reagents such as antisera and recombinant clones; thus it is important that the authors recognize the specific policies of a journal before submitting their work to it for publication. In any case, the unselfish exchange of information and reagents is a basic assumption of science, and every effort should be made to adhere to it provided that it does not compromise an individual scientist's research efforts. Each author should be able to defend the methods and data pertinent to his specific contribution. On a larger scale, each author has the responsibility to be able to agree with the general conclusions and interpretations of the paper. Any disagreements should be resolved prior to submission of the work for review. Ultimately, any individual author has the right and the responsibility to remove his name from a manuscript if he has substantial concerns with its conclusions.

Authors have additional responsibilities regarding the content of their manuscripts. Above all, the manuscripts must represent an accurate and complete reflection of the methods utilized and the data obtained. Sketchy outlines of methodology make it impossible for others to duplicate important experiments and may lead to unwarranted controversy over the results obtained. It is of importance to report data that are both supportive and unsupportive of the general conclusions of the paper. Withholding unsupportive data may suggest selection bias in reporting the results of an experiment. Despite the academic pressure, real or imagined, to demonstrate excellence with quantity rather than quality of publications, every effort should be made to avoid fragmentation of a complete body of work into separate publications. Moreover, the practice of publishing the same materials in more than one manuscript is inappropriate except in clearly identified review articles with citations of the original work. When ideas, concepts, or the text of others are used in a manuscript, appropriate citations should be made. Furthermore, prior work that served as the basis for a manuscript must be cited. In their citations, authors must strive to acknowledge data that conflict with their own theories as well as data that are generally supportive. It is important to acknowledge the sources of funding for a publication to ensure that the funding agencies are appropriately credited and, moreover, that any potential conflict of interest is identified. In general, abstracts may be somewhat less detailed because of their brevity; however, they must be considered as scientific publications and, as such, are subject to the same considerations regarding responsibility of authorship as full-length manuscripts.

INDUSTRIAL-ACADEMIC INTERFACE: ISSUES OF INTEGRITY AND MISCONDUCT

1. *Trainees should not be used to conduct contractual work that does not support their educational or scientific goals.*
2. *University legal counsel should be sought in issues arising over patents.*
3. *Contractual arrangements that would result in conflicts of interest should be avoided.*
4. *Individual entrepreneurial ventures should not interfere with a faculty member's responsibilities to the academic mission of the University.*

During the past two decades, universities have undergone a notable transition in their attitude toward and interactions with the industrial sector of our society. They have all but abandoned their traditional aloofness and are playing an important and active role in interfacing with industrial firms. Entrepreneurial interactions are developing as a means of seeking funds in our competitive environment and as an appropriate mechanism for keeping pace with advancing technology. These interactions vary from the formation of industrial consultantships to the long-term contracts for evaluation of drugs for human use. Industrial contracts involving the testing of materials and processes and the conduct of research are also common. All of these interactions and developments are accompanied by questions regarding appropriate rewards and obligations, and by mandates established by copyright and patent legislation. The fundamental premise of any guidelines in this area is that all scientific findings should have the greatest potential benefit to the public and therefore should be disseminated readily.

The use of students or fellows to conduct industrial research is appropriate only if the work has educational value. The free dissemination and/or discussion of the results of a student's or fellow's research on industrial contract work must be allowed. It is expected that all such work will have an educational value. Students should not be exploited by their mentors for the conduct of industrial research or contracts, and the work should fit within the interests or expertise of the laboratory. The sponsors of all such work must be disclosed.

Care should be taken to ensure that all those individuals directly involved in the development of a concept or device resulting in a patent should be so acknowledged. In this regard, the Intellectual Properties Office of the University of Michigan should be consulted in all matters involving patent application and processing. Each grant funding agency has its own guidelines for the filing and granting of patents. It is necessary to be aware of these guidelines and to adhere to them should a patentable device or process result from research funded by a specific

agency. Any questions regarding potential situations of conflict of interest (including patents, stockholding, etc.) should be referred to the appropriate legal office of the University.

The University has established policy regarding time spent in consulting and other enterprises external to the normal or expected performance of University personnel in discharging their primary responsibilities. Members of the Faculty should not engage in *excessive* outside efforts solely to enrich themselves financially. In discharging their service functions, many faculty members engage in industrial consultation. This is an activity that may be a stimulating and intellectually enriching experience to the faculty member, as well as a major benefit to industry. It is expected that University personnel will be ever mindful of their primary University responsibilities and adhere to the guidelines established by the University. University personnel establishing research contracts with industry also should be mindful of situations involving conflict of interest as defined in the next section. All consultantships or industrial affiliations must be disclosed to the University.

Individual entrepreneurial activities should not interfere with the University's academic mission. An excessive focus on personal financial gain within an academic setting could hamper the collegiality that is fundamental to investigative interchange. It is inappropriate to use University facilities and personnel to run any private enterprise. The educational mission and the overall goals of the University should be kept in mind when patent development is being encouraged at the University.

THE ACADEMIC ENVIRONMENT

1. *Commitment to Ethical Standards*
   a. Encourage open communication at all levels of scholarly activity.
   b. Maintain scientific quality by a process of peer review.
   c. Educate students, faculty, and technical staff in ethical standards.
   d. Avoid conflicts of interest.
   e. Discourage unwarranted competitive practices.
2. *Institutional Responsibilities (University, Department, Section)*
   a. Maintain consistent standards for evaluation of performance.
   b. Inform faculty of expectations and criteria for promotion.

c. Guarantee adequate time and resources for pursuit of scholarly activities according to specified expectations.

d. Focus attention on quality, as opposed to quantity, of scholarly activity.

3. *Evaluation for Promotion*[2]

a. Initiation

i. The candidate should state his goals and purposes upon appointment to the institution.

ii. Thr chairman should initiate the process of appointment or promotion.

iii. A departmental committee should review all matters of academic advancement.

b. The evaluation process should consider the candidate's research productivity, teaching excellence, administrative or other responsibilities, and evidence of peer recognition.

c. The departmental chairman should assume responsibility for the appointment/promotion proposal and insure its completeness and timely submission.

d. The review process should proceed according to University guidelines.

The University has the responsibility of establishing an environment that will nurture ethical behavior in any academic activity, whether it be teaching, research, patient care, or administration. Institutional policies and procedures must promote innovation and excellence while safeguarding against misconduct. Therefore, it is essential that universities assume the leadership role in identifying and eliminating the environmental factors that encourage unacceptable behavior. Over the long run, it will be the positive, rather than the punitive, measures that encourage creativity and progress and decrease the likelihood of scientific misconduct.

All members of the faculty should be expected to engage in investigative efforts and scholarly work. Scholarly investigation need not be the exclusive domain of those who have acquired research support. The importance of the scientific questions being asked, the

[2] Suggested criteria for promotion proposed by this committee are contained in Appendix E.

soundness of proposed hypotheses, the search for better understanding of human disease, or the caring for the sick should be among the most important measures of a faculty member's performance. Above all, the training of students and the dissemination of new knowledge are the most important functions of an institution of higher learning. Attention should be focused on results that have been subjected to intensive editorial review and placed in full view of a critical scientific community.

The responsibility for maintaining the highest ethical standards in science rests within individual institutions and with all persons engaged in research: professionals, trainees, and support personnel. Proper attitudes must be established so that all parties recognize the demands of the public trust that the system police itself. Constant reinforcement must be obtained through dialogue at all levels. Open discussions regarding all aspects of the work environment are essential. Science depends upon openness and the willingness of individual investigators to accept constructive criticism of work that has been conducted in earnest and with the serious intent of advancing scientific knowledge.

Students and staff personnel at all levels should be encouraged to engage in critical discussions of laboratory data during regularly scheduled group meetings. Data that do not support current hypotheses should be evaluated as intensely as those that show favorable results. Errors in experimental design or interpretation should be reviewed critically. A clear distinction must be made between error and fraud. The former, if truly accidental, can be tolerated, but once recognized must be corrected. The latter cannot be condoned under any circumstances.

Trainees and staff should be considered as part of the overall team that shares the common goals of learning and enjoying the successes of research. Professional evaluation and review of a trainee's work are fundamental aspects of the peer review process. Mentors and other members of the faculty should have an opportunity to hear presentations by trainees in the setting of laboratory discussions or in a more formal seminar format. Through open discussion and critical commentary, the research team will learn to correct previously unrecognized errors in design or concept.

On a more formal level, the institution should conduct educational sessions directed at teaching the highest ethical standards of scholarship. Attendance at such courses should be requested of all trainees and laboratory associates. Faculty members should be encouraged to participate actively in this educational effort.

A major principle in the ethical conduct of research is the avoidance of conflicts of interest. Specifically, this refers to situations in which a

faculty member stands to gain personally or professionally from a decision that he actively participates in making. The situation may involve the review of manuscripts or grants, discussions over the purchase of products from a corporation, or the hiring, appointment, or promotion of personnel. Additional aspects of this issue vis-à-vis academic-industry relationships have been explored above. It is imperative that a potential conflict of interest be identified voluntarily and immediately upon its recognition. Every effort should be made to redress any possible wrongs that may have occurred as a result of such a situation should it be identified after the fact.

The institution should not encourage and must avoid situations that lead to competition among scientists who hope to gain preferential status. Encouraging secrecy among research groups should be considered as an inappropriate method of stimulating productivity. The basis for rewarding performance should be made known to all participants. The institution should encourage its faculty to seek the advice and consultation of other members of the faculty and to discuss their research data with the aim of gaining a better understanding of the scientific problem. Likewise, trainees and staff should be encouraged and welcomed to work in other laboratories in order to gain the added expertise needed for the conduct of their respective research projects.

Evaluation of individual performance within the academic environment is a source of unavoidable pressure, particularly among young scholars. In order to minimize the negative aspects of this pressure, it is the responsibility of the University to maintain standards of evaluation that are widely and explicitly understood, rational, and applied in a consistent manner. The departmental chairmen must be responsible for maintaining consistency within their respective departments, while the dean and executive committee must ensure rational and consistent handling of evaluations at the levels of the Medical School and the University as a whole.

All members of the faculty should be informed at the time of initial appointment, and regularly thereafter, of the expectations and the criteria by which their academic activities will be judged. Thus, it is the duty of chairmen and/or section heads to formulate for members of the faculty clear job descriptions, which explicitly focus on the proportional mix of various activities including teaching, administration, service, and research. These expectations, while reflecting institutional standards of excellence, must *in toto* be attainable. Once agreement is reached on the academic responsibilities of each faculty member, it is the duty of the chairman and/or section head to assist in providing the necessary resources and to guarantee and safeguard time assigned for scholarly activities.

It is the responsibility of the chairman and/or section head to ensure that each individual is evaluated for his performance in the entire spectrum of his or her activities. To the extent that teaching, administration, and service are expected or assigned parts of a faculty member's scholarly activities, it should be the responsibility of that person's superiors to evaluate each of these activities in addition to research productivity.

As individuals are evaluated, those responsible for the process must focus on qualitative as well as quantitative criteria. Emphasis in the evaluation process must be on excellence of teaching and its significance to the educational enterprise of the Department and School, on the quality of patient care rather than on the volume of revenue, and on the quality and impact of scholarly research rather than on the number of publications or grant dollars generated.

Since the responsibility for initiating promotion recommendations resides within individual departments, chairmen, ordinarily in concert with a departmental Committee on Appointments, Promotions and Titles, must regularly monitor the academic progress of all faculty members at regular intervals to discuss advancement toward promotion and to assemble the necessary documents in a timely fashion when an individual is deemed deserving of promotion. The criteria of promotion should be rigorous enough to ensure that the faculty of the University of Michigan is of premiere quality, but flexible and comprehensive enough to be applied fairly to the broad spectrum of individuals who are working in this institution.

Individuals proposed for appointment to the faculty or for academic promotion should be requested to provide a personal statement to the promotions committee. The statement should reflect the individual's assessment of past achievements in investigation, teaching, administration, and institutional service. The assessment should also attempt to define the individual's role within the institution and commitment to the welfare of the institution. Future goals, research interests, and teaching efforts should also be recorded. This personal statement should accompany the promotion packet prepared by the departmental chairman.

The review of individuals for appointment or promotion will follow existing University guidelines. Suggested criteria by which individuals should be judged are presented in Appendix E.

APPENDIX E—CRITERIA FOR PROMOTION

1. *A candidate for promotion or appointment to the rank of assistant professor should have:*

   a. Completed formal training,
   b. Demonstrated a willingness and potential to contribute to the academic environment,
   c. Shown an ability to work independently, and
   d. Submitted to the review committee one first-authored manuscript or evidence of a principal role in a manuscript.

Candidates for the rank of assistant professor should have completed their formal training and demonstrated their potential to become independent investigators. They should be able to contribute to the academic environment of the institution, most importantly by carrying out the teaching and service missions of the departments they are joining. One manuscript for which the candidate is the primary author (or for which the candidate had a principal role) should be deemed sufficient for the institution to evaluate the candidate's potential for independent academic activity.

2. *A candidate for promotion or appointment to the rank of associate professor should have:*

   a. Demonstrated independence,
   b. Demonstrated a clear contribution to the academic environment,
   c. Demonstrated peer recognition, and
   d. Submitted to the review committee five first- or principal-authored manuscripts.

Candidates for the rank of associate professor will have achieved independence in investigative and scholarly activities. They will have demonstrated contributions to the academic environment, including the teaching and service activities of the department to which they belong. Candidates for associate professor will have peer recognition for their scholarship. Such recognition might include independent grant funding, membership in scholarly societies, or editorial work for scholarly journals. Instead of evaluating the quantity of manuscripts the focus should be placed on their quality, originality, and importance. Five manuscripts should be deemed sufficient for the institution to evaluate the candidate's scholarly activities.

3. *A candidate for promotion or appointment to the rank of professor should have:*
   a. Demonstrated a leadership role in contributing to the academic environment,
   b. Achieved a national and international reputation for excellence, and
   c. Submitted to the review committee ten representative principal-authored publications.

Candidates for the post of professor will have demonstrated a leadership role in contributing to the academic environment at the University of Michigan. They must have achieved national or international recognition for their scholarly activities. Candidates must have developed a focused program of scholarly investigation. Ten selected manuscripts should be deemed as sufficient for the institution to judge the maturity of the scholarly output of an individual prepared for advancement to professor.

11

Report of the Committee on Academic Responsibility

Massachusetts Institute of Technology

SUMMARY

The Committee on Academic Responsibility was charged to:

a. review the current situation with respect to the community values in connection with the conduct of academic research;
b. review our existing policies and procedures in connection with the conduct of research in view of the values held by the community;
c. compare our existing policies and procedures with guidelines and regulations of federal and private research sponsors;
d. suggest innovative education and mentoring programs directed towards raising the consciousness of our community concerning issues associated with the conduct of research and also propose mentoring programs related to faculty career development.

The committee found widespread recognition of our dual responsibility: that of educating the next generation of scientists and scholars for their professional responsibilities and of ensuring that the research and scholarship done on our campus meet the highest standards of integrity. All of us need to have a clear appreciation of the basic values of science and scholarship, and we must articulate these values clearly to our students.

We found that principles of ethical research conduct are not often explicitly discussed during the early phases of education of young scholars. Rather, individuals are left to develop their own personalized code of behavior, based in part on personal values and in part through specific examples set by their mentors. We believe that members of the faculty must develop an enhanced level of awareness of ethical

NOTE: Dated April 15, 1992; reprinted with permission from the Massachusetts Institute of Technology, Cambridge, Mass.

issues that confront scholars at all levels of experience, and provide for a more explicit and systematic discussion of these issues with their students. The responsibility to ensure systematic discussion of these issues rests with the departments, and we make recommendations for educational programs based in departments.

We define three behaviors in the conduct of research that merit Institute attention. The first is research misconduct. We define research misconduct as fabrication, falsification, and plagiarism in proposing, conducting, or reporting research or other scholarly activities. Other types of misconduct that can occur in a research setting but which are not unique to research activities are differentiated from research misconduct and defined as general misconduct. In addition, there is a range of questionable or improper research practices that we do not include in either research misconduct or general misconduct, but which can negatively affect the research enterprise, compromise the responsibilities of universities, and violate ethical standards.

We present a set of generic research practices and urge discussions in departments and laboratories to establish field-specific details and to determine at what thresholds deviations from these practices constitute improper or questionable research practices. We believe that discussing such research practices in research groups will contribute to our educational programs and that most disputes arising within groups about deviations from good practice should be resolved by informal discussions or mediation. We see an important role for informal mediation by faculty in departments and schools and have made recommendations to facilitate this. However, allegations of research misconduct cannot be informally resolved nor are they proper for a process of mediation.

We have made recommendations on institutional response to allegations of research misconduct, placing the responsibility for initial inquiry with the department head but providing central resources to ensure proper procedures and institutional memory. We have discussed and made provisions to protect the rights of the accused to a fair, confidential, and objective process and to ensure that those who bring allegations of research misconduct responsibly and in good faith are protected from retaliation and damage to their careers.

Finally, we believe that a period of stability in federal regulations is appropriate to enable universities to gain experience in the application of procedures to ensure the integrity of research done on their campuses.

CHARGE AND COMMITTEE PROCEDURES

The Committee on Academic Responsibility was established jointly by the president and the provost in May 1991 with the charge to:

a. review the current situation with respect to the community values in connection with the conduct of academic research;

b. review our existing policies and procedures in connection with the conduct of research in view of the values held by the community;

c. compare our existing policies and procedures with guidelines and regulations of federal and private research sponsors;

d. suggest innovative education and mentoring programs directed towards raising the consciousness of our community concerning issues associated with the conduct of research and also propose mentoring programs related to faculty career development.

In this report, we set out what we believe to be the consensus of the MIT community regarding the values that must be upheld in research conduct. We make specific recommendations for programs of education in research conduct. We discuss the regulatory environment in which scientific activity must now function. We propose a definition of research misconduct and make specific recommendations for procedures to deal with allegations of research misconduct.

This report is presented from a faculty community to our faculty colleagues and to the MIT administration. We present our recommendations and intend that these will be translated into policies and serve as a basis for the development of procedures. We intend that our report will serve as a basis for further discussion among members of the community and for the development of educational and mentoring programs. We believe that these actions will allow MIT to respond effectively to the rapidly changing environment. We have not discussed all details of procedures that fall within our charge nor addressed all of the federal regulations by which MIT is bound but only those which relate to important issues involving the responsibility of the Institute for research integrity, the role of the faculty in this process, and the rights of individuals caught in contentious situations. We expect that policies and procedures in this area will develop in an evolutionary manner as we gain experience.

We began our deliberations in May, 1991. We met with many members of the MIT administration, faculty, graduate students, and postdoctoral fellows and associates and reviewed a substantial body of literature dealing with the issues of responsibility in the conduct of

scientific research and scholarly inquiry. We read transcripts of congressional hearings and media coverage of developing cases. Our report benefited specifically from the ongoing study of scientific responsibility by the National Academy of Sciences. We reviewed procedures used by other universities to address allegations of research misconduct. We commissioned a study of education in research ethics that gathered educational materials of general usefulness, surveyed other universities to determine what courses and programs are in place or planned, generated a number of scenarios illustrating difficult issues that arise in the application of principles of good research practice, and produced a document containing material that may be useful to departments for their educational programs. **Copies of this document are available from the committee**.

Members of the community were most helpful to us, generously giving of their time and sharing openly with us their perceptions and experiences as they impinge on these issues. We benefited from descriptions of activities already under way in several departments and schools to deal with the issues raised herein, and from reports of relevant experiences elsewhere and lessons learned. In August [1991] we presented an interim report that was widely distributed throughout MIT. Many individuals came before us to discuss various aspects of these issues in the light of that report.

FINDINGS AND CONCLUSIONS

The committee found widespread recognition of our dual responsibility: that of educating the next generation of scientists and scholars for their professional responsibilities and of ensuring that the research and scholarship done on our campus meet the highest standards of integrity. We found that principles of ethical research conduct are not often explicitly discussed during the early phases of education of young scholars. It is critical that members of the faculty, both senior and junior, develop an enhanced level of awareness of ethical issues that confront scholars at all levels of experience, and provide for a more explicit and systematic discussion of these issues with their students. Programs dealing with the ethical conduct of research are most effectively carried out in departments and research groups.

We defined three behaviors in the conduct of research that merit Institute attention: research misconduct, general misconduct, and questionable or improper research practices. Each requires a unique institutional response.

Generic research practices provide a framework for discussions in research groups about research conduct; most disputes arising within groups about deviations from good practice should be resolved by informal discussions or mediation. Faculty have an important role to play in informal mediation of disputes and in acting as advisors to individuals with concerns about research conduct. However, allegations of research misconduct cannot be informally resolved nor are they proper for a process of mediation.

Effective institutional response to allegations of research misconduct in research carried out at MIT places the responsibility for initial inquiry with the department head but provides central resources to ensure proper procedures and institutional memory.

We must protect the rights of the accused to a fair, confidential, and objective process and ensure that those who bring allegations of research misconduct responsibly and in good faith are protected from retaliation and damage to their careers.

Finally, we believe that a period of stability in federal regulations is appropriate to enable universities to gain experience in the application of procedures for carrying through with their responsibility to ensure the integrity of research done on their campuses.

SUMMARY OF RECOMMENDATIONS

As a result of our deliberations and findings we make the following recommendations:

1. **That the MIT faculty and administration make explicit their commitment to academic integrity and to the establishment and maintenance not only of proper research conduct but also of an environment in which both research and teaching can be carried out effectively.**
2. **That each department form a working group to reflect on current practices, the values they promote, and changes in practices that would improve education and research, particularly with respect to the specific research conducted by members of that department.**
3. **That MIT establish a series of workshops on research conduct; that these workshops be organized at the level of departments, laboratories, or research groups and be of a size to ensure that individuals have an opportunity to speak; that these workshops be held periodically to provide new members with an opportunity to become familiar with the traditions and procedures**

of the group; and that attendance at these workshops be encouraged.

4. **That MIT move to establish procedures for mediation as a part of its procedures for dispute resolution and that consideration be given to application of the principles of mediation in the inquiry process when appropriate.**
5. **That each department designate individual faculty members to serve as advisors and informal mediators.**
6. **That MIT define research misconduct as fabrication, falsification, and plagiarism in proposing, conducting or reporting research or other scholarly activities.**
7. **That a single set of internal procedures including standards of proof, and rights of complainants and accused among others be used for the investigation of all allegations of research misconduct involving faculty and staff.**
8. **That the responsibility for inquiring into allegations of research misconduct be vested in heads of departments and interdepartmental laboratories or comparable administrative units; that this normally be done by setting up a fact-finding panel whose report provides the basis on which the head decides what further steps are appropriate, including a recommendation to the provost that a formal investigation is warranted.**
9. **That the department head submit all proposed plans and procedures for inquiries into allegations of research misconduct to the Office of the Provost for approval before the process is initiated; that the process to be followed in conducting inquiries and investigations be the responsibility of a specially designated individual(s) in the Office of the Provost; that the person(s) so designated be responsible for developing guidelines to be followed in carrying out inquiries and investigations.**
10. **That MIT ensure a supportive environment for individuals who come forward with concerns about research conduct, and that specific provisions to ensure the protection of complainants who act in good faith be a part of the plan for conducting an inquiry into allegations of research misconduct and be submitted to the Office of the Provost before the inquiry is initiated.**

In our report, we also make many suggestions and observations that we feel will improve the environment for research and education on our campus and improve the procedures for responding to allegations of research misconduct.

I. INTRODUCTION

In our role as a teaching institution as well as a research institute, we have a dual responsibility: that of educating the next generation of scientists and scholars for their professional responsibilities and of ensuring that the research and scholarship done on our campus meet the highest standards of integrity. In our discussion with members of the MIT community we have found widespread acceptance of these responsibilities. There is agreement that we must transmit the values of science and scholarship and the specifics of good engineering and research practice to the next generation—both to the undergraduate and graduate students in our classes and to the postdoctoral fellows and junior faculty. It is widely understood that formal instruction is only a part of the educational process and that the core experience in the education of almost every scientist and scholar is to be found in the informal teaching—one-on-one, more often than not—that goes on outside the classroom and officially scheduled academic exercises. Since the atmosphere in the different research groups and the relationships among their members is central to this process, constant attention must be paid to the consequences that actions of individuals and their informal behavior may have on this informal learning process.

We believe that the establishment of our committee represents an opportunity for the MIT community to engage in discussions about the shared values it holds in the conduct of research and in the education of students, and **we recommend that the MIT faculty and administration make explicit their commitment to academic integrity and to the establishment and maintenance not only of proper research conduct but also of an environment in which both research and teaching can be carried out effectively**.

We doubt that a direct cause-and-effect relationship between the environment for research and the occurrence of research misconduct can be established. Rather we assume that occasional allegations of research misconduct will occur in a large institution with an intense research focus such as MIT, and the Institute and its faculty must be prepared to deal effectively with these difficult issues. We make recommendations about education in research conduct because it is part of our educational responsibility to our students and will improve the climate for research and scholarship on our campus.

Although in our deliberations we concentrated primarily on research in science, broadly defined as the physical, biological, and social sciences and engineering, we have also had discussions with members of the Schools of Humanities and Social Science, and of Architecture and Planning, and conclude that the issues of professional conduct

encountered by these colleagues are not fundamentally different from those encountered by teachers and practitioners in science and engineering. In particular the values we discuss and the need for education in these values are not limited to individuals engaged in scientific research but are of crucial importance to the entire MIT community. We intend our discussions of research integrity to apply more broadly to scholarship and scholars throughout the Institute, including creative activities such as design in our definition of research. In some cases we must speak more specifically to science in responding to regulations governing the use of federal funds or in discussing research practices.

II. THE CHANGING ENVIRONMENT FOR UNIVERSITY RESEARCH

The last half century has seen the creation of a uniquely American institution, the research university, of which in many respects MIT is the prototypical example. Like universities of past generations, the modern research university pursues twin objectives: transmitting to the next generation the knowledge and understanding that mankind has gained in the course of its history, and extending the frontiers of what is known and understood. The relative importance of the latter objective has dramatically increased. In the modern research university, and in MIT in particular, innovative research is the engine that drives the entire enterprise.

The spectacular successes that American science has achieved in the last half century were obtained largely through research conducted in universities. This work was performed predominantly with funds supplied by agencies of the U.S. government. Although the U.S. government had previously provided funds to universities—e.g., under the Morrill Act of 1862 and subsequent legislation—the level of government support for university research increased sharply after 1940 under a unique partnership between universities and government.

The changes that have taken place in the political and economic situation of the world in the last decade—such as the collapse of the Soviet system, the emergence of Japan as the world's most dynamic economic power, the budget and banking crises, and the worsened economic conditions in the United States—have fundamentally altered the rationale that has justified the relationship between the U.S. government and the major research universities. The universities—and science in general—are perceived by many as not as central to the national interest as they were during World War II or after the launch of Sputnik, when science was seen by both the government and the

public as essential to our national survival. Today, science is perceived by some as yet another interest group whose claims to public funds must be severely scrutinized. Headlines we have seen in the papers during the last few years exemplify this changed attitude. However, since science is essential to the solution of many of the problems faced by the world, it is vital that the public's esteem for and trust in science be maintained.

In addition to changes in the relationship between the research university and its chief sponsor, the U.S. government, the last decade has also seen major changes in social relations—in particular, relations between individuals differing in race, sex, and position in the hierarchy. Science places considerable value on the autonomy and the contributions of the individual, and therefore it is expected that individuals would continually challenge the system to ensure recognition for their contributions and to ensure the development of their future careers. Hierarchical, paternalistic structures in university research laboratories are less likely to escape challenge by today's graduate students and postdoctoral associates. Federal laws and regulations governing the treatment of personnel and the environment for career advancement affect the freedom of action of laboratory directors and individual investigators, as do MIT's own policies with respect to our responsibilities to students, faculty colleagues, and Institute staff. All of us need to understand better the changes in the environment for the conduct of research, and we need to respond effectively to these changes.

The changes that have taken place during the last decade require that we modify and correct procedures and attitudes that do not respond to the new reality. All of us need to have a clear appreciation of the basic values of science and scholarship, of our responsibilities for transmitting them to the next generation, and of the many ways in which these can be compromised. We must not only articulate these values clearly but also internalize them as an essential part of our lives.

III. VALUES IN RESEARCH

Research is the attempt to reveal principles or laws that govern observed phenomena. The highest standards of conduct and practice are necessary to assure the integrity of the results. Values essential in research conform to those that ideally govern behavior and activities in the general society. Among these are honesty, performing one's craft with skill and thoroughness, respect and fairness in dealing with others, and responsibility to people and institutions.

Honesty is the foundation of scholarship. Deception in the proposing, conducting, and reporting of scientific and scholarly research subverts this enterprise. Skill and thoroughness, and other aspects of craftsmanship, are essential elements in conducting research and advancing a field. Good research requires good research practice; departure from this principle is often the cause of nonproductive scientific dispute. While it is clearly desirable to be first in reporting research results, this should not be done at the cost of "cutting corners." Scientists must take appropriate care to ensure the integrity and accuracy of their work.

An important aspect of research practice is the proper reporting of the results of one's work. Data, procedures, and controls must be fully disclosed in publications to allow the experiment to be replicated and the results and conclusions to be evaluated. Criteria used to select the data presented should be explained and defended. Such disclosures are essential to ensure the proper functioning of the system by which the priority, credit, and support for research are decided.

Errata should be promptly submitted to correct errors discovered after the publication of results. While research is inherently a risky enterprise, every effort must be made to minimize error. One way to decrease the probability of error is to make the research data available to all collaborators for their review. As a minimal requirement, each coauthor should be prepared to take responsibility in his or her area of expertise for the evaluation of data and procedures as well as for the conclusions of the paper. Ideally, all authors should be able to take responsibility for and to defend the conclusions of the paper as a whole. Research data should be retained for a reasonable time after publication to allow for examination by others.

Respect for and fairness to others requires that researchers be scrupulous in assigning proper credit for intellectual accomplishments. Significant research contributions by individuals in a group project must receive acknowledgment through authorship on publications, or other suitable means. While there are varied practices with regard to authorship, fairness requires that each author should have made a significant contribution to the work. Specialized contributions that do not merit authorship should be acknowledged. In addition, the published results of others used in research publications should be properly referenced.

Education is the primary function of a university, and it must play a significant role in university research activities. The education and development of postdoctoral fellows and associates and graduate students in research are as important as obtaining research results. Faculty have the responsibility to communicate to the next generation of scientists the

values that govern research practices as well as knowledge and research expertise in their fields.

Although errors in science can be reduced by adherence to good research practice, their total elimination is probably not possible. Errors generally create scientific disputes and are ultimately rectified by the self-correcting mechanisms inherent in the scientific enterprise. While most fraudulent research can be expected to be corrected by these same mechanisms, research misconduct is so damaging to science and scholarship that the public record must be corrected whenever it is identified. This requires an appropriate institutional response when research misconduct is alleged.

Research misconduct is a violation of the trust that society places in the scientist. In order to search for truth, the scientist is privileged to be granted resources in a compact with institutions, government, and society in general. Research misconduct is a betrayal of this compact. When trust erodes, so does support. In addition, research misconduct can have harmful practical consequences. It is wasteful of resources and time: not only the resources used by the offending scientist, but also those used by other scientists who attempt to verify or extend fraudulent results. When fraudulent results influence medical, technical, and political decisions, they can have harmful consequences to society in general.

Secrecy is antithetical to the tradition of university research that basic knowledge obtained in research and scholarly endeavors should be available to all. Since the education of young scholars comes in part from participation in the debate that typically occurs in a collegial research environment as new ideas and results are described, proprietary and classified research in universities is detrimental to the objectives of education. Faculty engaging in such research are not able to divulge resulting ideas and knowledge to students and colleagues in general, eliminating this part of their efforts from the educational mission of the university and thus reducing their effectiveness as teachers and as mentors. In addition, students and postdoctoral associates participating in this type of research are not able to get appropriate credit and recognition for their work in open publications and meetings, which can be highly damaging to their careers.

While we recognize that a certain degree of confidentiality might be understandable before results are published, we were concerned by reports that competition among groups and individuals has sometimes resulted in the imposition of excessive restrictions on the free exchange of information, even among faculty and students in the same department. Such informal "classification" of information in a research area cannot help but interfere materially with the effectiveness of teaching.

Conflicts of interest can be highly detrimental to the research environment. They can affect the researcher's objectivity and consequently distort research results. In the peer review process they can lead to unfair and wrong decisions based on personal interest or advantage. Conflict of interest must be avoided or fully disclosed. Such disclosure allows an institution, whether a journal, a professional society, a university, or a federal agency, to conclude whether the conflict of interest as disclosed is acceptable under its rules and regulations.

MIT has specific policies dealing with classified and proprietary research and specific policies for outside professional activities, including rules applicable to potential conflicts of interest in research conducted at MIT. In our discussions, we met with several individuals, including junior members of our faculty, who reported instances of poor mentorship or poor research environment that were driven by apparent conflicts of interest on the part of faculty members. Although we believe that MIT has established thoughtful and effective policies and procedures to monitor the outside professional activities of its faculty, we recommend that these policies be reviewed with special emphasis on how such activities impact on a faculty member's effectiveness as a teacher and as a mentor.

IV. RESEARCH MISCONDUCT

It is important to define clearly various categories of departures from accepted values in scientific research in order to enable the Institute to respond appropriately to allegations of such behavior. The most serious of these is **research misconduct**. Research misconduct is a deliberate act to falsify research results.

A different term, **scientific misconduct**, is used in regulations that govern research supported by certain federal agencies. The definitions of scientific misconduct used by two federal agencies as a basis for their regulations are as follows:

PHS Policies and Procedures

> Misconduct or misconduct in science is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

NSF Policies and Procedures (revised May 15, 1991)

> Misconduct means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or (2) retaliation of any kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.

Fabrication is presenting fictitious data or results; falsification is altering data or results, including selective omission of data without scientific or scholarly justification; and plagiarism is using the words or ideas of others without acknowledgment. The definitions of **scientific misconduct** above also include "other practices that seriously deviate from those that are commonly accepted within the scientific community." The federal government has looked to the scientific community to define such practices in reaching judgments about specific cases that occur on university campuses. The scientific community has strongly protested the vagueness of this language as being open to abuse.

Because of the severity of the sanctions for research misconduct, it is necessary to have a clear definition of what is to be sanctioned. In our review of scenarios of research misconduct and other examples of egregious acts that surely merit attention, action, and possible sanction from the Institute, we found that all incidents that we would characterize as **research misconduct** can be encompassed by the categories of fabrication, falsification, and plagiarism. By definition, therefore, research misconduct in research supported by NSF or NIH constitutes **scientific misconduct**. We have identified no "other practices which seriously deviate from those commonly accepted within the scientific community" that we believe should be characterized as research misconduct, and therefore **we recommend that MIT define research misconduct as fabrication, falsification, and plagiarism in proposing, conducting, or reporting research or other scholarly activities**.

Research misconduct does not include errors in judgment or mistakes in the recording, selection, analysis, or interpretation of data. A scientific disagreement about results that have been fully documented in a publication is not the basis for a charge of misconduct. Conversely, an allegation of misconduct cannot be countered by asserting that the science was correct if the data initially used to advance a scientific claim were fabricated. Between error and misconduct lies a range of attitudes and behaviors such as carelessness, negligence, reckless disregard, and deliberate disregard in the handling of research results that, while not falling within the scope of research misconduct, nonetheless are quite corrosive to the research environment.

There are other types of misconduct that can occur in a research setting, but which are not unique to research or scholarly activities and should thus be differentiated from research misconduct. We define these as **general misconduct** and include the misappropriation of funds or equipment, harassment, vandalism, unreported conflicts of interest, etc. These are offenses that violate legal statutes or Institute rules and can be addressed through established mechanisms. Many examples of misconduct that are unacceptable in the research environment would fall under this category; for example, deliberate interference with the research apparatus of others could be considered vandalism. Because existing complaint and disciplinary procedures can address these issues, we do not consider the issue of institutional responses to allegations of **general misconduct** to be a part of our charge nor do we include this category under research misconduct. However, because federal regulations quoted earlier define scientific misconduct to include behaviors we would consider general misconduct, such as retaliation against people who allege misconduct, a determination of which situations require the procedures and reports mandated by federal regulation must be made in each case. In these cases we would follow the procedures for handling allegations of research misconduct (outlined later) which are consistent with federal guidelines for handling allegations of scientific misconduct.

In addition to **research misconduct** and **general misconduct**, there is another broad range of practices that require institutional attention, viz., **questionable or improper research practices**. These are practices that we do not place under the classification of either research misconduct or general misconduct, but which negatively affect the research enterprise, compromise the mentoring and educational responsibilities of universities, and in general violate ethical standards.

V. RESEARCH PRACTICES

Below is a set of generic research practices based on guidelines that have been collected from a variety of sources—research institutions, universities, and professional societies—with field-specific references removed or reworded to make them generally applicable. These are generally viewed as a framework for the proper performance of research and mentoring. Because of differences between fields, there should be discussions in departments and laboratories to establish the field-specific

details and to determine at what thresholds deviations from these practices constitute improper or questionable research practices. While we do not consider such deviations to constitute research misconduct, they interfere with the responsible practice of research and should be strongly discouraged. We believe that discussing such research practices in research groups will contribute to our educational programs and that most disputes arising within groups about deviations from good practice should be resolved by informal discussions or mediation.

A. Data Management

1. *The results of research should be recorded and maintained in a form that allows access for analysis and review. Research data should always be immediately available to scientific collaborators or supervisors for such examination.*
2. *Research data, including primary experimental results, should be retained for a sufficient period to allow examination and further analysis by others. After publication, the primary research data generally should be made available promptly and completely to other responsible scientists who seek further information.*

B. Publication Practices

1. *Other than oral presentation in scientific meetings, publication in a professional journal should normally be the mechanism for the first public disclosure of new findings.*
2. *Timely publication of new and significant results is important for the progress of science. Similarly, it is the obligation of each scientist to provide prompt retractions or corrections of published work when necessary.*
3. *Multiple publication of the results of a scientific investigation or of the same or similar data is inappropriate. Each publication should make a unique and substantial contribution to its field.*
4. *Each publication should contain sufficient information to enable the informed reader to assess the validity of the publication's conclusions. Ideally, each scientific paper should contain all the information necessary for the scientific peers of the authors to repeat the experiment. Brief communications should be followed by publications containing this information.*

C. Authorship

1. *"Honorary authorship" is never acceptable. Authorship should be limited to those who have made a significant contribution to the conceptualization, design, execution, and/or interpretation of the research study. All those who have made such contributions should be offered the opportunity to be listed as authors.*
2. *Each coauthor should take responsibility for the full evaluation of data and procedures and for the conclusion of the paper in his or her area of expertise. Ideally, all authors should take responsibility for the conclusions of the paper as a whole. Other individuals who have contributed to the study should be acknowledged, but should not be identified as authors.*
3. *The submitting author should make every effort to ensure that each author has reviewed the manuscript and authorized its submission. The submitting author has the responsibility to coordinate the responses of the group of authors to inquiries and challenges and must assure that the manuscript as published has been approved by all authors.*

D. Peer Review

1. *Peer review can serve its intended function only if the members of the scientific community provide thorough, fair, and objective evaluations. Although peer review is a difficult and time-consuming activity, scientists have an obligation to participate in the peer review process and, in doing so, they make an important contribution to science.*
2. *Scientists should not make any unauthorized use of information or ideas that are obtained through peer review. Any information contained in the material subject to review should be held as confidential.*
3. *Peer review requires that the reviewer be expert in the subject under review. The reviewer, however, should avoid any real or perceived conflict of interest. Normally, such a conflict of interest would require a decision not to participate in the review process and to return any material unread. In any event, the reviewer should disclose any potential sources of bias.*

E. Training and Education

1. *Each student engaged in research should have a designated primary research mentor. It is the responsibility of this mentor to*

provide a training environment in which the student has the opportunity to acquire both the conceptual and technical skills of the filed.

2. *The supervised research experience should extend beyond the performance of tasks assigned by the supervisor; the student should be provided, over time, with an increasingly independent role in the choice and performance of research projects.*
3. *Mentors should not negatively impact the careers of students or postdoctoral associates to benefit the mentor's research program.*
4. *The research experience must impart to the student appropriate standards of scientific conduct. The mentor must convey these standards both by instruction and by example.*
5. *Research supervisors should discuss the authorship policies and other intellectual property issues currently used in their research group with potential new members of the group.*
6. *Mentors have a responsibility to provide students and postdoctoral associates with a realistic appraisal of their performance and with advice about career development and opportunities. Discussion should take place about continuation of the line of research after the student or postdoctoral associate leaves the laboratory.*

VI. EDUCATION IN RESEARCH CONDUCT

Ethical behavior in the conduct of scholarly research is of central importance in the educational programs of all academic institutions, but is of special significance in those with a major research emphasis, such as MIT. From our discussions with a variety of faculty, postdocs, and graduate students, we found that principles of ethical research conduct are not often explicitly discussed during the early phases of education of young scholars. Rather, individuals are left to develop their own personalized code of behavior, based in part on personal values and in part through specific examples set by their mentors. A number of postdoctoral associates indicated that this mechanism for developing principles of ethical conduct can lead to considerable confusion and uncertainty regarding their responsibilities and prerogatives within their research groups. Issues of authorship, publishing in general, and intellectual property were most often cited by the postdocs as issues needing a more forthright, explicit discussion by their mentors.

We met with a large group of postdocs following the issue of our interim report. They stated that our interim report had been useful in promoting discussion in their research groups about research conduct. In most cases these discussions were welcomed by the faculty, who participated along with their students. The graduate students with whom

we met were unanimous in their desire for more explicit discussion of these issues at the departmental level. Both graduate students and postdocs agreed that an initial discussion of these issues with potential research supervisors should have occurred, but all were uncertain about how to initiate such a discussion.

Complex issues of authorship and intellectual property arise quite naturally in the context of academic research. Students coming into a group, for example, are not always sure "who owns the data." Collaborative research often involves agreements about the time of publication, sometimes across several university groups. When is a student free to publish the results of the experiment? When is it appropriate to publish a specific set of experiments? Other issues arise when a student leaves the laboratory for a new research position at another institution. The student may be involved in the preparation of grant proposals both to continue the research in the new position and to provide for the continued work of the laboratory at MIT. Questions can arise as to "who owns the problem." What material and equipment will the student be allowed to take on to the new position?

In our meetings with graduate students and postdoctoral associates we were told of authorship policies that seemed to us to deviate from good practice. Several individuals reported to us that in certain groups the group's leader treats research conducted by the students as part of his or her own property. It would be difficult to exaggerate the damage that such conduct inflicts on the atmosphere of trust that is required for science and scholarship to flourish.

Where there exists confusion today about issues of research practice among students, there will exist uncertainty when they must lead their own research groups and provide guidance to the next generation. Problematic behavior in research conduct can result from lack of awareness of what constitutes appropriate behavior, from insufficient emphasis being placed on the importance of appropriate behavior, or from significant flaws in the character of particular individuals.

While we believe that this report represents a first step toward increasing the awareness of all members of the MIT community regarding the many issues of academic responsibility and research conduct that face us in the 1990s, we also believe that in order to sustain this awareness and further improve the community's understanding of these issues, the report should be followed by the establishment of specific educational programs. Because of the importance of mentorship in the establishment of values of ethical research conduct, we think it is critical that members of the faculty, both senior and junior, develop an enhanced level of awareness of ethical issues that confront scholars at all levels of experience, and

provide for a more explicit and systematic discussion of these issues with their students.

Toward this end, several activities are under way, and others should follow. First, an Institute-wide seminar series that deals with the changing relationship between research universities and the federal government was initiated by the Program in Science, Technology and Society and has been well attended by faculty from throughout MIT. Such a discussion helps faculty to focus upon their broader responsibilities set in a historical and national context. We suggest that a seminar series of this type be continued every year, perhaps sponsored by the Office of the President or Provost, in order to emphasize the strong support by the highest levels of the MIT administration for such faculty involvement. In addition we note the establishment of a School-wide committee by the Dean of Science. The charge of this committee has been to define further appropriate standards of academic behavior, to define and contrast differences in practices that may exist from field to field, to increase the awareness of the faculty regarding issues of academic responsibility, to facilitate the creation of novel educational programs for postdoctoral and graduate students, and to coordinate education programs initiated by departments within the School. Other schools may wish to establish such a committee.

Since the fundamental responsibility for educational programs in research conduct rests with the department, **we recommend that each department form a working group to reflect on current practices, the values they promote, and changes in practices that would improve education and research, particularly with respect to the specific research conducted by members of that department.** An important role of departmental working groups would be to develop specific educational programs as well as to discuss some of the less well defined roots of interpersonal conflict that lead to general problems within research laboratories. Results of the deliberations of these working groups could periodically be reported to the department as a whole to encourage further discussion among the faculty, students, and research staff. Based on these discussions, individual faculty members would be strongly encouraged to have similar discussions with members of their own research groups.

In addition to stimulating individual discussion between faculty members and their research groups, individual departments should institute (perhaps on an annual basis) explicit discussions of research practices, in which a variety of faculty members and research groups participate. The involvement of several faculty members in these discussions would provide students with a broader exposure to these issues than they would receive as members of a single research group.

Individual faculty members will also benefit and will be aided in dealing with the issues that arise with their own students. In addition, such discussions, if formalized and continued on an annual basis, would be one way to fulfill new federal requirements for training in the ethical conduct of research.

What would be the content of such discussions? Many interesting discussions would be in the gray areas, where no single principle guides action and yet the issues involved are important and contentious. One can begin to lay out what seems to be reasonable principles of research behavior, which, when applied to specific cases, will evoke very different reactions. The use of scenarios to engage a discussion group in the specifics of a case is a particularly valuable approach to the discussion of responsible research conduct. Although there will be a few areas in which all will readily agree, individual, filed, and group-specific differences in research practices will quickly emerge. These discussions can reveal that such issues are invariably complex, that reasonable individuals can differ in their point of view, that a common framework exists within which these issues can be debated, that such issues are proper to discuss and debate in a research environment, and that individual faculty are open to discussions with students about their concerns. Recently, during a retreat, the Whitehead Institute organized a discussion session that involved the use of such scenarios. This discussion was led by an experienced "facilitator" and included the entire faculty and research staff of the Institute. Feedback from the participants has been extremely positive.

We recommend that MIT establish a series of workshops on research conduct; that these workshops be organized at the level of departments, laboratories, or research groups and be of a size to ensure that individuals have an opportunity to speak; that these workshops be held periodically to provide new members with an opportunity to become familiar with the traditions and procedures of the group; and that attendance at these workshops be encouraged. We encourage senior members of the administration to participate in such workshops.

VII. GOVERNMENT REGULATIONS AND MIT POLICIES AND PROCEDURES

VII.1 Overview

Universities have been subject to an increasing set of regulations affecting the conduct of federally supported research. Since the university is the official recipient of the funds, the primary responsibility

We present examples of scenarios involving the conduct of research that have been useful to stimulate discussions among students and faculty in educational programs; scenarios courtesy of the Whitehead Institute.

Late One Night *Participants:* John Palant, graduate student
Sandra Dunn, postdoc
Barbara Steel, professor

(After a group meeting on Tuesday afternoon.)

Professor Steel: Sandra, you were unusually quiet at group meeting today. I thought you'd planned to discuss the results of your last fractionation. I wanted to go over the data with you this morning, but when I checked at your bench at eleven o'clock you hadn't come in. Is something wrong?

Sandra: No, nothing's wrong. I was reading the gels late last night and I overslept. I have a meeting now outside the building, but I'll knock on your door when I come in tomorrow.

Professor Steel: I'll be here, but try to catch me before lunch. I have appointments most of the afternoon.

(Three days later, in the hallway.)

Professor Steel: John, have you seen Sandra? She said she'd stop by on Wednesday to go over her data with me, but I haven't seen her since group meeting.

John: She hasn't been around much during the day, but I know she's been working at night. You know, it's strange. Monday she said she had an idea that might help me find the co-activator for my DNA binding protein. I asked her about it at the meeting, but she said she'd been wrong and I should forget about it. I've been so frustrated the last few weeks that I haven't been coming back in after dinner.

Professor Steel: I know it's been hard, but I'm sure you're on the right track. You found the DNA binding protein; you just need to find the co-activator to make the whole thing work. The changes we discussed at group meeting might do the trick. I've got a committee meeting now. Will you leave a note on Sandra's desk asking her to call me?

John: Sure, I'll let you know on Monday how things worked out.

(Monday morning in Professor Steel's office. A knock at the door.)

Professor Steel: Come in. Oh, Sandra, it's you. I've been trying to reach you for three days. Where've you been?

Sandra: Take a look at these *(she hands Professor Steel some papers)*.

Professor Steel: What are they?

Sandra: I've drafted two papers. One describes the work we planned to talk about last week. I realized when I read the gels last Monday that I'd accidentally found the answer to John's problem. Suddenly, it was clear that we had an entirely new class of DNA binding proteins and their partner-co-activators. I just needed on more experiment to confirm the results.

(Professor Steel quickly reads through the two papers.)

Professor Steel: This is terrific. I can't believe we didn't see this before. But Sandra, what about John? Why didn't you tell him you'd found the answer to his problem? I mean, this is his thesis project. You could have done the last experiment together. He should be included in the final paper too.

Sandra: I don't think so. I've thought about it a lot. I put his name on the first paper because I started with his technique for isolating the DNA binding activity; but the second paper on the co-activator and its implications for all regulation is mine. I want it to stand out in the journal with just two authors.

Professor Steel: I can't force you to put John's name on the paper but I think you should consider it again. I like to think we all work together in this lab. Have you shown these papers to him yet?

Sandra: No, I thought I'd present them at group meeting tomorrow. What do you think?

Consider:

A. If you were Professor Steel, would you insist that John Plant be included in the second paper?

B. Should Sandra have done the experiment or should she have told John about her idea?

Home Runs *Participants:*

Jim Farber, postdoc
Daniel Stern, assistant professor
Dick Winston, professor
Anna Wong, graduate student
Paolo Donato, graduate student

(Between the fifth and sixth innings at a faculty-student softball game, postdoc Jim Farber stops to talk for a minute with Daniel Stern. Stern is an assistant professor; he and Farber had the same advisor in graduate school.)

Jim: Hi Dan, I haven't seen you at beer hour lately. What have you been up to besides hitting home runs?

Dan: Things have been very busy in the lab, and I've received ten papers to review in the past five weeks.

Jim: I don't know how you manage it all; anything exiting in the papers?

Dan: Well, as a matter of fact, Peter Van Norman's group in Seden has discovered the *pbj* gene has a third exon. It's top secret. I wouldn't tell you, but I know you stopped working on the gene last year.

Jim: Actually, we're working on a related gene, *pbh*; we suspect that the product of *pbh* might form heterodimers with the *pbj* protein. Oh look, you're up at bat and I better move into the outfield.

(One day later, Jim Farber is reporting his conversation with Dan Stern to his lab director Dick Winston and others in his research group.)

Dick: Jim, are you sure that Dan said *pbj* has a third exon? That would explain why we had so much trouble cloning it. It might also explain the problems we've been having with *pbh*.

Jim: I'm sure that's what he said. In fact, last night I came back to the lab after the game and reanalyzed our data on pbh. It all fits. I don't know why we didn't see it. We just need two experiments to confirm the results, and then we can write a paper that describes *pbh* and explores the relationship between the *pbj* products.

Paolo: Wait a minute, Jim. You can't use the information you got from Dan. He had no business telling you in the first place. You remember how secretive Van Norman's group was at the meeting in Madrid last month. You really should call them and tell them we've heard about their results.

Jim: I disagree. I didn't go looking for this information. Their paper most likely will be published before ours anyway.

Paolo: I can't believe you really feel that way. This information probably saved us two months work on *pbh* and it will help us confirm our theories about the relationship between *pbj* and *pbh*. We'be got to call Van Norman's group.

Anne: I think you're being overly dramatic, Paolo. If we give them the full credit for their contributions in our article, that should be enough. After all, if we call Van Norman's group now we'll probably get Dan in trouble. I'm sur he didn't realize the intensity of the competition between Van Norman's group and ours, and Van Norman will get the credit for cloning pbj. What do you think, Dick?

Consider:

A. Is Jim at fault in the first conversation (for asking Dan Stern if he's noticed anything interesting in the papers)?

B. How would you answer if you were Dick Winston?

Interviews *Participants:* Melanie Chang, postdoc
Larry Johnston, professor
Tom Plough, postdoc
Richard Estaben, postdoc

(Melanie Chang is a new postdoc in Professor Johnston's laboratory. Larry and Melanie have decided that she will work on a project begun four years earlier by Tom Plough. Tom published one paper in a relatively obscure journal and then picked up and wntirely different project based on his thesis work. His subsequent research was very successful and he is now in the process of interviewing for a junior faculty position. The first scene takes place on Monday afternoon in Professor Johnston's office.)

Larry: Melanie, I think you have to try the experiment again. I don't understand why it's not working. Tom describes the procedure very clearly in his paper. Have you asked him for help?

Melanie: No, he's been away on interview for the past two weeks. When I discussed the project with him before he left, he just said I should be very careful doing the extraction process.

Larry: Well, talk to him as soon as he gets back. I'm sure he'll be able to help you. You can't really move forward until you repeat his experiment.

Melanie: Larry, I know I've asked you this before, but I'm still not clear on the answer. Do you know why Tom dropped this idk project after he published the paper? Why didn't he follow up on the results himself?

Larry: Well, you know how imaginative he is. He came to me and said he had a new idea on some problem he'd encountered in his thesis project. He asked if he could spend a little time working on it before he continued on the idk gene. I told him to go ahead, and then the results were so exciting that he never looked back. In January, when I told him I was thinking of having you continue the idk work, he said he thought it was a good idea. He did say, though, that several aspects of the project had been very difficult technically, and that you might have some problems at first.

Melanie: Well, he was certainly right about that. I'll catch him as soon as he gets back. Maybe he can spend an hour or two with me in the lab.

(Late in the afternoon on Wednesday. . . .)

Melanie: Hi, Tom. I've been trying to call you. Do you have a few minutes to talk? You know I've decided to look for the cofactors that might explain your results with the *idk* gene in chickens. The problem is, I can't repeat your experiment. I'd like to go over the procedure with you; maybe you can tell me what I'm doing wrong.

Tom: I'd be happy to talk about it Melanie, but right now I have an appointment with Peter Yales across the street. Why don't you call me at home tomorrow.

Melanie: OK, I'll call you. I really need to meet with you as soon as possible.

(10 a.m. on Thursday . . . Melanie dials the telephone in her lab.)

Melanie: Hi, Janet. May I speak with Tom, please? *(She pauses a minute.)* That's strange, he told me yesterday that I should call him this morning. Did this trip to Michigan come up suddenly? *(She pauses again.)* Well, I guess he must have forgotten. Will you ask him to call me as soon as he gets home?

(Five days later, Melanie is standing in the lab shaking her head when her friend Richard Estaben walks by.)

Melanie: Richard, do you have time for a cup of coffee? I need your advice.

Richard: Sure, just let me return these samples to the cold room.

(Ten minutes later at a table in the cafeteria.)

Melanie: Richard, what would you do if you suspected that someone had faked the data on a paper?

Richard: I guess it would depend on the situation. Why?

Melanie: Well, as you know, I've been trying to repeat Tom Plough's work on the *idk* gene so I can start looking for a cofactor. I just can't make it work. I've tried asking Tom for help, but he keeps avoiding me.

Richard: You know how busy he is with interviews. Maybe it's just your imagination.

Melanie: I thought so too at first, but when he got back from Michigan and I still didn't see him in the lab I began to wonder. I called him at home and he said he's had a bad cold. I tried to make a joke about his avoiding me and he got very defensive. He suggested that the *idk* project might be too difficult for me.

Richard: Strange. I've never heard Tom say a negative word to anyone.

Melanie: I know it's not like him—he was one of the first people I met when I came here and he was extremely helpful about showing me around the lab. The only explanation I can think of is that he's hiding something. I know I'm repeating his procedures exactly. The results just aren't there. I've begun to wonder if he fudged the data.

Richard: I can't believe that's true. Why don't I come by the lab tonight and we'll go through your notebooks.

(Sometime after midnight, Melanie and Richard are hunched over the lab bench in Melanie's lab.)

Richard: I don't know what to say, Melanie. Tom's procedure makes perfect sense when I read it, but your results are clearly different.

Melanie: Thanks for going through it with me. Now I have to decide what to do. I guess I'll try to talk to Tom once more. I still hope I'm wrong. I know that everything he has done since the *idk* project has been above reproach. It's been repeated in at least four labs by people who've used his ideas as a starting point for new projects. I heard today he has three job offers. If I go to Larry with this and I'm right, it could mean the end of his career.

Richard: Tom's been my friend for three years. I don't know what to advise you. I suppose you could tell Larry that you'd rather work on something else and just drop the whole thing. Maybe it is a technical problem and we're just missing something obvious.

Consider:

A. Would you advise Melanie to confront Tom or proceed directly to Professor Johnston?

B. Does Richard Estaben (friend of both Melanie and Tom) have any responsibility to act on the information he has?

for fulfilling these requirements falls upon it. Since the faculty are the principal investigators and the supervisors of the research, they must accept the ultimate responsibility for fulfilling the university's obligations. Federal regulations govern the conduct of research and the treatment of students, faculty, research staff, and research subjects in areas such as safety, protection of human subjects, animal care, equal opportunity, harassment, and in financial affairs such as overhead and auditing practices.

As a result of several highly visible cases of alleged scientific misconduct, additional federal regulations have been established governing institutional response to charges of scientific misconduct. The regulations governing investigations of allegations of scientific misconduct in research supported by NSF or NIH require notification of the research sponsor at an early stage in the process, at the point when formal investigation of an allegation of scientific misconduct begins. The name of the accused scientist must be reported to the agency and may be placed in a data bank available to agency personnel. Certain restrictions, such as not being able to serve on an agency review panel, may be placed on this individual while the investigation is in progress. The conduct of the university investigation, its timing, its findings, and its outcome, is overseen by the agency, which receives a copy of the investigatory report. In some cases, the agency has disagreed with the findings of the university and has conducted its own investigation.

Before the advent of these regulations, MIT had established internal procedures (contained in *Policies and Procedures 1990*) to investigate charges of research misconduct (referred to as **academic fraud**; we will not further use the word **fraud** since its legal definition involves matters that may not be present in all cases of misconduct). These procedures were recently revised to accommodate the new regulations regarding misconduct in research supported by NSF or NIH which required a two-stage process that responds to allegations of scientific misconduct.

This remains an active area for legislation and regulation. The few, highly publicized cases that have occurred test the university's abilities to oversee the research done on its campus and to warrant continued public trust. While we know of no evidence that the scientific knowledge base has been seriously affected by these cases, the universities and the scientific community have been damaged in the eyes of the public and the Congress, not so much because they occurred but because a number were not well handled.

At MIT, our collective understanding of these issues and our ability to respond have shifted dramatically over the past few years. Although some important things can be learned from the few past cases that have occurred at MIT, our goal must be a robust set of policies and community attitudes that will allow us to respond to new challenges, the details of which we cannot possibly anticipate, while retaining the strengths of our institution.

We recommend that a single set of internal procedures including standards of proof, and rights of complainants and accused among others be used for the investigation of all allegations of research misconduct involving faculty and staff. If not otherwise subject to federal regulations, allegations of research misconduct by undergraduate and graduate students are covered under MIT policy on "Academic Honesty … Departmental Guidelines for Students."

VII.2 Resolving Disputes and Allegations About Research Conduct

Disputes are normal, inevitable, and often welcome elements of academic research. Disagreements about experimental design, research procedures, and data selection, retention, presentation, and their interpretation can play a constructive, self-correcting role in the research process. Disputes in science can act to make science itself error correcting even though individual scientists are fallible.

We found that the limited number of allegations of research misconduct that have occurred at MIT arose as one element of a complex situation that also included disagreements about authorship or

publication of research results or charges of inadequate mentoring or harassment. Individuals who have concerns about research or other misconduct, problematic research practices, failure of mentorship, or other unprofessional behavior have access to advice through multiple channels. Depending on specific circumstances, consultation can be sought from a research supervisor, another faculty member, a department or laboratory head, a dean or other senior administrator, an Institute ombudsperson, or a faculty member within a department designated to act as an advisor or informal mediator for the department. Efforts are made to ensure confidentiality in the earliest stages of this consultation and throughout any consultation with an ombudsperson. If a more formal case is contemplated, the individual will be advised as to the degree of confidentiality that can be assured.

This multiplicity of channels is designed to maximize access to institutional resources for individuals who have concerns about research conduct. However, their full utilization by members of the MIT community is impeded by lack of awareness of their availability, and also by the hierarchical structure of the research community in which the faculty occupy a dominant position. The perception that when allegations of research misconduct are made, the faculty within a department or laboratory will react in a unified manner to protect its members is widely shared by junior members of the community, especially graduate students and postdoctoral associates. Means need to be found to change this perception, and to create an environment in which all members of the community can be assured that voicing concerns in a responsible manner can be done without risk of damage to reputation or career.

Experience to date indicates that in many cases, vague and complex concerns may be brought forward by an individual, who may be under stress. Under such circumstances, an important role for the individual from whom advice is sought is to assist in the articulation of specific elements of concern, and in particular to identify allegations of research misconduct and differentiate them from other types of disputes or accusations.

VII.3 Informal Resolution and Mediation

Since MIT is required to formally inquire into all allegations of scientific misconduct in research funded by NSF and NIH, allegations of research misconduct cannot be informally resolved nor are they proper for a process of mediation. However, many disputes, such as

those arising over proper research practices, can be resolved at the initial stage through informal means or through mediation.

Members of the faculty play an essential role in the resolution of disputes related to research conduct and education within the MIT community. However, an even more critical role for the faculty is to create an environment in which research values and practices are discussed by all members of the research community in a free and open manner. Such an open environment within individual research groups as well as departments and laboratories should be effective in minimizing the occurrence of disputes, and in facilitating early resolution of those that do arise.

Faculty members often participate in efforts to resolve disputes. Senior members of the faculty have an especially important role, lending the benefit of their experience in acting as mentors for junior faculty, creating an atmosphere of approachability for graduate students and postdoctoral associates, and in serving as role models for all junior colleagues. When called upon to participate in inquiries into allegations of misconduct, members of the faculty must balance the values of objectivity, fairness, and collegiality and at the same time remain sensitive to the vulnerability of the accused. Junior faculty may feel particularly isolated and fear that mere questions about their behavior create doubt concerning their scientific capabilities or their abilities as research supervisors and mentors.

Several departments have established a committee or designated individual faculty to act as confidants, informal mediators, and advisors for individuals who wish to bring concerns in an informal way. We believe that this will improve the academic and research environment before difficult situations develop and **therefore recommend that each department designate individual faculty to serve as advisors and informal mediators.** Consideration should also be given to making the list of such individuals available at a School-wide level. Such individuals should receive a common charge and specific guidance about their role in dealing with issues such as the degree of confidentiality that is due a complainant and all others attached to a case, their responsibilities to their department and to MIT, and the degree to which their actions will influence future events should a case of research misconduct develop. These individuals will need to be aware of Institute resources for referral of more serious cases that cannot be handled at the departmental level to individuals at the School or Institute level.

Many of the disputes that arise in an academic setting are appropriate for a process of mediation. Whether formal or informal, a

mediation process has several elements. It must be seen as fair and objective by all participants; it must be freely entered into by all parties; it begins with a phase of sharing facts and opinions; and at any point in the process one of the parties may exit, thus effectively ending attempts at mediation. In many of the disputes that arise, there will be three parties who have interests: two principals and MIT itself.

There are many paths to mediation. A process of mediation can be initiated by an Institute ombudsperson upon receiving a complaint. It can be initiated by a faculty member who has been designated to serve as an informal mediator upon receiving a request for resolution of a dispute. It can be suggested to parties in a dispute by a department head who would call on an individual within the community to act as an informal mediator, for example, the faculty member in the department or school who has agreed to play such a role.

Upon receiving an allegation, complaint, or request for resolution of a dispute in which all parties ask for mediation, the mediator has several options. The mediator might enter into a fact-finding process or in some cases set up a fact-finding panel. If a fact-finding panel is set up, all parties to the dispute should have an input into the selection of the panel. After the fact-finding process, the next step involves a mediator negotiating with the parties on the basis of the factual report. If mediation breaks down, the report is referred to an adjudicator, possibly the department head, who would render a decision.

In the area of research conduct, disputes are apt to have several issues combined. A dispute over authorship may lead to charges of poor mentorship, conflict of interest, or [poor] research practices, and many also lead to charges of research or other misconduct, such as fabrication or misappropriation of funds. In these latter cases, if the fact-finding panel determines that charges of misconduct have substance, this portion of the dispute must be reported to the department head as discussed below.

MIT is beginning to use mediation as a mechanism to resolve disputes. We believe that there is much to be gained by incorporating the possibility of mediation into the process of inquiry (see below) in certain types of cases. If the inquiry committee is appropriately charged, then depending on their findings, their report can serve either as a basis for a department head's decision with respect to possible research misconduct or as a basis for a mediated settlement.

We therefore recommend that MIT move to establish procedures for mediation as a part of its procedures for dispute resolution and that consideration be given to application of the principles of mediation in the inquiry process when appropriate.

VIII. PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

VIII.1 Inquiries

Federal regulations require an inquiry as the first element of institutional response to charges of scientific misconduct in research supported by NSF or NIH. We view the setting up and conducting of inquiries as one of the most difficult phases of institutional response to charges of research misconduct. In no case is an inquiry sufficient to produce definitive evidence of research misconduct. This finding can be made only after a more formal process of investigation. The inquiry does not establish a presumption that research or other misconduct has occurred. Although faculty may be reluctant to see an inquiry proceed to an investigation unless the inquiry produces convincing evidence that research misconduct **has occurred**, inquiries are designed only to determine whether allegations of research misconduct **have substance**: that is, they are not frivolous, unfounded, or unsubstantiated. A finding that the allegations **do not have substance** will effectively end the institutional response to a charge of research misconduct.

MIT uses inquiries to deal with a wide range of issues, and MIT policies are silent, and therefore flexible, on the question of who conducts an inquiry and the nature of the complaint that will bring an inquiry into being. Federal regulations are silent on the specific requirements of who initiates and who conducts inquiries and how inquiries should be conducted beyond requiring that they be thorough, fair, prompt, confidential, and objective.

NIH regulations define inquiry as "information gathering and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct **warrants an investigation.**" These regulations require an inquiry into all nontrivial allegations or other evidence of possible misconduct that relate to funding from NIH. A written report must be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The accused individual must be given a copy of the report and may append comments as part of the record. The inquiry must be documented in sufficient detail to permit later assessment of the basis for a finding that an investigation was not warranted; these documents are retained for three years.

NSF defines an inquiry as "preliminary information gathering and preliminary fact-finding to determine whether an allegation or apparent instance of scientific misconduct in the conduct of research funded by

NSF has substance." NSF requires an investigation if the allegations have substance.

Consistent with our recommendation that MIT use a single procedure to deal with allegations of research misconduct, in cases not covered by federal regulations, we think that MIT should proceed to an investigation using the same standard, namely that the allegations have substance.

Inquiries should begin only after a formal allegation has been made or other substantial evidence has been produced suggesting possible misconduct or other violations of MIT policies. Allegations involving faculty or students should be brought to the attention of the department head; allegations involving research staff to the laboratory director. In some cases, the allegations should go directly to the dean of the school. In our report we use the term "department head" to refer to the senior officer in this role, including laboratory directors and deans as appropriate in this use. Allegations should normally be presented in written form and be as specific and detailed as possible. Specific evidence should also accompany the allegations whenever possible. After reviewing a number of cases and examining the procedures used by a substantial number of universities, we make the following recommendations concerning the initiation of an inquiry:

That the responsibility for inquiring into allegations of research misconduct be vested in heads of departments and interdepartmental laboratories or comparable administrative units; that this normally be done by setting up a fact-finding panel whose report provides the basis on which the head decides what further steps are appropriate, including a recommendation to the provost that a formal investigation is warranted; and further that the department head submit all proposed plans and procedures for inquiries into allegations of research misconduct to the Office of the Provost for approval before the process is initiated; that the process to be followed in conducting inquiries and investigations be the responsibility of a specially designated individual(s) in the Office of the Provost; that the person(s) so designated be responsible for developing guidelines to be followed in carrying out inquiries and investigations.

Upon receiving an allegation of research misconduct, a department head may conduct an inquiry or may set up a committee to conduct the inquiry. Members of such a committee must be impartial and be perceived to be disinterested. In many publicly controversial cases of scientific misconduct, charges of conflict of interest among members of inquiry committees abound. Friends, coworkers, or antagonists are not appropriate members of such a committee. Department heads may despair at choosing an inquiry committee from inside a department

because of its effects on the department. In some departments it may be impossible to select a committee without perceived bias. For such reasons, nondepartmental committees bringing the necessary expertise may be the best choice. The accused and complainant should have an opportunity to challenge the composition of the inquiry committee.

The charge to the inquiry committee should be in writing and should be as specific as possible given the allegations or other evidence. We believe that, whenever possible, the charge to the committee should be limited to determining the facts and the substance of the allegations and should not charge the committee to recommend whether a further investigation should be carried out. That is, we are suggesting a separation in the role of fact-finder and adjudicator. If no evidence of research misconduct is found by the fact-finding committee, then their report can serve as a basis for mediation of the dispute should the parties involved decide to enter into such a process. If the committee find that the allegations of research misconduct have substance, the report of the fact-finding committee provides the basis upon which the department head makes a recommendation to the provost as to whether an investigation should be carried out.

There are several reasons for this separation in roles. First, it limits the scope and responsibility of the inquiry committee, charging them to focus on the key elements of their task: evaluation of evidence and finding of fact. It places the judgmental role with the department head, and the provost. It does not burden the committee with recommending a particular administrative outcome. It should reduce the potential for tension between committee members and other departmental members who may not agree with the final outcome based on the limited information available to them.

The committee should be briefed concerning the Institute guidelines for inquiries, including evaluation of evidence, burden and standards of proof, and the level of certainty of committee findings to be achieved. The committee is not asked for a finding of facts that misconduct occurred, since the Institute must proceed to an investigation whenever allegations are found to have substance, that is, "if there is reason to believe."

The committee would gather, hold, and examine all evidence, including original data as appropriate, and would allow the accused to present evidence in writing and to meet with the committee. The evidence that such a committee would be expected to gather and evaluate includes all forms of data that faculty members have competence to evaluate: research data in its various forms, direct testimony from witnesses, publications and drafts, financial records, correspondence, logs, and other laboratory records.

Inquiry into the possibility of research misconduct should not be conducted as an adversarial process between an accused and a complainant. The accused has the right to contest all of the assertions brought against him/her but not to challenge the particular individual who brought them. In some cases the committee might not elect to meet with the complainant. However, in some cases, because of eyewitness testimony, dispute about the interpretation of physical evidence, or other issues, the participation of the complainant would be required.

We expect that in most cases the committee would take testimony from both the complainant and the accused in separate closed sessions. The accused should receive a copy of the charge to the committee and the evidence against him/her and be allowed to present evidence on every key point.

We believe that given the preliminary nature of inquiries, and the many uses that MIT makes of inquiries, that attorneys should not be present at inquiries. Since the only definitive outcome of an inquiry is a finding that no misconduct has occurred, there is no finding of misconduct by the accused. We have also suggested procedures to insulate any subsequent investigation from the inquiry process to protect the rights of the accused.

The role of the complainant during the inquiry and later investigation, if any, deserves careful consideration. One possibility is to have a two-branch process. In one branch, the individual who brings evidence to the department head may wish to have no further involvement with the case. If substantial evidence of misconduct is presented in the allegation on which a determination can be made without the involvement of the individual bringing an allegation, then that individual's participation is not required. In many cases, because of career pressures and fear of retaliation, this would be the preferred course. For example, a graduate student could take evidence of plagiarism to a department head who would then act on behalf of the Institute. In this case the Institute acts as the complainant, and there is no requirement that the initial complainant be made known to the accused. This individual plays no further role in the process: would not be called as a witness, would not continually furnish information, and would not be informed about the progress of the case.

In the second branch the complainant becomes a principal in the case, putting forward the initial allegation, providing documentary evidence and testimony to the inquiry and investigation committees, and receiving and responding to sections of committee reports that deal with issues raised by the complainant. If the case proceeds to a formal

investigation, the identity of this person would become known to the accused.

The latitude of the inquiry is an issue. It should be neither a freewheeling inquiry into every possible issue involving the accused nor need it be constrained to deal only with the issues originally raised in the initial allegation. If in the course of a careful examination of the evidence directly related to the initial allegation, the inquiry committee discovers evidence of possible misconduct not known by the complainant, then this becomes part of the inquiry, and the evidence and the findings of facts should be reported to the department head as part of the committee report. The accused should be kept informed of the issues being considered by the committee.

The nature of inquiry into charges of research misconduct deserves careful thought. The issue is not, "Is the science correct?" at this point. Error is not misconduct; conversely, assertions that are true but made on the basis of fabricated data do constitute research misconduct. The inquiry committee is not charged with initiating repetition of the research in question, but rather with determining whether a factual basis existed at the time of submittal for the claims made in a publication.

The product of the inquiry process is a written report from the committee in response to their charge, accompanied by the decision of the department head to recommend to the provost whether a formal investigation of a charge of research misconduct is warranted, using the standards prescribed bylaw and by MIT policy. The department head may decide that although there is no evidence of research misconduct, other violations of Institute policies may have occurred and may recommend to the provost that an internal investigation be initiated to deal with allegations and possible sanctions by internal procedures. If the nature of the dispute or the possible violations of Institute policies are such that mediation is an option for resolution of the dispute, then the inquiry report can serve as the basis for a mediated settlement at the request of all of the parties. In any case, the provost must be notified about the outcome and receive a copy of the report.

VIII.2 Research Misconduct Investigations

Federal regulations require investigation into all allegations of scientific misconduct (in research funded by NSF and NIH) that have substance. MIT uses investigative panels for a variety of purposes. It can be the final fact-finding or appeal panel in a grievance; it can be a committee set up to consider a recommendation to remove tenure; it can be a committee investigating a charge of research misconduct. MIT

has policies and procedures in place to deal with these issues. The charge to our committee is to review these policies and procedures as they apply to allegations of research misconduct and to review the regulatory requirements when the research in question involves the expenditure of government funds, most specifically funds provided by either NSF or NIH. In these latter cases, federal regulations govern aspects of the procedures that MIT must follow, and impose on individuals found guilty of research misconduct downstream consequences that can include criminal prosecution. Implications of these consequences necessarily affect MIT's handling of such investigations.

Based upon our review of cases and procedures from other universities, we endorse MIT's current policy that the responsibility for the conduct of a formal investigation into allegations of research misconduct is vested in the provost, and that normally the provost establishes a fact-finding panel whose report provides the basis upon which the provost adjudicates the charges and determines what further steps, if any, are needed.

Such a formal investigation of charges of research misconduct will be initiated by the provost, typically upon recommendation of the department head, generally following an inquiry. The Institute must at this stage notify NSF or NIH if they are involved in funding the research in question; the regulations also require notification at the allegation stage under certain circumstances.

We support the separation in roles for the committee as fact-finder and the provost as adjudicator. The charge to the committee should be specific as to the finding of facts and the level of certainty to be established concerning the facts that will enable the adjudicator to decide whether research misconduct has occurred. At the investigation stage, the standard of proof increases beyond "a charge having substance," which was appropriate for the inquiry stage. Because of the implications for the career and reputation of the accused, we suggest that an appropriate standard for a determination that research misconduct has occurred is a finding of fact by "clear and convincing evidence" (this lies between the criminal standard of "beyond a reasonable doubt" and the civil standard "by a preponderance of the evidence").

The charge to the investigation committee may contain a mixture of allegations of research misconduct and other violations of Institute policies. It is important that the charge separate these issues to aid the committee in hearing testimony and in finding fact based on which the Institute must determine the truth of each allegation. Since the implications for a finding of research misconduct differ from those for

violation of internal policies, the committee must keep these issues distinct.

The committee would be given all of the physical evidence (laboratory notebooks, manuscripts, etc.) that the inquiry committee had gathered and would also collect additional data as appropriate. The evidence that the committee would be expected to gather and evaluate is data that faculty members have competence to evaluate: research data in its various forms, publications and drafts, direct testimony from witnesses, financial records, correspondence, logs, and other laboratory records. We believe that the committee should not gather forensic evidence that requires for its evaluation expert testimony beyond that related to the science in question, such as handwriting analysis, fingerprints, and paper or ink analysis, nor use data such as surreptitious audio or video tape recordings or other data that violate Massachusetts law, and institutional policies such as the policy on privacy.

We suggest two mechanisms to insulate the investigation process from the informal inquiry: first, that no individual serve on both committees; second, that the investigation committee not be given a copy of the report of the inquiry committee. They should not interview or discuss the case with members of the inquiry committee. This insulation of the investigation should ensure that the committee focuses on its charge and the evidence. Procedural error or findings from the less formal inquiry should not influence the fact-finding aspect of the investigation.

Confidentiality is essential in the conducting of inquiries and investigations. This is obvious with respect to the testimony of both the accused and the complainant. It should, but may not, be obvious with respect to all participants in the process, including particularly the members of the committee. They must be formally bound by a directive and an agreement of confidentiality. They cannot break confidentiality to respond when the principals in the case criticize their activities, impugn motive to questions asked during closed meetings, or charge favoritism, or when colleagues take sides in the case.

To the extent possible, members of the investigation committee should be chosen from outside the department of the person charged as well as utilizing individuals from outside from contiguous departments to provide the necessary expertise. The accused should have an opportunity to challenge the makeup of the committee but should not have a veto. The committee should have adequate staff and budget to carry out their task. They should be briefed by a designated individual in the Office of the Provost about their charge, about rules of evidence, issues of due process, and about the standard of proof and level of certainty to be used in reaching their findings.

The latitude of the investigation is an issue. It must not be constrained to deal only with the issues originally raised in the initial allegation or outlined in the charge. If, in the course of a careful examination of the evidence directly related to the initial charge, the investigation committee comes across serious evidence of possible misconduct that was not known by the complainant or uncovered during the inquiry, then this becomes part of the investigation. The accused must be kept informed of the issues being considered by the committee.

The accused will receive a copy of the charge to the committee and must be given the opportunity to respond in writing, in meetings with the committee, and by presentation of evidence. If the accused wishes the committee to call witnesses, their names and the nature of their testimony should be given to the committee in writing. The committee would attempt to interview the witnesses suggested by the accused consistent with the developing lines of investigation.

We believe that the accused should be allowed to attend all of the evidentiary hearings of the investigation committee that deal with the issue of research misconduct. One reason is that the scientific chain of reasoning that leads the committee to understand the allegations and eventually to render a finding can be long and tortuous. Fairness is served if the accused is present to understand in detail the reasoning that is being used to charge and assess culpability. The accused would not respond at that point in the proceedings unless asked by the committee, nor question witnesses, but would be able to specifically respond to the charges in writing and by testimony at a later date. The committee will thus be aided in more specifically and accurately carrying out their charge.

Accurate record keeping of evidentiary hearings for the purpose of fairness to the accused puts an administrative burden on the committee. If the accused is present, the burden on the committee shifts to record keeping for the purpose of reaching and justifying their findings and in some cases communicating these to the sponsoring agency. For those portions of the investigation that deal with aspects of the case other than research misconduct, the accused need not be present but should receive an accurate summary of the testimony presented. The committee is of course free to deliberate in executive session. It is the responsibility of the chair to structure the hearings to protect the rights of both the accused and the other witnesses.

The role of attorneys at this stage in the process deserves some consideration. An individual is of course always free to consult attorneys at any point in life for any reason. The issue is their participation in institutional processes. Various universities deal with this issue in various ways. Some allow attorneys to be present but do

not allow them to speak. Others do not permit their attendance at any phase of university proceedings. By custom and tradition, MIT has not permitted attorneys to participate in Institute proceedings for either students, faculty, or employees.

However, special circumstances apply when the investigation concerns research funded by the federal government. In this case, a finding of scientific misconduct may give rise to criminal charges being filed against the accused. In this case, there is an issue of "self-incrimination" during the Institute procedures. In cases involving students, MIT has decided to hold in abeyance a student discipline case when the student was also under possible indictment by a court for the same incident. In the case of scientific misconduct, we are not free to do this because of the time limits set by the agencies and our responsibilities to carry through the federally mandated process. Thus, we may be asking the accused to participate in an Institute procedure where there exists some possibility of self-incrimination. Therefore, we suggest provisions be made for the accused to bring an attorney for counsel when testifying, if desired. In this case, the role of the attorney is restricted to that of a confidential advisor to the accused. The attorney would not be present during the testimony of other witnesses, nor raise questions or objections with the committee.

At any time in the proceedings, the chair may rule that the presence of the attorney is interfering with the committee procedure and may refuse permission of the accused's attorney to attend the hearing. In this case provisions should be made for the accused to have access to the attorney outside the hearing room or by telephone as the hearing progresses.

We believe that members of the community have an obligation that is inherent in their positions as MIT faculty, staff, or students to participate in Institute administrative processes such as those discussed herein. If the accused refuses to participate, the committee will proceed as best they can and base their findings on the evidence presented. In the case of research funded by NIH and NSF, if the committee cannot make a finding because of the refusal of the accused to participate, MIT may have no choice but to refer the case to the agency for investigation.

The outcome of the investigation is a written report containing a summary of the evidence and a finding of fact to the standard of certainty outlined in the charge. The accused receives a copy of this report and may append a response. The complainant receives a copy of those portions relevant to the complainant's allegations and may append a response. The provost receives the report plus the appended responses, adjudicates the case, and decides on an appropriate action within the framework of MIT policy and procedures. In all subsequent

Institute proceedings, including appeals and hearings to remove tenure, we recommend that in the absence of new and significant evidence, the facts not be refound but used as the basis for further procedures. If the sponsoring agency is NIH or NSF, the outcome of the investigation and the actions taken must be reported; the agency may take additional action.

IX. PROTECTION OF COMPLAINANTS

MIT must ensure that individuals who raise allegations in good faith do not experience retaliation by any supervisor. We suggest that this concern be dealt with early in the process by appropriate means, such as by making alternative arrangements to have the individual's work supervised and evaluated, and by ensuring fair and objective letters of recommendation. Part of the setting up of an inquiry should include a plan to ensure the protection of the complainant. Alternatively, individuals who raise allegations maliciously may be guilty of general misconduct.

We recommend that MIT ensure a supportive environment for individuals who come forward with concerns about research conduct, and that specific provisions to ensure the protection of complainants who act in good faith be a part of the plan for conducting an inquiry into allegations of research misconduct and be submitted to the Office of the Provost before the inquiry is initiated.

X. RIGHTS OF THE ACCUSED

Great sensitivity is required toward protecting the rights of the accused, who is after all a colleague and member of our scholarly community and who is presumed innocent of the allegations until the investigation is complete. There is a natural imbalance between the institution and the individual. In this process their interests will collide. The Institute will have legal resources and will carry through the required processes to fulfill its responsibilities. The individual will feel isolated and may lack resources to fully protect his or her rights. The rights of the accused during the proceedings described above are adequate notice of the charges, and an opportunity to respond in an impartial, fair, timely, and objective process. We have outlined procedures to provide **adequate notice**: receiving the charge; attendance at evidentiary hearings during the investigation; and the opportunity to

receive the committee reports. We have outlined procedures to provide the **opportunity to respond**, including having an impartial committee; an opportunity to present witnesses; and an opportunity to respond to the committee report. The accused has a right to avoid self-incrimination related to a potential criminal proceeding, and we have recommended the option of the accused, if he or she testifies, having the right to consult an attorney—but not otherwise having lawyers participate. The accused has the right to a confidential proceeding; individuals who disclose facts concerning the case to individuals without a need to know may violate MIT policy and may risk civil suits. Current MIT policy also grants the right to be accompanied to MIT proceedings by an MIT advisor.

Procedures to ensure these rights differ between inquiry and investigation. Since only an investigation can result in a finding of misconduct and lead to sanctions as well as public disclosure, the procedures are necessarily more formal.

Our suggestions for procedures to safeguard the rights of the accused, in this and in previous sections, are based in part on our perceptions of the unwritten covenant between faculty and administration about the values inherent in our relationship. The suggestions we have made are directed toward providing protections for faculty, students, and staff who are accused of what in scholarship is a capital crime.

XI. INSTITUTIONAL MEMORY

Because the process of inquiry and investigation into allegations of research misconduct is carried out with a high degree of confidentiality, there is little opportunity for the MIT community to learn about how to respond effectively to new cases as they arise. And yet, because of the importance of these issues to the Institute and its faculty, staff, and students, we must effectively deal with such cases. The thrust of our procedural recommendations is to ensure that possibly serious cases immediately come to the attention of senior officials who can ensure that proper procedures are followed. We also believe that there is a need to establish a formal mechanism to ensure institutional memory for these issues.

Some of the important functions requiring such institutional memory are to provide assistance and advice to a department head concerning the selection of and the charge to a committee of inquiry; to foster consistency of procedures and standards across departments; to brief committees of inquiry and investigation as to their charge, evaluation of evidence, standards of proof, and fair process requirements; to ensure

that plans are made to protect complainants who act in good faith; and to make available knowledgeable advisors in the event that the inquiry or investigation takes an unexpected turn. Some universities have established a standing faculty committee to provide these functions and to ensure that past experiences are used to guide future actions. We believe that this function can be more effectively provided by centralizing the activity within the Office of the Provost.

The provost will be the adjudicator after the investigation (if any) is completed, and should not be involved at this stage in the process of developing evidence. Rather, the provost should identify individuals within MIT who can ensure that proper processes are initiated in response to allegations and who can advise committees on procedural issues and charge such individuals with carrying out these functions. Therefore, we have recommended above that MIT establish a function within the Office of the Provost to guide the processes of responding to allegations of research misconduct.

The earlier section of our report on responding to allegations can be interpreted as setting up procedures for these processes. However, such procedures must be continually updated to respond to changing regulations and legislation. Part of the responsibilities of this individual would be the development of procedures for inquiries and investigations and the continual review and update of these, both to respond to changes in federal regulation and to improve their effectiveness.

XII. INTERACTIONS WITH THE FEDERAL GOVERNMENT

For research supported by NIH and NSF (currently), the end of the Institute's investigation begins the response of these federal agencies. MIT is required to furnish to these sponsoring agencies the evidence, the findings and the conclusions of its investigation, and the actions taken in sufficient detail to permit a thorough evaluation of the outcome and basis for the Institute's findings and to allow the agency to repeat the investigation if it wishes. At this point, actions of the accused, the Institute, and the individuals who participated in the process, as complainants, as members of faculty committees, or as Institute officials, may be subject to further scrutiny. The accused may be censured or debarred from future federal funding. The Institute may be criticized for its handling of a case. Individuals involved may be accused of conflict of interest, of making false accusations, or of negligence for their roles in carrying out an inquiry or investigation. It is thus imperative that the Institute give full attention to these matters.

The scientific community has expressed its concern about the vagueness and the inconsistencies between agencies in the definition of scientific misconduct as well as concerns about failures of due process and confidentiality on the part of federal agencies. A dialogue is ongoing that, it is hoped, will resolve some of these issues, thus enabling universities and the federal agencies to fulfill their responsibilities while protecting the rights and reputations of the individuals involved and ensuring the productivity and creativity of the scientific enterprise. We endorse MIT's efforts to join with other universities, professional societies, and individual members of the scientific community in working cooperatively with federal agencies to improve procedures for the federal response to allegations of scientific misconduct.

The past few years have seen considerable turmoil surrounding the issue of institutional response to allegations of scientific misconduct. During these past few years, universities have put in place federally mandated procedures to deal with such allegations that occur on their campuses. The National Academy of Sciences … established a Committee on Scientific Responsibility and the Conduct of Research … [that reported in April 1992]. We urge a period of stability with respect to new federal regulations to give universities and the scientific community an opportunity to gain experience with these procedures.

Part C

Specific Research Policies and Practices

12

Policy for Recording and Preserving Scientific Data

Dana-Farber Cancer Institute

INTRODUCTION

It is both necessary and appropriate that the Dana-Farber Cancer Institute unequivocally identify and establish specific guidelines and a policy related to the development and maintenance of the scientific record. The underlying principle is the uncontestable fact that original experimental data must be recorded and retained in a form which will readily permit independent analysis, verification of originality and authenticity, and validation of interpretations and conclusions.

Equally uncontestable is the Institute's ownership and stewardship of the scientific record. This responsibility is clearly based on the assignment to the Institute of "all ideas, inventions, discoveries, improvements and the like, whether patentable or not (including all data and records pertaining thereto) and all right, title, and interest … therein" by the individual on executing the Institute's Invention Agreement. This agreement applies to all individuals associated with the Institute in the conduct of research and utilizing the Institute's resources.

POLICY

As the legal owner of the scientific record, the Institute requires that all primary scientific data generated within its facilities and with its resources be accurately and faithfully recorded, responsibly maintained, and permanently retained.

NOTE: Issued in October 1987; reprinted with permission from the Dana-Farber Cancer Institute, Boston, Mass.

GUIDELINES

The following will serve as guidelines for implementation of the policy. Where required, specific procedures and individual responsibilities are identified.

1. Recording of Data—All primary data are to be entered into a notebook provided by the Institute for this purpose. The investigator is responsible for all data entries. The notebook will contain lined, numbered pages; no pages are to be removed or made illegible. Entries must be dated and signed. Data generated as printouts must be permanently fixed to the notebook pages. Data in other forms, such as photographs or data on computer disks, must either be included in the notebook or be maintained physically with the notebook. Unusual problems associated with data records will be resolved on consultation with the director for research.

   Further guidance on record keeping procedures will be found in Appendix E of the Harvard Medical School *Guide to Protecting and Managing Intellectual Property*.
2. Retention of Data—The laboratory chief is responsible for maintaining and preserving all laboratory notebooks. All investigators within the laboratory are responsible to the laboratory chief for notebooks assigned to them. On leaving the Institute, investigators are required to deposit the original notebooks with the laboratory chief. Similarly, the laboratory chief, on leaving the Institute, is required to deposit all original notebooks from the laboratory with the director for research. The laboratory chief must arrange with the director for research for the safe storage of notebooks no longer needed in the immediate laboratory area.
3. Access to Data—The investigator will have ready and complete access to all notebooks which he employed during his association with the Institute. On leaving the Institute, the investigator is entitled to a copy of the notebooks, but not the original notebooks, which will be permanently retained by the Institute.

The Institute president, or his appointed representative(s), similarly will have ready and complete access to all notebooks currently in use or retained by the laboratory chief. Such access will be immediate on request to the laboratory chief and will be for reasonable cause as determined by the Institute president.

IMPLEMENTATION

This policy is effective immediately; a supply of notebooks is available at the Research Administration Office. Notebooks will be issued without charge to individual investigators. An inventory record of notebooks issued to individuals will be maintained and, on leaving the Institute, the individual will be required to clear the record, either returning the notebooks or transferring responsibility to another individual.

13

Guidelines on Research Data and Manuscripts

Brain Tumor Research Center
Department of Neurological Surgery
School of Medicine
University of California, San Francisco

§1 RESPONSIBILITIES OF BTRC PRINCIPAL INVESTIGATORS

Principal Investigators (PIs) have final responsibility for:

…the validity and quality of the data and manuscripts generated from their laboratories.

…fulfilling BTRC and UCSF research and publication standards, policies, and procedures.

…orienting staff, research fellows, and residents to those standards, policies, and procedures and to the maximum extent possible, seeing to it that they are upheld.

…overseeing the work done by staff, research fellows, and residents, to assure that each has the knowledge, information, and skills necessary to meet BTRC standards.

NOTE: These are developing guidelines, a working document reflecting the standards of the faculty of the BTRC, the Department of Neurological Surgery, and the School of Medicine, University of California, San Francisco. Suggestions for additions or revisions should be directed to the BTRC/IRDM Advisory Committee in care of the address given below.

Developed and written by the BTRC Advisory Committee on Internal Review of Data and Manuscripts (IRDM): Susan Eastwood, ELS(D) Chair; Philip H. Cogen, MD-PhD, John R. Fike, PhD, and Harold Rosegay, PhD-MD, with Michael Berens, PhD. Developed in consultation with Scientific Director Dennis F. Deen, PhD, Director Charles B. Wilson, MD, and the principal investigators of the BTRC.

§2 ORIENTATION OF BTRC RESEARCH PERSONNEL

§2.1 BTRC personnel receive a brochure describing the BTRC research and publication policies and procedures recommended in these guidelines, as well as the School of Medicine, University of California, San Francisco, Guidelines to Promote Ethical Conduct in Research (Appendix A[2.1]), and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM) (Appendix B[2.1]).[1]

The BTRC brochure includes a directory to sources of information about, e.g., animal care, radioisotope usage, human experimentation requirements, biohazard safety, and statistical support (Appendix C[2.1]).[2]

§2.2 Fellows and residents beginning work in the BTRC attend an orientation consisting of two 90-minute sessions sponsored by the BTRC. This program provides an overview of the research and publication processes in the BTRC and the resources available to the BTRC research group. Faculty attend the program at least once to familiarize themselves with and provide suggestions related to the information it contains.

§3 RESEARCH DATA

§3.1 Data Management and Review

In general, two primary forms of data records are maintained in each BTRC laboratory: the *methodology notebook* and the *experimental notebook*. Laboratories with several investigators and/or research projects keep a *laboratory master log. A data selection file* containing data selected for publication and documents related to publication is kept for each paper resulting from a study. BTRC standards for accurate collection and recording of data and for storing data are detailed in **§4** of these guidelines.

§3.1.1 The PI has final responsibility for the validity of the data.

§3.1.2 The PI has final responsibility for maintaining methodology notebooks and laboratory master logs relevant to the PI's laboratory and for seeing to it that those books

and all experimental notebooks, data selection files, and related data and records are kept and stored according to BTRC standards.

§3.1.3 The PI has final responsibility for ensuring that data (a) are collected and recorded in the experimental notebook according to BTRC standards and (b) are stored in a comprehensible way for others to have access to them.

§3.1.4 In some laboratories, a "data manager"—at UCSF usually a staff research associate or specialist designated by and responsible to the PI—may maintain methodology notebooks, oversee experimental notebooks, have laboratory management responsibilities, and/or instruct new fellows and residents in laboratory techniques and protocols. In such laboratories, PIs meet with their data manager to review research progress and data at least once each month (see §3.1.6).

§3.1.5 The PI holds scientific meetings with junior investigators, residents, and fellows once each month, at which time the PI reviews the experimental notebooks and related data and records. To fulfill the educational purposes of the BTRC, though, PIs are encouraged to meet more frequently with these personnel, about once a week, particularly on a one-to-one basis (see §3.1.6).

§3.1.6 PIs are encouraged to initial and date the latest page of each experimental notebook reviewed in the event that documentation of these reviews is needed at a later date.

§3.1.7 The BTRC's scientific director (D. Deen) reviews all methodology and experimental notebooks and related data and records at least twice each year.

§3.2 Statistical Design and Analysis

Investigators are encouraged to consult a statistician when designing a study and interpreting statistical data. Statistical support is available through the Northern California Cancer Program, which is willing to review statistical aspects of BTRC protocols.

§3.3 Use of Pooled BTRC Data

An investigator wishing to base a study on pooled computerized BTRC data that was generated by anyone other than him/herself alone must discuss the project with the BTRC's scientific director and the PI who derived the data *before work begins* to assure proper authorship, acknowledgment, and attribution of ideas and data.

§3.4 Ownership of Data

Methodology and experimental notebooks and related data and records are the property of the University of California. They may not be removed from the BTRC, although investigators may take a photocopy of all or part of them from the BTRC. [Note: When a PI resigns from the University, arrangements can generally be made to transfer ownership appropriately.]

§3.5 Storage of Data

PIs must store all data notebooks and related data and records in the BTRC for 5 years after the date when funding for a study ends. They may then continue to store them in the BTRC or may make arrangements with the office of the BTRC administrative director (M. Barker) to have them moved to the UCSF storage facility at Oyster Point; the BTRC administrative office keeps a record of retrieval information.

§4 STANDARDS FOR BTRC DATABOOKS

§4.1 Data Notebooks

§4.1.1 Bound Notebooks with Consecutively Numbered Pages. These databooks, with a permanent (sewn) binding, are the hard copy of choice for data recording. Duplicate pages in the notebooks are intended for generating carbon copies.

§4.1.2 Loose-Leaf Binders. These are used instead of bound data notebooks at the PI's discretion, to log all or portions of experimental records or generated data. Each page must be identifiable as consecutive and belonging to a specific experiment according to a system created and followed in the laboratory (e.g., an experiment-identification number followed

by the sequential page number and investigator's or technician's handwritten initials: 1.23*MT*); the BTRC's administrative director keeps a record of each laboratory's experiment-identification system in order to properly archive and retrieve data. When an experiment is completed, the consecutive pages of data and notes may be inserted into a plastic sleeve(s) for permanent storage in a binder for the one experiment, or in one binder including all experiments for the study.

§4.1.3 Data and Relevant Material That Must Be Stored Separately (e.g., computerized data files, microscope slides): see 4.4.4-4.4.6.

§4.2 Laboratory Master Log

For studies involving several investigators, or for laboratories with several investigators and/or research projects, the PIs keep a master log that serves to catalog the experiments of the whole study or laboratory. This central log, a hardbound databook with consecutively numbered pages, should contain:

- the titles of the studies done by everyone in the laboratory,
- the investigators' names,
- the inclusive dates of the experiments, and
- the location of the experimental notebook and any raw data, computer files, or other relevant materials stored separately for each logged experiment.

§4.3 Methodology Notebook

§4.3.1 In each laboratory, certain techniques or protocols are used in common on a daily basis, such as specific cell culturing techniques (e.g., cell transfers, dilutions, cell counting, media preparation), irradiation techniques, tumor implantation procedures, neurologic examinations, animal anesthesia, electrophoresis procedures, and others. Specific details about each of these commonly used methodologies (including the statistical methodologies) are documented and numbered or assigned reference notations that facilitate citation in experimental notebooks. Such documentation serves to standardize all experiments that generate data of the same form and is also instrumental in training new laboratory personnel.

- Notebooks have a section for each technique, and each section contains all versions of the technique, each dated for reference.
- A "table of contents" to the methodologies is kept at the front of the notebook.
- The specific entries in the methodology notebook are modified as improvements in the procedures are developed. Changes are noted precisely *and dated* in the methodology notebook.
- Outdated or discontinued methods remain in the methodology notebook, with a notation of the precise date the modified or new method(s) went into effect (e.g., so that earlier methods can be readily retrieved for reference in writing a manuscript).

§4.3.2 The methodology notebook is the final and absolute arbitrating reference when questions of technique are raised in the context of the educational and training responsibilities of the BTRC.

§4.4 Experimental Notebook

§4.4.1 The experimental notebook is the vehicle by which the experiment is fully documented.

§4.4.2 The first several pages of the notebook are reserved for a "table of contents," in which are listed, as the study develops, the experiments and the pages on which the data are located.

§4.4.3 The following *minimum* information is entered for each experiment; PIs are encouraged to make up a "boilerplate" page that can simply be filled in with this information.

- Title of study
- PI's name
- Date the study starts; date it ends
- Associate investigator's name(s) (i.e., research associate specialist and/or postdoctoral fellow, resident, or graduate student)
- Brief statement of hypothesis or study goals
- Cell line (passage no.)
- Animal strain and supplier

- Specific animal identification no. (large animals)
- Source of analyzed material
- Tumor type and passage no.
- Drug type (lot no. and/or source), dose(s), dilution(s)
- Radiation source and dose
- Special reagents (e.g., antibodies, probes)
- Cell culture batch/medium
- Serum batch/medium
- Experimental design

…study-specific treatment groups, projected number of subjects, and all other elements of the study design with reference to specific techniques or protocols from the methodology notebook [refer to each specific protocol or technique by its designation (e.g., number) in the methodology notebook].

…statistical methodology added to or deviating from that in the methodology notebook.

…a "time line" illustrating the sequence of study events (e.g., start, cells added, medium added, …).

- Specific notes about special procedures or steps that differ from the techniques specified in the methodology notebook (e.g., changes in incubation time or temperature, concentration of trypsin, tumor cell inoculum, infusion rates, anesthetic procedure). *Any variance from the routine procedures recorded in the methodology notebook must be noted in detail* [refer to each specific routine protocol or technique by its designation (e.g., number) in the methodology notebook].
- Raw data, or explicit instructions for locating the raw data or retrieving them from storage (see 4.4.4). *Of particular importance are notations about excluded data or animals, with detailed information about why those data or animals were excluded.*
- A brief conclusion of the experiment, including a "value judgment" about the validity of the experiment, whether the study needs to be repeated to validate it, what can and cannot be definitively concluded from the data, and other observations. Simple concluding

descriptions such as "bad study," or "data suspect," are not acceptable. It is essential to document why the study or data were considered suspect. Justifications for positive judgments must similarly be recorded.

§4.4.4 Raw Data. Whenever possible, raw data are stored together with the experimental notebook; e.g., they may be stapled on the duplicate page following the related databook entry, or placed in a plastic sleeve(s) and inserted in the binder. Data too unwieldy to include is listed in the experimental notebook as it is collected, is described sufficiently for recognition, and is annotated with the name of investigator and explicitly where the data can be found (e.g., location of the tape or disc and its identification number). Raw data include, but are not limited to,

- handwritten notes on, e.g., cell or colony counts, tumor dimensions, physiologic endpoints, daily observations on animals, or other visually measured data (e.g., CT or NMR tapes) from which observations were made,
- photographs, photomicrographs and negatives
- spectra, EEG, evoked potential recordings
- films, scans, images
- slides (e.g., histologic sections)
- dated hard copy from computerized data files (see 4.4.5).

§4.4.5 Computerized Data Files. In the data notebook are included dated hard copy from these files or, if this is too unwieldy, dated summaries that describe the files sufficiently to find and recognize them, including the location of the data file and the particular computer disc(s) on which the data are stored.

§4.4.6 Blinded, Cooperative, or Multicenter Studies. Data for blinded or double-blind studies are kept in separate (perhaps smaller), bound notebooks by the respective investigators and are brought together with the experimental notebook(s) as a single unit for storage at the end of the study, when the code is broken. Data management for cooperative or multicenter studies is developed along these guidelines as the need arises.

§4.4.7 Standards for Keeping Experimental Notebooks

§4.4.7.1 Each entry in the experimental notebook should be able to stand alone, to permit others to replicate the work at any time, whether immediately or even years after it is made.

§4.4.7.2 Experiments are logged in the notebook in chronological sequence.

§4.4.7.3 Data are recorded chronologically as they are collected on consecutive pages of the experimental notebook.

§4.4.7.4 Entries should be organized in such a way that someone not familiar with the specific experiment recorded can retrieve all the pertinent details of the study, from the hypothesis to the published article. Notes entered at the time of the experiment summarizing the goals, details, or problems can be invaluable during subsequent analysis or defense of the results and are therefore encouraged. Optimally, the experimental notebook is a journal of the study.

§4.4.7.5 Databooks are kept only in ink and must contain no erasures or "whited-out" changes.

- An entry made by mistake is deleted only by drawing a single line through it, preferably in ink of a different color. The deleted material must remain legible beneath the overstrike. Large blocks or a page to be disregarded are crossed over with an "X" or diagonal line and marked, e.g., "OMIT." The page must remain legible.
- The corrected data are written beneath or beside the original entry. The explanation for the alteration is clearly written in close proximity to the alteration—preferably on the same page or on the facing page.

§4.4.7.6 If any changes are ever made in the experimental notebook—including a change in values, correction of a mistake, or like alterations—it is absolutely required that those changes be dated and initialed by the person making the alteration, and a clear explanation noted as to why the alteration was made.

§4.4.7.7 In permanently bound databooks containing duplicate (often perforated) numbered pages, only the original bound-in page is used to record data. The duplicate page is used only for a carbon copy or to paste in auxiliary material, e.g., photographs; it is otherwise simply left blank.

§4.4.7.8 Whether permanently bound or loose-leaf, only databooks with consecutively numbered pages should be used. Pages must never be torn from a databook.

§4.5 Data Selection File

Manuscript preparation involves the selection of specific experimental data from the experimental notebook.

§4.5.1 A data selection file, filed separately from the experimental notebook and clearly cross-referenced to it, is kept for each paper to be submitted for publication.

§4.5.2 The data selection file consists of:

- Those data selected for reporting and their analyses (including, e.g., graphic presentations and statistical manipulations). These are photocopied from the original experimental notebook and cross-referenced to that notebook page by page (unless the cross-reference is evident on the photocopy).
- The rationale for selecting the specific data used in that particular paper, recorded narratively ("I selected this datum on the basis of X; I excluded this datum on the basis of Y."), including justification

for the selection of specific data to make a curve or other statistical representation.

- A document naming the coauthors and detailing their specific contribution(s) to the study (Appendix D[4.5.2]).
- A document naming the persons cited in the acknowledgments as contributing to the paper and detailing their specific contribution(s) to the study (Appendix E[4.5.2]).
- Any other material considered pertinent to selection of data, to authorship, or to any substantial related matter arising during the development of the paper.

§4.5.3 At the completion of a research project, the data selection file for each paper developed from the project is archived in the BTRC together with the experimental notebook(s) for the project and the photocopies of the relevant material from the methodology notebook(s).

§5 AUTHORSHIP

§5.1 The first author of a paper is named, coauthors selected, and order of authorship assigned before a study begins. Although changes may take place, such an initial plan provides a context for the relative responsibilities and expectations of each investigator.

§5.2 Authorship is based on the URM, which makes clear the distinction between an author and a contributor to the paper. Contributors are named and their contribution to the study and/or paper specified in the Acknowledgments section of the paper.

§5.2.1 The senior author is the PI responsible for the validity of the data reported and may or may not be the first author of the paper. If the senior author is not the first author, his or her name appears last in order of authorship.

§5.2.2 The first author is the person who generates the data, collects and/or collates the data for review by coauthors, and writes the first draft of the paper.

§5.2.2.1 The first author is responsible for maintaining and archiving the data selection file (see 4.5).

§5.2.2.2 If the first author leaves the BTRC before the data selection file is complete, responsibility for maintaining it reverts to the senior author.

§5.2.3 The first and senior authors jointly decide whether or not another participant is to be a coauthor. Other coauthors of the paper are named in the order of the importance of their contribution to the research being reported.

§5.3 Order of authorship may be changed with the agreement of the first author and the senior author and according to URM principles; e.g., if any author recommends that changes of personnel over the course of a study call for revision of the initial authorship. All coauthors must be notified of authorship changes before a paper is submitted for publication.

§5.4 Disputes regarding assignment or order of authorship that cannot be resolved among the authors should be addressed to the scientific director of the BTRC. The BTRC Advisory Committee on Internal Review of Data and Manuscripts (IRDM)[3] can be consulted as a resource in resolving such disputes.

§6 COAUTHORSHIP

§6.1 All coauthors meet at least once to discuss the selected data and the results of the work, and to reach agreement on their conclusions, the general direction of the paper, and the work of others, if any, to be referenced or acknowledged.

§6.1.1 This meeting is usually conducted in person but it may be by conference call or computer communications (e.g., Popnet).

§6.1.2 If these alternatives are unworkable, the senior author telephones the absent coauthor(s) or sends him/her a summary of the coauthors' meeting. In such cases, the resolution of any disagreements on the work among coauthors should be documented in letters that are archived in the data selection file.

§6.2 Coauthors are encouraged to review raw data.

§7 MANUSCRIPT SUBMISSIONS

§7.1 BTRC papers must meet the standards and requirements specified in the URM, except for details of style or format that conflict with the instructions of the journal to which the paper is being submitted.

§7.2 BTRC papers must include a notation of all funding for the work reported. To assure that all relevant sources of funding (e.g., donor gifts as well as grants) are acknowledged, consult the BTRC administrative director (M. Barker).

§7.3 BTRC papers are generally submitted from the Department of Neurological Surgery Editorial Office, which maintains and archives the manuscript file and provides forms needed for documentation.

§7.3.1 The senior author is the editor's principal contact regarding the paper, but the senior author may assign a coauthor (e.g., the first author) to follow the editorial process.

§7.3.2 The senior author may request a minimum review and an estimate of need for further editing of a paper. Minimum review consists of checking the correlation of numbers throughout the paper, reference citations, fulfillment of journal requirements, and the required documentation.

§7.4 An Author's Agreement form (Appendix F[7.4]) containing all coauthors' signatures must accompany every paper submitted from the BTRC. One copy of the form is included in the data selection file and one in the manuscript file. All coauthors must personally sign this form (or a copy, see 7.4.2). Signatures *in absentia* are never legally acceptable. If an author's whereabouts is unknown, this is noted on the form and in the cover letter to the journal.

§7.4.1 Before the initial submission and any subsequent substantially revised submission (see 7.4.4), the senior author or a designated person (e.g., a coauthor, editor) sends one copy

of the "prefinal" (penultimate) draft of the paper, covered with the Author's Agreement form, to each coauthor in turn for final review; if differences still must be settled among coauthors, the paper goes through another draft.

§7.4.2 When the version of the paper to be published is satisfactory to all coauthors, they sign the Author's Agreement form and return it to the Editorial Office. Authors who have left the BTRC are sent a separate copy of the final manuscript and form, if necessary by courier or fax.

§7.4.3 The paper is submitted after all coauthors' signatures are obtained.

§7.4.4 When, after journal peer review, revision of a paper involves additional or different data, a substantial revision of conclusions, a change in authorship, or a change in order of authorship, the renewed agreement of all coauthors is documented on a new Author's Agreement form. This documentation is not needed if the outcome of the original coauthor meetings has not changed. What constitutes "a substantial revision of conclusions" is at the PI's discretion.

§8 PUBLICATION OF NEGATIVE RESULTS, CORRECTIONS, ERRATA, AND RETRACTIONS

The BTRC supports submission for publication of (a) papers reporting results that disprove or fail to replicate earlier published conclusions, (b) a correction of published work that is scientifically flawed, (c) errata in published reports, and (d) a retraction of any report determined fraudulent (see Appendix G[8]).[4]

BTRC personnel are responsible for informing their coauthors when a correction or retraction is warranted and for publishing it in the journal that published the paper originally. All coauthors on the original paper should coauthor a retraction together with any other investigator(s) later involved in the work. Conflicts and questions in this regard that cannot be resolved among authors are addressed to the scientific director of the BTRC. The IRDM Committee may be consulted as a resource in resolving such disputes.

§9 QUESTIONS OF RESEARCH OR PUBLICATION PRACTICE OTHER THAN AUTHORSHIP

§9.1 BTRC personnel should refer questions or problems about research publication practices to their immediate supervisor and/or PI or, if necessary, to the BTRC scientific director. The IRDM Committee or any of its members may be contacted as a resource for information or consultation.

§9.2 BTRC personnel should refer any allegation of improper practice or misconduct in the performance or publication of research to their immediate supervisor and/or PI or, if necessary, to the BTRC scientific director. The person alleging the claim should be able to support it with documentation. All BTRC personnel involved with such an allegation must observe due process during all phases of inquiry. The IRDM Committee or any of its members individually may be consulted as ombudsmen or as a resource for information or consultation by any member of the BTRC.

§9.3 BTRC personnel should refer any question, problem, or allegation not resolved through the channels just described to the chairman of the Department of Neurological Surgery and thereafter, if necessary, to an appropriately responsible University officer.

SUMMARY CHECKLIST BTRC PROTOCOL ON RECORDING DATA AND PREPARING FOR PUBLICATION

_____ **Review relevant literature (ongoing)**
_____ …read original sources in their entirety
_____ …photocopy references or log complete and accurate citation
_____ **Plan experimental study design**
_____ …obtain statistical consultation
_____ …review and photocopy relevant sections from the appropriate methodology notebook for reference
_____ **In the experimental notebook, initially record**
_____ …title of study
_____ …PI's name
_____ …date the study starts (inclusive dates after study ends)
_____ …associate investigator (e.g., SRA, postdoctoral fellow, resident)
_____ …brief statement of hypothesis or study goals

_____ …cell line (passage no.); animal strain and supplier, specific animal i.d. no. (large animals); source of analyzed material; tumor type and passage no.

_____ …drug type (lot no. and/or source) and dose(s); radiation source and dose; special reagents (e.g., antibodies, probes); cell culture batch/medium; serum batch/medium

_____ …experimental design in detail (e.g., treatment groups, projected number of subjects), correlated specifically with the *methodology notebook*

_____ **Perform study, recording**

_____ …specific notes regarding special procedures or steps that differ from specific techniques (including statistical) taken from the *methodology notebook,* record of any variance from usual BTRC procedures in specific correlation with the *methodology notebook*

_____ …raw data, including handwritten notes on data collection, endpoints, daily observations, location of photomicrographs and negatives, and particularly notations about excluded data or animals, with detailed information on why they were excluded

_____ …a "time line" illustrating the sequence of study events (e.g., start, cells added, medium added, … etc.)

_____ …brief conclusion, including a "value judgment" on the validity of the experiment, whether the study needs to be repeated to validate it, what can and cannot be definitively concluded from the data, and other observations

_____ **Analyze data**

_____ **Meet with all coauthors at least once** to discuss the raw and selected data, the results of the work, to agree on conclusions, the general direction of the paper, and work to be referenced in the paper

_____ **Create a data selection file** …in consultation with coauthors as much as possible

_____ …selected data from the *experimental notebook* and their analysis, including graphic presentations, statistical manipulations, are archived in a *data selection file,* clearly cross-referenced to the *experimental notebook*

_____ **Select pertinent references**

_____ **Select and analyze journal most relevant to the work**

_____ **Write the paper for the journal chosen**

_____ …send a working draft to coauthors

_____ …revise paper until final revisions are complete

_____ …complete and archive documentation in the file

_____ …statement and order of authorship, contributors acknowledged, permission to use "personal communications"

_____ …send paper to Editorial Office for editorial consult

_____ …final draft sent from Editorial Office to all authors together with the Author's Agreement form, which all coauthors must personally sign

_____ …Submit paper to journal together with signed Author's Agreement

NOTES

1. International Committee of Medical Journal Editors: *Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URM).* N Engl J Med 1990; 324:424-428.

2. From the *Faculty Guide to Research Support Services, University of California, San Francisco* [Hittleman KJ, Flynn B] published by the Office of the Senior Vice Chancellor, Academic Affairs, and available in the UCSF Dean's Office and the UCSF Library.

3. Appointed by the scientific director of the BTRC.

4. International Committee of Medical Journal Editors: *Retraction of Research Findings.* **Ann Intern Med** 1988; 108:304.

14

PHS Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding

National Institutes of Health

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include organisms, cells, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, and crystallographic coordinates. Some specific examples are specialized and/or genetically defined cells, including normal and diseased human cells; monoclonal cell lines; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; and transgenic mice. The Public Health Service (PHS) provides the following statement of policy concerning unique research resources developed through its awards.

A. PHS POLICY ON DISTRIBUTION OF RESEARCH RESOURCES

It is the policy of the PHS to make available to the public the results and accomplishments of the activities that it funds. Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, when these resources are developed with PHS funds and the associated research findings have been published or after they have been provided to NIH under contract, they should be made readily available for research purposes to the scientific community. This policy applies to NIH intramural research as well as extramural research funded by grants, and cooperative agreements, and contracts.

Investigators who have such resources are encouraged to consult the appropriate PHS program administrators who may be of assistance

Reprinted from *NIH Guide for Contracts and Grants* 17(29):1, September 16, 1988.

in determining a suitable distribution mechanism. For research and development contracts, approval should be obtained from the NIH Contracting Officer before distribution of unique resources, unless the terms of the contract permit distribution without prior clearance of the Contracting Officer. In order to facilitate the availability of unique or novel biological materials and resources developed with PHS funds, investigators may distribute the materials through their own laboratory or institution or submit them, if appropriate, to entities such as the American Type Culture Collection or similar repositories. In the case of unique biological information such as DNA sequences or crystallographic coordinates, investigators are expected to submit them to the appropriate data banks because they otherwise are not truly accessible to the scientific community. When distributing unique resources, investigators are encouraged to include pertinent information on the nature, or quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources do not identify original donors or subjects, directly or through identifiers, such as codes linked to the donors or subjects.

B. DISTRIBUTION COSTS

Institutions and investigators may charge the requester, if necessary, for the reasonable cost of production of unique biological materials, and for packaging and shipping. Such costs may include personnel, supplies, and other directly related expenses. It should be noted, however, that such a charge accrues as general program income. This should not be an impediment to the distribution of materials, but investigators and institutions are advised that:

a) for grants, the income is governed by 45 CFR Part 74 and it must be reported on the Financial Status Report. Questions regarding these policies and the treatment of income should be directed to the Grants Management Officer.

b) for contracts, the income is governed by Federal Acquisition Regulations (FAR) 45.610-3. Contracting Officers must be contacted before generating any revenues from the distribution of materials. Any contract under which research resources would be sold requires specific contract instructions. Existing contracts may require an amendment and specific approval of the Contracting Officer to render them allowable.

C. INVENTIONS AND COMMERCIALIZATION

This policy does not discourage, impede, or prohibit the organization that develops unique biologic materials or intellectual property from commercializing the materials or licensing them for commercial purposes. Investigators may make their materials available to others with appropriate restrictions and licensing terms as they and their institutions deem necessary.

Institutions are reminded that some of these products may be inventions subject to the various laws and regulations applicable to patents and need to be reported. When reporting is required, it should occur at the earliest possible time. (See P.L. 96-517, P.L. 98-620, and 37 CFR 401.)

15

Guidelines for Professional Conduct

American Physical Society

The constitution of the American Physical Society states that the objective of the Society shall be the advancement and diffusion of the knowledge of physics. It is the purpose of this statement to advance that objective by presenting ethical guidelines for Society members.

Each physicist is a citizen of the community of science. Each shares responsibility for the welfare of this community. Science is best advanced when there is mutual trust, based upon honest behavior, throughout the community. Acts of deception, or any other acts that deliberately compromise the advancement of science, are therefore unacceptable. Honesty must be regarded as the cornerstone of ethics in science.

The following are minimal standards of ethical behavior relating to several critical aspects of the physics profession.

A. RESEARCH RESULTS

The results of research should be recorded and maintained in a form that allows analysis and review. Research data should be immediately available to scientific collaborators. Following publication the data should be retained for a reasonable period in order to be available promptly and completely to responsible scientists. Exceptions may be appropriate in certain circumstances in order to preserve privacy, to assure patent protection, or for similar reasons.

Fabrication of data or selective reporting of data with the intent to mislead or deceive is an egregious departure from the expected norms

NOTE: Dated November 3, 1991; reprinted with permission from the American Physical Society, Washington, D.C.

of scientific conduct, as is the theft of data or research results from others.

B. PUBLICATION AND AUTHORSHIP PRACTICES

Authorship should be limited to those who have made a significant contribution to the concept, design, execution, and/or interpretation of the research study. All those who have made significant contributions should be offered the opportunity to be listed as authors. Other individuals who have contributed to the study should be acknowledged, but not be identified as authors. The sources of financial support for the project should be disclosed.

Plagiarism constitutes unethical scientific behavior and is never acceptable. Proper acknowledgment of the work of others used in a research project must always be given. Further, it is the obligation of each author to provide prompt retractions or correction of errors in published works.

C. PEER REVIEW

Peer review provides advice concerning research proposals, the publication of research results, and career advancement of colleagues. It is an essential component of the scientific process.

Peer review can serve its intended function only if the members of the scientific community are prepared to provide thorough, fair, and objective evaluations based on requisite expertise. Although peer review can be difficult and time-consuming, scientists have an obligation to participate in the process.

Privileged information or ideas that are obtained through peer review must be kept confidential and not be used for competitive gain.

Reviewers should disclose conflicts of interest resulting from direct competitive, collaborative, or other relationships with any of the authors, and avoid cases in which such conflicts preclude an objective evaluation.

D. CONFLICT OF INTEREST

There are many professional activities of physicists that have the potential for a conflict of interest. Any professional relationship or action that may result in a conflict of interest must be fully disclosed.

When objectivity and effectiveness are threatened the activity should be avoided or discontinued.

It should be recognized that honest error is an integral part of the scientific enterprise. It is not unethical to be wrong, provided errors are promptly acknowledged and corrected when they are detected. Professional integrity in the formulation, conduct, and reporting of physics activities reflects not only on the reputations of individual physicists and their organizations, but also on the image and credibility of the physics profession as perceived by scientific colleagues, government, and the public. It is important that the tradition of ethical behavior be carefully maintained and transmitted with enthusiasm to future generations.

Physicists have an individual and a collective responsibility to ensure that there is no compromise with these guidelines.

Part D

Policies and Procedures for Handling Allegations of Misconduct in Science

16

Framework for Institutional Policies and Procedures to Deal with Fraud in Research

Association of American Universities
National Association of State Universities and Land-Grant Colleges
Council of Graduate Schools

The "Framework for Institutional Policies and Procedures to Deal with Fraud in Research" was developed during the Summer and Fall of 1988 through the efforts of an interassociation working group. The working group included staff from the Association of Academic Health Centers (AAHC), the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the American Council on Education (ACE), the American Society for Microbiology (ASM), the Council of Graduate Schools (CGS), the Council on Government Relations (COGR), the Federation of American Societies for Experimental Biology (FASEB), the National Association of College and University Attorneys (NACUA), and the National Association of State Universities and Land-Grant Colleges (NASULGC). The document was revised to reflect the advice of a review group convened by the cooperating associations, a meeting of the American Association for the Advancement of Science/American Bar Association (AAAS/ABA) National Conference of Lawyers and Scientists, the AAU, ACE, NASULGC Joint Committee on Health Policy, the AAU Executive Committee, and the AAU Biomedical Research Committee. The "Framework" will be revised again in the near future to take into account final PHS regulations on fraud and misconduct in research.

The existence of those regulations makes the issuance of this framework timely, but it would be necessary even if no regulations were forthcoming. This document grows out of the conviction that universities, not the sponsors of research, are responsible for the conduct of their faculty and staff. In order to fulfill that responsibility, they must have fair, workable, and expeditious procedures for dealing with alleged transgressions of accepted standards.

We have chosen to offer guidance toward that end by the device of a "framework" rather than by a more prescriptive method. That is only appropriate, given the differing circumstances and existing policies and procedures among American universities. An acceptable process will require that all of the main elements of the framework be present, but there is and should be latitude for each institution to find the ways best suited to its condition.

The associations appreciate the financial support of the AAAS/ABA National Conference of Lawyers and Scientists, for the work of Lisa Poor, administrative fellow, Washington University School of Medicine, who worked with association staff in producing this document.

Robert M. Rosenzweig, President
Association of American Universities

NOTE: Dated November 4, 1988; reprinted with permission from the Association of American Universities, Washington, D.C.

INTRODUCTION

Fraud in research undermines the scientific enterprise in ways that go far beyond the waste of public funds. Although an uncommon event relative to the large scientific literature, violations of accepted standards inevitably appear in this as in all human pursuits. Institutions engaged in research have a major responsibility not only to provide an environment that promotes integrity, but also to establish and enforce policies and procedures that deal effectively and expeditiously with allegations or evidence of fraud.

In dealing with this problem it is important not to create an atmosphere that might discourage openness and creativity. Good and innovative science cannot flourish in an atmosphere of oppressive regulation. Moreover, it is particularly important to distinguish fraud from the honest error and the ambiguities of interpretation that are inherent in the scientific process and are normally corrected by further research.

Many institutions have adopted and published policies to deal with these problems. The primary goal of this document is to assist institutions as they refine such policies or as they move to adopt new ones designed to assure careful and thorough handling of allegations of fraud. It expands upon the guidelines presented in two 1982 publications: "The Maintenance of High Ethical Standards in the Conduct of Research," by the Association of American Medical Colleges (AAMC), and the "Report of the Association of American Universities Committee on the Integrity of Research," by the Association of American Universities (AAU).

This document also has taken into consideration the 1986 Public Health Service (PHS) guidelines, "Policies and Procedures for Dealing with Possible Misconduct in Science," and the 1987 regulations issued by the National Science Foundation (NSF), "Misconduct in Science and Engineering Research." The PHS guidelines and NSF regulations describe those agencies' preferred procedures for the institutional handling of allegations of research fraud. Those procedures normally have four stages:

1. An inquiry to determine whether the allegation or related issues warrant further investigation,
2. When warranted, an investigation to collect and thoroughly examine evidence,
3. A formal finding, and
4. Appropriate disposition of the matter.

It is important to note that any new policies and procedures to deal with allegations of violations of the integrity of research must be incorporated into existing institutional policies and procedures for employment and academic conduct. Institutions must be vigilant to provide all parties with appropriate due process. It is reasonable to expect that different situations may require specific accommodations to ensure the protection of the rights of all involved individuals. Institutions should be alert to possible harm to any parties throughout the process. An institution may choose, following an investigation, to refer any "findings" to its standing disciplinary procedures, or to develop processes specific to cases of fraud and misconduct in research.

The several stages of an institution's review process are discussed in detail in the remainder of this document. However, it seems useful to identify at the start the imperatives that should guide any institutional review process for dealing with allegations of fraud:

- Institutions should ensure that the process used to resolve allegations of fraud does not damage science itself.
- Institutions should provide vigorous leadership in the pursuit and resolution of all charges.
- Institutions should treat all parties with justice and fairness and be sensitive to their reputations and vulnerabilities.
- Procedures should preserve the highest attainable degree of confidentiality compatible with an effective and efficient response.
- The integrity of the process should be maintained by painstaking avoidance of real or apparent conflict of interest.
- The procedures should be as expeditious as possible, leading to the resolution of charges in a timely manner.
- Institutions should document the pertinent facts and actions at each stage of the process.
- After resolving allegations, institutions should discharge their responsibilities both internally—to all involved individuals—and externally—to the public, the sponsors of research, the scientific literature, and the scientific community, to the extent that is appropriate and allowable.

DEFINITION OF RESEARCH FRAUD

Research fraud is a form of scientific misconduct involving deception. It should be distinguished from honest error, which can occur inadvertently in any enterprise. It is often difficult when

confronted with an allegation to determine where along the spectrum from error to fraud a particular case will lie.

There is significant debate within the scientific community and in government about the appropriate scope of policies for dealing with the problem and about the definition of behaviors covered by such policies. Specifically, there is no agreement on the definitions of "fraud" or "misconduct." Until the debate over appropriate scope and definition is resolved, institutions may wish to simply reference in their policies the definitions contained in federal regulation. The NSF defines misconduct as follows:

> (a) "Misconduct" means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research; (2) material failure to comply with Federal requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet other material legal requirements governing research.

The PHS has published the following definition in a pending Notice of Proposed Rulemaking (NPRM):

> "Misconduct" or "misconduct in science" as used herein is defined as (1) fabrication, falsification, plagiarism, deception, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research; or (2) material failure to comply with federal requirements that uniquely relate to the conduct of research.

However, some institutions, feeling that these definitions are too broad, may wish to adopt a more precise definition of scientific fraud, such as that contained in the 1982 AAU policy statement. That definition includes the following:

1. *Falsification of data*—ranging from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results.
2. *Plagiarism*—representation of another's work as one's own.
3. *Misappropriation of others' ideas*—the unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.

In formulating such a definition of fraud, institutions should be aware of the need for policies and procedures to address allegations relating to other forms of scientific misconduct. Examples of this kind of conduct would include inability to produce verifiable primary data

supporting reported research results or violations of governmental or institutional rules and regulations regarding the conduct of research.

Some institutions may choose to consolidate in a single policy their procedures for dealing with all forms of alleged scientific misconduct. In such a case, the institution may wish to leave the determination of the point at which misconduct becomes fraud to ad hoc determination on the basis of the particular facts of each case. Such an approach permits the development of an institutional "common law" articulating acceptable scientific research standards. If an institution has separate policies and procedures for dealing with forms of misconduct other than fraud, it is suggested that the relevant sections be included in an appendix to the policies and procedures designed to address fraudulent behavior.

PROCESS FOR HANDLING ALLEGATIONS OF RESEARCH FRAUD

Initiation of an Inquiry

The responsibility to pursue an allegation of research fraud belongs to the institution and must be carried out fully to resolve questions regarding the integrity of the research. Even in the absence of a specific complaint, the institution should be alert to questionable academic conduct that might raise legitimate suspicion of fraudulent research. In the inquiry and any investigation that may follow, the institution should focus on the substance of the issues and should be vigilant in not permitting personal conflicts between colleagues to obscure the facts.

In order to address all allegations of research fraud expeditiously, an institution should designate one or more senior administrators to whom allegations should be reported. Because universities are organized differently, they will choose to delegate this responsibility to meet the needs of their own organizational structure. The designated individual(s) could also:

1. provide education about fraud,
2. interpret the institution's fraud policy,
3. counsel staff, and
4. disseminate the policy.

The designated senior administrator(s) should pursue all allegations to resolution. If there is a conflict of interest, the case should be referred to an alternate senior administrator. To avoid unnecessary

delays and confusion, it is advisable to predetermine the administrative alternate (s).

Institutional policies should state clearly that the senior administrator will counsel confidentially any individual who comes forward with an allegation of fraud. Some concerns brought to the senior administrator's attention may not fall within the scope of the policies and procedures developed to address fraud. Regardless of the nature of the concern, the senior administrator should seek to assist in its resolution through whatever institutional processes may be appropriate to the particular case, such as referral to the department chairman, the personnel office, or the faculty grievance procedure. If the senior administrator determines that the concern is properly addressed through policies and procedures designed to deal with fraud in research, the inquiry and investigation procedures should be discussed with the individual who has questions about the integrity of a research project. If the individual chooses not to make a formal allegation but the senior administrator believes there is sufficient cause to warrant an inquiry, the matter should be pursued; in such a case, there is no "complainant" for the purposes of this document.

Even if the respondent leaves the institution before the case is resolved, the institution has a responsibility to continue the examination of the allegations and reach a conclusion. Further, an institution should cooperate with the processes of other involved institutions to resolve such questions.

Inquiry

Structure

The inquiry process may be handled with or without a formal committee. Regardless of the approach chosen, it is the responsibility of the senior administrator to ensure that the inquiry is conducted in a fair and just manner. The inquiry phase is critical; institutions should consider whether more than one person should be involved in conducting the inquiry. If the committee method is utilized, the committee should be formed under the guidelines presented in the "Investigation" section below.

Individuals chosen to assist in the inquiry process should have no real or apparent conflicts of interest bearing on the case in question. They should be unbiased and should have appropriate backgrounds for judging the issues being raised.

Institutions should consult their own legal counsel to minimize the risk of liability for actions taken in the conduct of the inquiry and

investigation. Institutions should also make clear any policies on providing legal counsel to complainants and respondents.

Purpose

Whenever an allegation or complaint involving the possibility of fraud is made, the designated senior administrator should initiate an inquiry—the first step of the review process. In the inquiry stage, factual information is gathered and expeditiously reviewed to determine if an investigation of the charge is warranted. An inquiry is not a formal hearing; it is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

Process

Upon initiation of an inquiry, the senior administrator is responsible for notifying the respondent within a reasonable time of the charges and the process that will follow. If the committee method is to be used, the committee members should be appointed and convened.

Whether a case can be reviewed effectively without the involvement of the complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit the complainant to remain anonymous. While it may be desirable to keep the identity of the complainant confidential during the inquiry phase, local laws that provide for open access to certain records may make such confidentiality impossible. During the inquiry, confidentiality is desirable in order to protect the rights of all parties involved.

The senior administrator should assume responsibility for disseminating the information to the appropriate individuals. Normally notification should be made in writing and copies filed in the office of the senior administrator. The safety and security of all documents must be assured.

When the inquiry is initiated, the respondent should be reminded of the obligation to cooperate by providing material necessary to conduct the inquiry. Institutional policies should state clearly that uncooperative behavior may result in an immediate investigation and other institutional sanctions.

Each institution should develop policies regarding the role of legal counsel in this and other phases of these proceedings. Those responsible for conducting the inquiry must be aware of the institution's policies.

Due to the sensitive nature of allegations of fraud, institutions should strive to resolve cases expeditiously. Deadlines should be established to facilitate the process. It is recommended that the inquiry phase be completed within 30 days of the initial written notification of the respondent. A 30-day period is consistent with the 1986 PHS guidelines and the 1987 NSF regulations. If the committee or whatever body is convened anticipates that the established deadline cannot be met, a report, citing the reasons for the delay and progress to date, should be submitted for the record, and the respondent and appropriately involved individuals should be informed.

Findings

The completion of an inquiry is marked by a determination of whether or not an investigation is warranted. There should be written documentation to summarize the process and state the conclusion of the inquiry. The respondent should be informed by the senior administrator whether or not there will be further investigation. If there is a complainant, he or she should be likewise informed.

Allegations found to require investigation should be forwarded promptly to the investigative body. Federal regulation requires that the agency sponsoring the research also be notified at this point.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all involved parties, should be taken. The proceedings of an inquiry, including the identity of the respondent, should be held in strict confidence to protect the parties involved. If confidentiality is breached, the institution should take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. Policies should state that allegations that have not been brought in good faith may lead to disciplinary action.

The institution should seek to protect the complainant against retaliation. Younger, less senior people are particularly vulnerable. Individuals engaging in acts of retaliation should be disciplined in accordance with the appropriate institutional policies.

Investigation

Purpose

An investigation should be initiated when an inquiry issues a finding that investigation is warranted. The purpose of investigation is to explore further the allegations and determine whether fraud has been committed. In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent should be informed when significant new directions of investigation are undertaken. The investigation should focus on accusations of fraud as defined previously and examine the factual materials of each case.

Structure

The investigative body may take any of several forms: an ad hoc committee to handle one specific case, a combination of standing committee and one-time-only appointed members, or a standing committee. Members of the investigative body may be chosen from within or outside the institution.

Regardless of the structure chosen, conflicts of interest must be examined scrupulously and any relationship with parties to the matter must be fully disclosed. Those investigating the allegations should be selected in full awareness of the closeness of their professional or personal affiliation with the complainant or the respondent. Any member of a standing committee who has an unresolvable conflict of interest in a given case should not be permitted to be involved in any aspect of the committee's handling of that case.

Whether a standing committee or an ad hoc committee is utilized, it is important that the committee have appropriate scientific expertise to assure a sound knowledge base from which to work.

Process

Upon receipt of inquiry findings that an investigation is warranted, the senior administrator should initiate investigation promptly, and the complainant and respondent should be notified of the investigation. All involved parties are obligated to cooperate with the proceedings in providing information relating to the case. All necessary information should be provided to the respondent in a timely manner to facilitate the

preparation of a response. The respondent should have the opportunity to address the charges and evidence in detail. The institutional procedures should address the role of legal counsel in the investigation.

Institutions may wish to adopt, as a matter of policy, a mechanism that would allow interim administrative action to be taken when justified by the need to protect the health and safety of research subjects and patients, or the interests of students and colleagues. Administrative action could range from slight restrictions to suspension of the activities of the respondent.

As previously noted, federal regulations require that the agency sponsoring a research project in which fraud is suspected should be notified as soon as the decision has been made to undertake an investigation. It is recommended that this practice be extended to include notification of all sponsors of research. The institution may wish, in turn, to seek assurances of the confidential treatment of this information. Significant developments during the investigation, as well as the final findings of the committee, should be reported to the sponsor. When the investigation is concluded, all entities initially notified of the investigation should be informed of its final outcome.

An institution's policy should require that an investigation be conducted as expeditiously as possible. The adoption of a specified time period of 120 days for the completion of an investigation is recommended, to reflect the seriousness with which an institution views accusations of fraud and to be in compliance with the PHS guidelines and NSF regulations. However, an institution may choose to acknowledge formally in its procedures that the nature of some cases may render the time period difficult to meet. It should be noted that an institution's ability to complete an investigation within a specified time period will depend heavily upon factors such as the volume and nature of the research to be reviewed and the degree of cooperation being offered by the subject of the investigation. An institution may choose to specify interim reporting to monitor the progress of an investigation. If the deadline cannot be met, an interim report should be submitted to the senior administrator with a request for an extension.

Findings

The findings of the investigative committee should be submitted in writing to the senior administrator. The respondent should receive the

full report of the investigation. When there is more than one respondent, each shall receive all those parts that are pertinent to his or her role. All federal agencies, sponsors, or other entities initially informed of the investigation also must be notified promptly. The institution should retain the findings of the investigation in a confidential and secure file.

Investigations into allegations of fraud may result in various outcomes, including:

1. a finding of fraud;
2. a finding of serious scientific misconduct short of fraud;
3. a finding that no culpable conduct was committed, but serious scientific errors were discovered;
4. a finding that no fraud, misconduct, or serious scientific error was committed.

Thus, an investigation of fraud may disclose evidence that requires further action even in those cases in which no fraud is found.

If an investigation has been launched on the basis of a complaint, and no fraud or misconduct is found, no disciplinary measures should be taken against the complainant, and every effort should be made to prevent retaliatory action against the complainant if the allegations, however incorrect, are found to have been made in good faith. If the allegations are found to have been maliciously motivated, disciplinary actions may be taken against those responsible.

Appeal and Final Review

Institutions may chose to provide respondents with an additional appeals process at this point through a written appeal of the investigative committee's decision. Appeals should be restricted to the body of evidence already presented, and the grounds for appeal should be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision making. New evidence may warrant a new investigation. The appeal should be filed promptly after a finding has been made. The institution should specify a senior administrative official (e.g., provost) to hear the appeal. After an appeal is concluded, an institution may also wish to provide for a final review by its chief executive officer or designee. The institution should note that the decision of the review is final.

Disposition

Responsibility for determining the nature and severity of disciplinary action should be specified in an institution's policy. This may, but need not necessarily, be done through the institution's regular faculty disciplinary or grievance procedures. Many actions may be available to the institution. Examples include:

- Removal from particular project,
- Letter of reprimand,
- Special monitoring of future work,
- Probation,
- Suspension,
- Reduction of salary,
- Reduction of rank,
- Termination of employment.

Consideration also should be given to formal notification of other concerned parties not previously notified, such as:

- Sponsoring agencies, funding sources;
- Coauthors, co-investigators, collaborators;
- Editors of journals in which fraudulent research was published;
- State professional licensing boards;
- Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated;
- Professional societies;
- Where appropriate, criminal authorities.

17

Principles and Procedures for Dealing with Allegations of Faculty Misconduct

Harvard University Faculty of Medicine

The integrity of the teaching, research, and clinical programs of the Faculty of Medicine requires that the Faculty pay careful attention to and resolve in an equitable manner allegations of misconduct of faculty appointees and fellows.

Because of variations in such factors as the kind of misconduct alleged, the seriousness of the allegations, the nature of the dispute over the facts, and the interests and involvement of other private or public institutions and agencies, the course of action that will enable the Faculty to fulfill this responsibility in the best possible manner is likely to vary from case to case. Accordingly, the procedures set forth below permit flexibility and are designed to provide a framework that should enable equitable resolution of allegations of misconduct in a wide variety of circumstances. When applying these procedures to a specific case, persons acting on behalf of the Faculty and others involved in the proceedings should keep in mind the following concerns:

— The importance of the Faculty's maintaining standards consistent with the highest traditions of teaching, patient care, and research in medicine and with the lawful obligations of the Faculty.

— The responsibility of the Faculty to the public and the scientific community and to the private and public institutions and agencies with which the Faculty is affiliated or has contractual or other arrangements.

— The necessity of the Faculty's protecting the rights and reputations of all individuals, including the person who is alleged to have engaged in misconduct and the person who has made the allegation.

NOTE: Adopted by the Faculty Council (Harvard University Faculty of Medicine) December 14, 1989. Reprinted with permission from Harvard University School of Medicine, Cambridge, Mass.

— The necessity of the Faculty's resolving allegations with care and objectivity, with ample opportunity for all interested parties to be heard, and as promptly as the circumstances permit.

Procedures

1. The Office of the Dean shall have principal responsibility for assessing a proper response to allegations[1] of misconduct concerning faculty appointees and fellows. To enable the Office of the Dean to meet this responsibility, all allegations of misconduct, whether initially received by a department head or other person, shall be promptly brought to the attention of the Office of the Dean (and where appropriate, the chief executive officer of an affiliated institution) unless they are clearly frivolous or otherwise lacking in substance.
2. Upon receipt of an allegation of misconduct, the Office of the Dean and, in those instances where the faculty member has a dual appointment, the chief executive officer of the other institution, shall determine, after such consultation as may seem appropriate, whether primary responsibility for resolving the allegation rests with the Faculty or with another institution. For example, primary responsibility for resolving an allegation of misconduct in connection with care of a patient would ordinarily reside in a hospital. In the case of an allegation pertaining to externally funded research, primary responsibility ordinarily rests with the institution that has administered the research grant or contract. An affiliated institution that has received support for research by a Harvard appointee may request, however, that allegations related to research by such appointees be dealt with by the Medical School. In any case, where the interests of two or more institutions are significantly implicated, it is expected that such inquiry and any investigation will proceed with the simultaneous participation of all concerned institutions, with agreement regarding which institution bears primary responsibility.
3. If primary responsibility rests with the Faculty, the Office of the Dean shall determine whether, taking into account the nature of the allegation, it is appropriate to attempt to resolve the matter through informal processes and discussions. The affected department head shall ordinarily have the responsibility for such efforts. Final resolution through informal means shall require the approval of the Office of the Dean. When primary responsibility rests with an affiliated institution, notice of resolution should be transmitted to the Office of the Dean.

4. If the matter is not resolved under paragraph 3, and if in the view of the Office of the Dean further proceedings are required, the Office of the Dean shall, in the absence of any specific Faculty procedure designed to cover the subject matter of the allegation, refer the allegation to the Committee on Faculty Conduct[2] with the request that the committee make such factual inquiry, investigation, findings, and recommendations to the Office of the Dean as seem appropriate to the circumstances. If there is a dispute over facts or for other good cause, the Office of the Dean, after consultation with the chairperson of the committee and other appropriate people, may first create one or more panels of inquiry of one or more individuals, who need not be members of the committee, to inquire into the facts and submit the result of its inquiry to the committee. In deciding upon the size and composition of the panel, the Office of the Dean, to help ensure competence and objectivity, shall take into account such factors as:

a. the subject matter of the inquiry, including the desirability of the panel's possessing competence in a specialized area or investigative skills,
b. the desirability of including on the panel persons associated with another affiliated hospital or individuals who are not members of the Faculty or are not associated with Harvard University, and
c. the importance of selecting people who have had no prior involvement in the subject matter of the inquiry.

The committee, with the benefit of a report from the panel of inquiry, if one is created, and after such further investigation, deliberations, and proceedings as it deems appropriate or necessary taking into account any applicable governmental regulations, shall submit its report to the Office of the Dean. The committee will submit conclusions and, ordinarily, comments on gravity of offense, possible sanctions, and prevention of future misconduct.

5. The Office of the Dean, after receiving comments on the report from such other people as may seem appropriate, shall decide the matter and take such action or make such recommendations as may be required. In cases involving another institution, the dean will confer with the chief executive officer of such institution in reaching a final resolution and applying appropriate sanctions. Sanctions may range, for example, from a letter of censure, to probation and monitoring, to termination of appointment.

6. The Office of the Dean, in carrying out its responsibilities under these procedures, shall bear in mind the concerns of the Faculty as set forth in the preamble and in particular:

a. The importance of care, fairness, and objectivity, and of the appearance of these attributes.

b. The necessity of informing at the appropriate time other Faculty and University officers, including the chairperson of the Committee on Faculty Conduct, the head of the department(s) involved, and the general counsel to the University, of the existence of allegations, and of consulting with these and other Faculty and University officers as resolution of allegations progresses.

c. The responsibility of informing and consulting with officers of affiliated institutions and of other private and public institutions and agencies to the extent necessary to meet in good faith the obligations of the Faculty to others, and of coordinating the Faculty's proceedings with those of affected institutions and agencies.

d. The importance of protecting the reputations of individuals and to that end ordinarily maintaining confidentiality to the extent practicable and to the extent consistent with other obligations of the Faculty during the course of and at the conclusion of proceedings.

e. The need to protect the rights of the person alleged to have engaged in misconduct, including the right to be informed with specificity at the appropriate time of the allegations and the evidence in support of the allegations, and the need to discuss with that person the procedures to be followed.

f. The need to protect the rights of individuals who, in good faith, make allegations.

g. The importance of using the staff resources of the Faculty and the University to aid in any inquiry and of broadening the scope of any inquiry, when indicated, to make certain that the full obligations of the Faculty are met.

h. The need to make certain that the president of the University is informed when allegations may constitute grave misconduct under the Third Statute of the University and that resolution of the matter proceeds with this fact in mind.

7. The Office of the Dean and the Committee on Faculty Conduct shall maintain records of any proceedings in which they are involved.

II. PRINCIPLES AND PROCEDURES FOR DEALING WITH ALLEGATIONS OF FACULTY MISCONDUCT

Addendum

When an allegation of misconduct by a Faculty appointee or fellow pertains to research, research training, applications for support of research or research training, or related activities for which Public Health Service (PHS) funds have been provided or requested, the following additional principles and procedures shall be observed in accordance with applicable governmental requirements:

1. Where the Office of the Dean determines that there is an allegation or other evidence of possible misconduct that would be subject to the Final Rule of the PHS entitled "Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," or any successor document ("PHS Rule"),[3] the Office of the Dean, after consultation with the chair of the committee and other appropriate people, shall create one or more panels of inquiry as described in the "Principles and Procedures for Dealing with Allegations of Faculty Misconduct." The panel(s) shall conduct an inquiry in accordance with the requirements of the PHS Rule and shall present a written report of the findings within sixty calendar days to the Committee on Faculty Conduct.
2. Within thirty days after receiving the report of the panel of inquiry, the committee shall determine whether the findings of that inquiry provide sufficient basis for conducting an investigation. If deemed to be necessary, such investigation shall be conducted in accordance with the requirements of the PHS Rule and with such additional assistance from the members of the panel of inquiry as the committee shall deem necessary and appropriate.
3. In the event the committee concludes that an investigation is warranted, the Office of the Dean shall report this decision in writing to the Director, Office of Scientific Integrity (OSI) of the National Institutes of Health, on or before the date the investigation begins and shall take any other actions required by the PHS Rule.
4. The committee shall submit a report of its investigation including any recommended sanctions to the Office of the Dean upon its completion. Unless an extension of time has been granted by OSI in accordance with the requirements of the PHS Rule, such report shall be submitted to the Office of the Dean within ninety days of the initiation of such investigation.

5. After receiving the final report and such comments from other persons as may seem appropriate, the Office of the Dean shall decide the matter and take such action or make such recommendations as may be deemed fitting, including submission of the final report to the OSI and any other actions required by the PHS Rule. In cases involving another institution, the dean will confer with the chief executive officer of such institution in reaching a final resolution.

NOTES

1. An allegation will ordinarily be made by a written statement describing the misconduct in sufficient detail to form the basis of an inquiry.

2. The Committee on Faculty Conduct, appointed by the dean, shall consist of nine faculty members with overlapping three-year terms.

3. "Misconduct" or "misconduct in science" means fabrication, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include error or honest differences in interpretations or judgments of data.

18

Procedures for Investigating Academic Fraud

University of Chicago

Report of a faculty committee under the chairmanship of Richard A. Epstein. Passed unanimously by the Council of the University Senate on December 10, 1985. The following is the distributed, corrected version issued January 24, 1986.

I. INTRODUCTION

Academic fraud is a threat to the intellectual integrity on which the advancement of knowledge depends. Academic fraud can taint the reputation of the University and of its honest scholars and researchers. It can compromise the position of collaborators, subordinates, and supervisors. Fraudulent research can lead other investigators down fruitless paths of inquiry, at enormous costs to knowledge, morale, careers, time, and money. Its occurrence places great strains upon collegial interaction.

The incidence of academic fraud is difficult to measure and is, one hopes, very small, but there have been a number of recent notable examples at other prominent universities. Academic fraud could happen here. One lesson learned from the reported cases is that *ad hoc* procedures do not allow universities to respond well to charges of academic fraud. Specific procedures developed in advance should help reduce the risks to everyone involved.

In recognition of the importance of the issues, the provost constituted the Committee on Academic Fraud in November, 1984. The committee had available to it the procedures now in place in the University to deal with academic fraud in the biological sciences. Its charge was to consider the standards and procedures that might be suitable for the University as a whole, including the biological sciences. This report recounts some of the major problems that the committee faced in its

Reprinted with permission from the University of Chicago, Chicago, Ill.

deliberations. It also sets out its major recommendations for University procedures and the reasons for adopting them.

II. DEFINING ACADEMIC FRAUD

The first task of this committee was to define academic fraud. In the abstract the definition seems easy, even if the identification of fraud in individual cases is not. The definition of fraud distinguishes between an honest mistake and deliberate misstatement made with an intention to deceive others. Academic fraud involves a deliberate effort to deceive and includes plagiarism, fabrication of data, misrepresentation of historical sources, tampering with evidence, selective suppression of unwanted or unacceptable results, and theft of ideas.

Some cases of academic fraud are easy to detect and prove. For example, the discrepancies between the published work and the records, notes, or data on which it is said to rest may be so great that intentional misrepresentation is the only possible inference. In other cases the inference is more difficult to draw. Some errors are unavoidable in any research; others may be the result of negligence, but not fraud. Whether research techniques were very sloppy or deliberately misleading sometimes raises difficult issues of fact and judgment. Making the appropriate judgment about research techniques requires sophistication about both the subject matter and the research and the research methods of the work under review. Finally, charges of the theft of scholarly ideas are hard to verify because ideas are often "in the air." Cases of simultaneous discovery are common in science.

Nonetheless, the distinction between fraud and negligence must be observed. The Committee on Academic Fraud has a limited mission. It is not a committee for the correction of poor scholarship, as the merits of scholarly work are best assessed in the ordinary academic marketplace. Yet once a question of fraud exists, it must be investigated under established procedures. Should it become clear that fraud is not involved, then the investigation should cease, regardless of the degree of carelessness found in the work under scrutiny.

III. INSTITUTIONAL STRUCTURE

A. The Standing Committee

On the model of the present biomedical procedures, the committee recommends that a Standing Committee on Academic Fraud be formed

to oversee and coordinate the University's handling of academic fraud cases. The Standing Committee should be composed of six faculty members appointed by the provost and drawn from among different academic disciplines in the University. The central functions of the Standing Committee shall be (1) to appoint specific panels with subject matter expertise to handle charges referred to the Standing Committee after preliminary investigation within the departments; (2) then to review the work of the appointed panel to see that it has followed these procedures in the individual case and, in evaluating the evidence, has not made any material errors, apparent on the fact of the record; (3) where charges of academic fraud are sustained, to inform the proper administrative officials within the University so that they can send notice of the fraud and its extent to appropriate persons outside the University; and (4) whenever necessary because current or past members of the University have been charged with or found guilty of academic fraud at other institutions, to appoint a panel to investigate the extent of fraud and to review its work.

The committee believes that this structure, while complex, is necessary. Given the need for special expertise, no single committee can do the direct investigating work itself. In addition, the structure we recommend ensures the diffusion of responsibility, since any purported fraud will be looked into by many individuals at three different levels of inquiry. The complex structure, therefore, provides an important check against sustaining false charges against an individual member of the University, while helping protect the individuals who serve on the Standing Committee or its panels from allegations of personal spite. Any investigation made pursuant to these procedures only determines whether fraud has been committed; it has no disciplinary functions, as these are lodged in the offices of the president and provost and are governed by separate University procedures.

B. Procedures of the Standing Committee on Academic Fraud

Any charge of academic fraud shall be handled in several stages. First, there shall be a preliminary examination by the responsible administrative official, who shall give notice that an inquiry is taking place to the appropriate dean, or where that official is the dean, to the provost. Second, if not terminated at this stage, the case then shall be referred to the Standing Committee on Academic Fraud. Third, the Standing Committee shall then refer the case to a special panel for investigation on the fact of fraud. Fourth, where fraud is found, then

the Standing Committee shall ordinarily refer the case to a new panel for an investigation into the extent of fraud.

1. The Initial Complaint.

Identifying academic fraud depends upon the willingness of individual members of the University community to report possible instances of academic fraud to persons with administrative responsibility for academic departments. Charges of academic fraud will sometimes be made by coworkers of the accused; they will sometimes come from other colleagues; they will sometimes be made by investigators and scholars outside the University. Charges of fraud are always an emotional matter; the procedures must be able to cope with cases in which coworkers fear retaliation by the accused or his or her friends and with cases where the charges are motivated by personal bitterness. Persons who make credible charges must be protected, while every effort must be made to discourage frivolous accusations.

The procedures set out are designed to ensure that an impartial and thorough review of the charges will be undertaken at a preliminary level, so that only those charges based on sufficient evidence to merit a further investigation will be referred to the Standing Committee. It should be stressed that so long as there is any reason to believe that academic fraud has been committed, the matter should be promptly forwarded to the Standing Committee. To secure these objectives, the procedures control any conflict of interest that might arise, for example, because the party charged and the administrative official have collaborated on research that is the subject matter of the charges. The procedures further provide that the administrative official responsible for reviewing the case should notify his or her dean (or where the dean is the responsible administrative official, the provost) that charges have been brought. The administrative official shall be free to consult in confidence with those persons in the University who might be able to provide useful assistance. Where the administrative official believes that there are no sufficient reasons to press the case forward, he or she may dismiss the charges, giving appropriate notice to the dean or provost, as the case may be, and to the party making the charges. In cases where the charges are dismissed, the administrative official may decide whether or not to notify the party charged of the charges made. Where the party charged has been informed of the charges, then he or she should be notified that they have been dismissed.

Where the preliminary investigation gives the responsible officer reason to believe that the case may have to be forwarded to the Standing

Committee on Academic Fraud, then he or she shall notify the party charged and provide an informal opportunity for the matter to be discussed before making the final decision about whether to forward the matter to the Standing Committee. Within a reasonable time thereafter the administrative official shall inform the party charged, the party making the charges, the appropriate dean, and the provost as to whether or not the case has been forwarded to the Standing Committee. The official shall forward the case to the Standing Committee where the charges cannot be dismissed as being without substantial merit.

2. Fact of Fraud.

Once the Standing Committee has received the charges of academic fraud from the appropriate administrative officer, it must appoint a panel, with at least three members, to investigate the truth of the allegations. Typically, the panel will be composed of members of the University who are knowledgeable about the subject matter of the work suspected of being fraudulent, but who are not working with the accused on the same or similar projects. Normally, members of this panel shall be drawn from within the University, but, when necessary, persons outside the University may be appointed to the panel. Since the Standing Committee must review the work of the panel, no member of the Standing Committee shall serve on the panel. The panel may inquire of whom it chooses but in any event must give the accused an opportunity to be heard and to call a reasonable number of witnesses to be examined in the course of the proceedings. The panel must also allow the accused to pose question to witnesses but may determine in its discretion whether the questions posed by the accused shall be oral or in writing.

One of the most vexing problems faced by the Committee on Academic Fraud was whether lawyers should be permitted to be present at the hearings. In general the committee believed that their presence would not often be necessary, but it recognized that the party charged might want the assistance of a lawyer when a career is at stake. The procedures we recommend set out the basic rules that regulate the role of lawyers before the panel. The essential rule is that the party charged has the right to bring a lawyer whenever he or she has the right to be present. When the party charged brings a lawyer to panel proceedings, the panel may request the University to supply it with a lawyer for its assistance. The panel may also determine whether it wishes to proceed by oral examination or written exchanges. The panel may meet in executive session at any time to prepare for the examination of

witnesses, to review the evidence, to prepare its report, and for whatever other purposes it regards as appropriate.

The procedures also take into account that the panel may not be able to gain access to relevant evidence obtained under guarantees of confidentiality unless the guarantee is waived. The procedures provide, however, that the party charged shall normally provide tabular information and summary data used in the preparation of reports, unless it is shown that this information involves a breach of some confidentiality agreement. Where confidential information is provided for the limited purposes of this investigation, then all parties involved in the case shall endeavor to ensure that confidential information is used only for the purposes for which it has been released.

Upon the conclusion of its investigation, the panel shall write a report that summarizes the evidence presented and indicates whether it has been unable to obtain relevant evidence. Where evidence is unavailable, the report should indicate whether the party charged claims that it has been destroyed, and, if so, whether the panel accepts the claim. Where the evidence is withheld, the report should indicate whether the panel believes that the party charged had good reasons for not presenting the information requested, i.e., a valid claim of confidentiality. The report shall indicate whether fraud has been found, and it shall give the panel's reasons for all its conclusions. The panel shall forward the report to the Standing Committee, which shall provide a copy of the report to the party charged, who has a right to comment upon it. When both the report and comments are received, the Standing Committee shall review the record it receives from the panel. Where the panel has found the party charged guilty of academic fraud, then the Standing Committee can reverse the decision and remand the case to the panel, or assign it to a new panel only where it thinks that the panel's findings are manifestly against the weight of the evidence or that the panel has applied a clearly improper standard of fraud. The Standing Committee itself cannot make a determination of fraud. Where the panel has found the party charged innocent of the charges of academic fraud, then the Standing Committee can remand the case to the panel or assign it to a new panel only if it finds by clear and convincing evidence that the panel's finding was tainted by the perjury of the party charged or the improper suppression of evidence not known to the panel.

Where academic fraud is found, a second panel will normally be required to examine its extent. There is a clear need for separate panels. The finding on the fraud issue should be made as quickly as possible and should not be deferred until a detailed examination of much of the scholarly output of the party charged has been carried out. Where the volume of work done by the party charged is substantial,

Section 5 of the procedures ordinarily directs that the investigation be focused on recent work or on work whose subject matter is closely connected with the research found fraudulent by the fact of fraud panel. The committee does not believe that it is possible to specify exactly the scope of inquiry for the panel investigating the extent of fraud, as that may depend in part upon the nature of the panel's initial findings. The extent of fraud panel will operate under basically the same rules as the fact of fraud panel, and its work will also be reviewed by the Standing Committee after opportunity to comment in writing is provided the party under investigation. The procedures also provide that appropriate notice shall be given to appropriate parties outside the University by the appropriate dean, and the provost shall be notified of the outcome at each stage of the proceedings.

C. Coordination of Investigations with Outside Institutions

Many researchers work at different institutions at various stages of their careers. Charges of fraud may be brought or established against someone who is no longer at The University of Chicago. Similarly someone now at The University of Chicago might be the subject of an investigation elsewhere, or might even be found guilty of academic fraud at another institution. In such cases, the committee believes that prompt action may be required at this University. Where investigations are known to be taking place elsewhere, the Standing Committee should keep abreast of developments so that it is in a position to initiate an investigation if and when a finding of academic fraud is made at another institution. When a finding of academic fraud is made elsewhere about a person currently or formerly associated with The University of Chicago, then the Standing Committee should determine whether an investigation should be undertaken here and, when necessary, constitute a panel to carry out that investigation. Any investigation conducted at the University should be coordinated with ongoing and completed investigations elsewhere.

D. Additional Rules

In order to ensure that there will be no gaps in the rules, the Standing Committee is given the power to supplement and clarify the rules contained in these procedures in a manner that is consistent with the basic structure of the overall system of review.

IV. CONCLUDING OBSERVATIONS

No set of procedures will be able to respond to all questions that might arise in responding to a single charge of academic fraud. The committee has done its best to anticipate the many problems that might arise in any case of academic fraud and believes that the procedures it recommends should prove serviceable in the event that allegations of fraud arise in the University.

COMMITTEE ON ACADEMIC FRAUD

Richard A. Epstein, *the James Parker Hall Professor in the Law School*, Chairman.

Charles M. Gray, *Professor in History and the College, Master of the New Collegiate Division, Associate Dean of the College, and Lecturer in the Law School*.

Jack Halpern, *Louis Block Distinguished Service Professor in Chemistry*.

Robin W. Lovin, *Associate Professor in the Divinity School*.

David Malament, *Professor in Philosophy, the College, and the Committee on the Conceptual Foundations of Science*.

Bernard Roizman, *the Joseph Regenstein Distinguished Service Professor and Chairman in Molecular Genetics & Cell Biology, Professor in Biochemistry & Molecular Biology, and the Committee on Genetics and Chairman of the Committee on Virology*.

John R. Schuerman, *Professor in the School of Social Service Administration and Member of the Committee on Public Policy Studies*.

MINORITY STATEMENT

I wish to address the issue of the role of attorneys in the proposed procedures for handling accusations of academic fraud. I want to begin, however, with some comments on a larger issue with which the committee struggled. In my view, that issue concerns the counterpoising of two quite different approaches to finding truth, the legal and the scholarly. Both are powerful models of discovery and proof. In the proposed procedures the committee has attempted to adopt elements of both, presumably in order to enjoy the benefits of both.

In the main, under the committee's proposed procedures, the investigations will be conducted by a group of scholars who are familiar with the relevant research area. The qualifications of such a group are

a thorough grasp of accepted methods in the field, of the state of knowledge in the field, and a commitment to the values of scholarship. But the cumulating finding of fraud turns on a determination of intent, the state of mind, the motivation of the accused. Because the legal system has well-worked-out procedures for making judgments on intent, we have tended to turn to those procedures as models (although in the legal system the ultimate determination of intent is often made by a layman jury). In my view, it would be best to allow the scholarly examination of the facts to proceed without the intrusion of another system for establishing truth.

Because of the potentially momentous consequences of these proceedings for the person under review, the committee has chosen to adopt some values and procedures of the legal system. That is, under the draft procedures a lawyer may be present at meetings of the committee with the accused and meetings of the committee with other persons. In addition, provision is made for modified cross-examination of witnesses. If the committee seeks the advice of experts uninvolved in the case, those experts may be required to submit to cross-examination. I believe that fairness and justice are afforded through other procedures the committee is proposing, without the use of these components of the legal system.

I am troubled by the committee's effort to provide some, but not all, features of a legal system. The features that are provided do not seem to be there to enhance the likelihood that truth will be found; in fact the committee appears to feel that the presence of lawyers in these meetings is not desirable. There is a belief that the proceedings can retain a non-legalistic character if lawyers are allowed in a limited role. It seems to me likely that once lawyers are present, the proceedings will shift in tone, from scholarly inquiry to legalistic battles. Evidence will be considered not in light of scientific criteria but in terms of the courtroom. There is potential for intimidation of scholars who must be able to make judgments on scientific grounds.

The framing of proper procedures must obviously balance competing interests, the interest in ridding the body of scholarship of falsehood, the interest of the institution in maintaining its integrity, and concern for fairness to the person under review. I submit that the procedures contemplated by the committee will unduly jeopardize the interests of scholarship and the University. I submit further that a proceeding without lawyers would continue to have substantial protection for the accused. Decency, civility, and objectivity are all high ideals of the academy and would be expected to pervade the deliberations of the investigating committees. The possibility of eventual appeal to the courts remains (through suits for defamation of character, violation of

employment contract, and probably other actions). That possibility both preserves important rights of an accused found in the University process to have been fraudulent in research and provides additional incentive for the relevant committees to proceed with care.

John Schuerman

PROCEDURES FOR INVESTIGATING ACADEMIC FRAUD

Section 1. Scope of the Work

The Standing Committee on Academic Fraud shall be appointed by the provost to coordinate the University's efforts to investigate allegations of academic fraud. Academic fraud means plagiarism; the deliberate falsification, misstatement, and alteration of evidence or data; the deliberate suppression of relevant evidence or data; and the deliberate misappropriation of the research work and data of others.

Section 2. The Standing Committee on Academic Fraud

The provost of the University shall designate a Standing Committee on Academic Fraud which shall consist of six members drawn from different areas within the University. The members of the Standing Committee shall serve for terms of three years. The initial appointments shall be for staggered terms, with two of the members appointed for one year, two for two years, and two for three years. The provost shall designate the chairman of the Standing Committee.

Section 3. The Initial Complaint

A. Procedures

Any person who has reason to believe that any faculty member, staff member, or student has engaged in an act of academic fraud should make a report of that act to the first responsible administrative officer with supervisory power over the person so charged. Charges against students are subject to these procedures only to the extent that they involve dissertations of students who have received their degrees or work published or submitted for publication; other cases of alleged academic fraud by students shall be subject to the normal disciplinary

rules governing students. In the normal case governed by these procedures, the responsible academic official will be the department chairman, but when there are sections within a department it typically will be a section head. Where there are no departments, it will typically be the dean. When such charges are brought to any other person, they should be referred to the appropriate administrative official.

The administrative officer shall conduct a preliminary and informal investigation to see whether there is any substantial merit to the charges in question. That official shall have the right to consult in confidence with any person whose advice he or she finds appropriate before passing on the matter, and shall in any event notify his or her dean (or where the dean is in charge of the case, the provost) that the matter has been raised and thereafter of its disposition. When the charges are determined to be without substantial merit, then the matter may be dismissed without any written report being filed and without giving any notice to the party charged, provided always that if the party charged has been given notice of the charges, then he or she shall be given notice that they have been dismissed. In all cases, the party making the charges shall, however, be informed that the case has been dismissed.

When the allegations cannot be dismissed as being without substantial merit, then the administrative officer shall give the party charged an informal opportunity, which may take place without the presence of lawyers, to respond to the charges that have been made. If the administrative officer is then satisfied that the case is not without substantial merit, the matter shall be forwarded to the Standing Committee on Academic Fraud, together with all records and evidence in the case. When the case is forwarded to the Standing Committee, notice shall be given to the person charged and to the person who initially brought the matter to the attention of the administrative officer. Notice that a case has been forwarded to the Standing Committee shall also be sent to the Office of the Provost. Whenever possible, the decision whether or not to refer the matter to the Standing Committee shall be made within fifteen days after the matter has first been raised.

B. Conflict of Interest

Where the responsible administrative official charged with investigating a complaint perceives that he or she has a conflict of interest, he or she should refer the matter to the next superior administrative official. In consultation, the two shall decide whether the responsible administrative official should remove himself or herself from handling the case. If removal is necessary, the superior administrative

official may refer the matter to another person in the department for investigation, in which case the superior official may still receive any report that must be made before the complaint is dismissed or referred to the Standing Committee. Alternatively, the superior administrative official may act as the original investigating official, in which case his or her superior shall act as the reviewing officer.

A conflict of interest arises whenever the administrative officer has collaborated with the party charged on any research that is the subject matter of the complaint or on any matter closely related to it. It also arises whenever the administrative official is bound by blood or marriage to the party charged or whenever any compelling reason prevents him or her from making a fair and impartial disposition of the entire matter. The same standards for conflict of interest apply for the reviewing officer in any case.

Section 4. Inquiry into the Fact of Fraud

A. Selection of Panel

Upon receipt of a complaint of academic fraud, the Standing Committee shall constitute within fifteen days a special panel of not fewer that three members to investigate the charges. Members of the panel shall ordinarily be drawn from within the University and shall include persons not closely associated with the individual so charged, but who have knowledge of the field of research of the person charged. Where circumstances require it, the Standing Committee can appoint persons outside the University to the panel. No member of the Standing Committee shall be a panel member.

B. The Operation of the Panel

1. Collection of Evidence.

a. The panel shall examine the evidence to determine whether or not academic fraud has been committed. Upon request of the panel, the party charged shall turn over to this panel the following types of information relevant to the allegations of fraud raised by the case:

i. research notes, papers and notebooks, logs, source documents, computer printouts, and machine-readable materials;

ii. a list of all current and former collaborators and coworkers;

iii. a list of published abstracts, papers, and books and copies of abstracts, papers, and books pending publication or review; and
iv. a list of reports and grant applications submitted to outside foundations and funding agencies and copies of such reports and applications.

The panel may inspect the log materials, research notebooks, and other research materials of the person so charged and, when appropriate, may take written or oral evidence from the person charged, from other faculty, staff, and students in the University, and from any party outside the University. Copies of any written material or other exhibits presented to the panel shall be provided the party charged or, when that is not feasible, made available to the party charged for inspection. Judicial rules governing the admissibility of hearsay evidence, authentication of documents, and the like shall not govern the investigation of the panel except insofar as it chooses to adopt them. The proceedings shall be conducted in confidence to the extent possible.

b. Where confidential information is relevant to an examination of academic fraud, the party charged shall not be required to produce that information except in a form that preserves the confidential character of the information in question, unless a waiver can be obtained from the relevant parties protected by the promise of confidentiality. Summary data or intermediate tabulations shall be provided to the panel unless shown to violate the rights of privacy of other individuals.

2. *Right to the Assistance of a Lawyer or Other Person.*

The party charged shall have the right to be accompanied by a lawyer or any other person at any proceeding in which the party charged has a right to be present. If the party wishes to have a lawyer present when appearing before the panel, then he or she shall give the panel notice in writing in advance of the session at which the lawyer intends to be present. In the event that the party charged chooses to be accompanied by a lawyer, the panel may ask the University to provide it with a lawyer to assist it whenever the lawyer for the party charged is present. The party charged is entitled to have the panel consider evidence by a reasonable number of witnesses, to be present when the panel is taking oral testimony from witnesses, and to examine any witness who presents evidence, oral or written, to the panel. The panel shall determine the extent to which the examination of witnesses by the party charged shall be written or oral. When that examination is oral, the panel may limit the nature and the extent of the questioning

permitted. When the evidence from witnesses presented to the panel is in writing, a copy shall be presented to the party charged for review and comment.

3. Preparation of the Panel Investigation and Report.

The panel may meet in executive session to prepare for the examination of witnesses and collection of evidence, to evaluate the evidence presented to it, and to prepare its findings and reports. The panel shall prepare a report which shall summarize the evidence presented and give reasons for its findings on the question of whether academic fraud has been committed. When evidence is not presented to the panel, it shall note whether the party charged claims that it was destroyed prior to the investigation or whether it was withheld under a claim of confidentiality or other privilege. The panel shall indicate whether it accepts the explanation offered by the party charged for the nonproduction of evidence, and the extent to which the unavailable evidence affected its ability to make a finding on whether academic fraud has been committed. The panel shall be expected to make its final report within forty-five days after it is formed. A copy of the report shall be forwarded to the Standing Committee on Academic Fraud.

4. Review of the Panel Report by the Standing Committee.

The Standing Committee shall review the report of the panel after it provides the party charged with the panel report and an opportunity to comment on it in writing within fifteen days after its receipt. Where the panel has made a finding that the party charged is guilty of academic fraud, its decision shall be accepted by the Standing Committee unless it determines either that the decision is against the manifest weight of the evidence or that it rests upon a clearly improper interpretation of academic fraud. In either case the Standing Committee may reverse the decision of the panel, remand it to the panel with instructions for further consideration, or transfer the case to a new panel. Where the panel has made a finding that the party charged is innocent of academic fraud, then its decision shall be binding upon the Standing Committee unless there is clear and convincing evidence that the party charged, unbeknownst to the panel has committed acts of perjury or improperly has suppressed relevant evidence. Where the party charged has so misbehaved,

the case may be remanded to the original panel with instructions for further consideration, or assigned to a new panel. Copies of any decision made by the Standing Committee shall be provided to the panel and the party charged. The Standing Committee shall issue its report within fifteen days after receiving the comments from the party charged and provide copies of its report, the panel report, and the comments of the party charged to the appropriate dean and to the provost.

5. *Notice to Outside Parties at the Conclusion of the Fact of Fraud Investigation.*

When a person charged has been found to have committed academic fraud under this section, then the appropriate dean shall, as quickly as possible, send notice to all appropriate outside granting agencies, journals, and research institutions with whom the party found to have committed academic fraud is now or has been professionally affiliated. The notice sent to the outside parties need not include the entire report of the panel and statement of the accused, but it should summarize the conclusions reached by the panel and the comments made by the party charged, and should indicate the status of any further pending investigations. The report may indicate the Standing Committee's belief that other related work by the party charged may be contaminated by the fraud and the reasons for its belief. Any notice sent may include statements that collaborators of the party found to have committed academic fraud are innocent of any misconduct.

Section 5. Investigation into the Extent of Fraud

A. Appointment of Panel to Determine Extent of Fraud

Upon a finding of fraud, the Standing Committee, except where circumstances clearly suggest that academic fraud has been confined to the single instance under review, shall appoint a second panel to investigate whether the party found to have committed academic fraud has committed least three persons knowledgeable in the field of inquiry, including academic fraud on other occasions. That panel shall consist of at at least two from outside the University. Members on the fact of fraud panel constituted under Section 4 may serve on this panel.

B. Scope of the Extent of Fraud Investigation

The extent of fraud panel shall investigate (a) academic work, published or unpublished, that is closely connected to the work found fraudulent in the fact of fraud investigation, and (b) other work that the fact of fraud panel believes has fallen under suspicion. Where the initial findings of the extent of fraud panel so indicate, the investigation may be expanded to cover additional research of the party charged.

C. Conduct of Investigation

The powers of the extent of fraud panel, the rules of confidentiality, the rules of evidence, the right to examine witnesses and obtain relevant documents and records, the right to the assistance of a lawyer or other person, and all other procedural aspects of the extent of fraud investigation shall be the same as they are in the fact of fraud investigation. The extent of fraud panel shall have access to all evidence made available to the fact of fraud panel. Upon the conclusion of its investigation, the panel shall prepare a report which indicates which work should be withdrawn or retracted and which not. The report may also indicate the work of collaborators and coworkers that is not tainted by fraud. The report shall be forwarded to the Standing Committee within thirty days after the conclusion of its investigation.

D. Review of the Panel Report by the Standing Committee

The Standing Committee shall provide the party charged with a copy of the panel report and an opportunity to comment on it in writing within fifteen days of its receipt. Thereafter the Standing Committee shall review the report. The Standing Committee shall accept the report when the panel has applied the proper standards for evaluating academic fraud and has made no error in the evaluation of evidence that is apparent from the face of the record. When the Standing Committee does not accept the report of the panel, it may hold that some or all the work investigated is not tainted by fraud; or it may remand the case, in whole or in part, to the panel with appropriate instructions; or it may ask a new panel to review all or part of the work. At the conclusion of its review, the Standing Committee shall prepare its final report of the case which shall be provided to the panel and to the party under investigation. The report may be a simple acceptance of the panel report, but, where the panel recommendations are not accepted, then the

report should contain a statement of reasons for the actions of the Standing Committee. A copy of its report, the panel report, and the written comments by the party investigated shall be forwarded to the provost and to the appropriate dean, who shall ensure that notification is provided to the appropriate persons outside the University.

Section 6. Coordination of Investigation with Other Institutions

When the Standing Committee learns that any person currently or formerly associated with the University is under investigation elsewhere, it shall, when appropriate, request a report as to the status of its inquiry from the investigating committee. Where any person currently or formerly associated with The University of Chicago has been found guilty of academic fraud for work done at another institution, the Standing Committee on Academic Fraud shall when appropriate form a panel to investigate whether any work done at The University of Chicago has been tainted by that fraud. The panel shall operate under the rules set out in Section 5 of these procedures and shall coordinate its investigations with those undertaken at any other institution.

Section 7. Rule-making Powers of the Standing Committee

Consistent with the rules set out above, the Standing Committee shall have at any time the power to supplement and clarify the applicable procedures.

19

Draft Revision of Policy on Integrity of Research

University of California, San Diego

I. POLICY

Integrity of the research enterprise is central to the search for new knowledge. All individuals engaged in research at the University of California, San Diego, are responsible for adhering to the highest standards of intellectual honesty. Faculty and supervisors of research personnel (including graduate students, postdoctoral scholars) have a special obligation to set an example and create an environment which encourages absolute intellectual integrity. Open communication, an emphasis on quality (not quantity) of research and publications, appropriate supervision of personnel, maintenance of accurate and detailed records of research procedures and results, and suitable assignment of credit and responsibility for research and publications are all elements of intellectual honesty.

Types of research misconduct include plagiarism; failure to provide appropriate citations; falsification of data (from fabricating data to selective reporting); abuse of confidentiality; and deception or other practices that seriously deviate from those that are commonly accepted within the scholarly and scientific community for proposing, conducting, or reporting research. Misconduct does not include honest error or honest differences in interpretations or judgments of data.

University policies set forth expectations for high standards of ethical behavior for faculty and students involved in research and provide procedures for addressing allegations of misconduct in research. Those policies and procedures are set forth in the Bylaws of the Academic Senate, the University Policy on Faculty Code of Conduct and the Administration of Discipline, and University Policies Applying to

NOTE: Draft revised June 12, 1991; revision is ongoing. Reprinted with permission from the University of California, San Diego.

Campus Activities, Organizations, and Students—Part A, Student Conduct and Discipline. Procedures for administration of discipline also exist for other academic and staff employees in accordance with applicable personnel policies and collective bargaining agreements. (A list of policies that pertain to integrity of research at UCSD is attached.)

To foster intellectual honesty, schools, departments, and research units at UCSD are expected to develop guidelines and procedures which implement the above principles and which are designed to fit the distinctive research climate and needs of their individual disciplines. These guidelines may cover responsibilities of research supervisors, assignment of credit for publications, training of research apprentices, requirements for record keeping of experimental procedures and data storage, and standards for merits and promotions which value quality over quantity.

It is the responsibility of each individual engaged in research at UCSD to be informed of University policies relating to research and of the policies and procedures of the agencies funding his or her research. Copies of relevant policies are available in the office of the department in which the individual is working and will be provided at no cost. Each new employee engaged in research should be given a copy of this policy statement.

II. PROCEDURES FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

The University will continue to take prompt and vigorous action to investigate and address allegations of misconduct in research, based on the following principles:

- Institutional and academic responsibility for self-regulation;
- Mechanisms to protect to the greatest extent possible the due process rights of the accused, the interests of those making allegations, and the public interest;
- Compliance with requirements for timely notification of funding agencies;
- The highest degree of confidentiality compatible with an effective response and applicable sponsor reporting requirements (Appendix, item 3); and
- Precautions against real or apparent conflict of interest.

A. Reporting Misconduct

1. Suspicion of fraudulent or unethical research practices should be reported immediately to the chair of the department or the director of the organized research unit. A complaint may alternatively be made to the Dean of Graduate Studies and Research, Dean of the School of Medicine, the Dean of Marine Sciences, or their designees. Designees will be identified to persons who call the deans' offices and may be consulted confidentially by any faculty, student, or staff member with a question or concern about misconduct. Requests for investigations from outside the university should be directed to the appropriate dean.
2. The individual filing a complaint may choose to keep his or her identity confidential. If the individual has directly observed unethical behavior, however, he or she should be informed that it may be necessary in the absence of sufficient other evidence to testify before a faculty committee to that fact in order for an investigation to proceed.
3. If the person receiving the complaint determines that it is groundless, a preliminary inquiry should not be undertaken. The person making the complaint should be informed of the decision not to proceed. A brief memorandum to the file should be prepared and maintained by the chair, director, dean, or designee.
4. If the individual receiving the complaint determines from the complaint and/or from other information that unethical conduct may have occurred, then a preliminary inquiry shall be undertaken. If the initial report of misconduct is oral, the individual receiving the complaint shall put it in written form, with supporting documentation if available, before a preliminary inquiry can proceed. A copy of the written complaint should be forwarded to the dean.

B. Preliminary Inquiry

1. The dean, upon receiving the complaint, shall appoint an investigator or a faculty committee to conduct a preliminary inquiry to determine whether there is reasonable cause to believe that the policies and regulations of the University have been violated. The preliminary inquiry should be initiated immediately and the appropriate funding agency notified if required.
2. Within fifteen (15) days of receiving the written complaint, the dean shall, after seeking advice of General Counsel, inform the accused in writing of the complaint, the name of the person or committee members who will conduct the inquiry, and the process to be followed.

3. The investigator or faculty committee should be extremely circumspect during the inquiry—contacting only those absolutely required and apprising them of the need for confidentiality. No extra-University inquiries should be made at this juncture unless absolutely necessary and only after consultation with the dean.
4. If the investigator or faculty committee determines that the complaint is groundless, is insubstantial, or does not indicate a violation of University policy, no action need be taken other than to prepare a brief report of the preliminary inquiry to be retained by the dean. The dean shall send a copy of the report to the Vice Chancellor-Academic Affairs. The person who filed the complaint and the accused shall be informed in writing of the results of the preliminary inquiry.
5. If the individual who reported the alleged misconduct is dissatisfied with the outcome described in 4 above, he or she may appeal to the Vice Chancellor-Academic Affairs. The vice chancellor will review the report of the preliminary inquiry and the evidence submitted by the accuser in support of the appeal, and determine whether the inquiry should be pursued further, the inquiry should be closed, or a formal investigation should be conducted.
6. If, after a preliminary inquiry, the investigator or faculty committee determines that a violation of university policies or regulations has, or may have, occurred, a written report of the findings, including the evidence to support the findings, shall be submitted to the dean. The person who filed the complaint and the accused shall be informed in writing of the results of the preliminary inquiry.
7. The dean may consult the faculty committee or, if an investigator was used, an ad hoc committee of faculty to decide whether to seek an informal resolution or whether to proceed with a formal investigation. The decision shall take into consideration the seriousness of the violation of ethical standards as well as University policies.
8. If the dean and the accused reach an informal resolution, then the resolution shall be committed to writing, signed by both parties, and maintained by the dean. Those with a need to know should be informed of the outcome. NOTE: In cases involving faculty covered by Academic Senate Bylaw 230, the deans' authority is limited to the imposition of the disciplinary action of Written Censure which has been delegated to the deans by the Chancellor.
9. This stage of the inquiry shall normally be completed within thirty (30) calendar days of the date of the formal notification to the accused referred to in II.B.2. above. If an extension of time is required, the accused shall be notified, and the record of the inquiry shall include documentation of the reasons for exceeding the 30-day period.

C. Formal Investigation

1. If an informal resolution cannot be achieved, or if the still-suspected violation is deemed a serious form of research misconduct, the dean, after consultation with the department chair or director of the organized research unit and the Academic Senate, and within thirty (30) calendar days of receiving the report of the preliminary inquiry referred to in II.B.6. above, shall appoint an Ad Hoc Investigative Committee which shall be charged to conduct a thorough investigation.
2. The Ad Hoc Investigative Committee shall be composed of at least three faculty members, including at least one with expertise in the research area under investigation and at least one faculty member from another department. If the accused holds an academic appointment but is not a faculty member or a student, then the investigative committee shall have at least one member who holds appointment in the same title series as the accused.
3. The dean and the members of the Ad Hoc Investigative Committee shall take precautions against conflicts of interest by requiring explicit disclosure of possible conflicts and excusing any members of the committee whose conflicts are serious.
4. The person accused of misconduct shall be informed in writing of the appointment of the Ad Hoc Investigative Committee and its membership.
5. The accused shall be informed of his or her right to be represented when being interviewed by the Ad Hoc Investigative Committee.
6. In carrying out its investigation, the Ad Hoc Investigative Committee shall act as promptly as possible, ensure fairness, and secure necessary and appropriate expertise (which may include experts from off campus) to carry out a thorough and authoritative evaluation of the relevant evidence. If requested by the committee, university counsel will be assigned to assist in the investigation.
7. The committee shall provide the accused the opportunity to respond to the allegations in the complaint.
8. The dean, in consultation with the Ad Hoc Investigative Committee, shall inform the funding agency at appropriate times consistent with agency requirements that an investigation is being undertaken and of the results of the investigation.
9. The dean and the Ad Hoc Investigative Committee shall undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

10. If the Ad Hoc Investigative Committee determines that the allegations are not supported by the evidence, it shall inform the dean in writing. The dean will notify the appropriate funding agency and will inform everyone who has knowledge of the case of the outcome of the investigation.
11. If the Ad Hoc Investigative Committee determines that the accused has engaged in unethical or fraudulent research practices, it shall submit a written report of its findings and recommendations to the dean and may recommend a disciplinary action.
12. To the greatest extent possible, the committee's decision should be supported by documentary evidence. If documentary evidence is not available, the testimony and reasoning that led the committee to its conclusion should be presented in detail.
13. The Ad Hoc Investigative Committee shall submit its findings and recommendations, along with the documentary evidence, within one hundred twenty (120) calendar days of its appointment. Extensions of time for good cause may be granted by the appointing authority.

D. Discipline

1. The dean shall as soon as possible provide the accused with a copy of the Ad Hoc Investigative Committee's findings and recommendations and with an opportunity to respond in writing within fourteen (14) calendar days.
2. The dean may propose a disciplinary action. If the accused accepts the disciplinary action, the dean will take appropriate steps to implement the disciplinary action. If the accused is subject to the provisions of Academic Senate Bylaw 230, the disciplinary action, excepting Written Censure which has been delegated to the deans, must be approved by the chancellor.
3. If the accused does not accept the proposed disciplinary action, the dean shall submit the findings of the committee to the appropriate administrative officer indicated below with the recommendation that disciplinary proceedings be initiated in accordance with Section E of these procedures.
4. Disciplinary proceedings shall normally be completed within sixty (60) days from the date the complaint was received. Extensions of time for good cause may be granted by the Vice Chancellor-Academic Affairs.

Faculty covered by Bylaw 230	Vice Chancellor, Academic Affairs
Non-Senate Academic Appointee (unrepresented)	Department Chair or ORU Director
Non-Senate Academic Appointee (represented)	See Memorandum of Understanding with UC-AFT
Staff Appointee	Immediate Supervisor or Department Chair
Postdoctoral Scholar, Fellow or Trainee, or Visiting Scholar	Dean of Graduate Studies, Dean of SOM, or Director of SIO, as appropriate
Graduate Student	Dean of Graduate Studies
Graduate Medical Student	Dean of SOM
House Staff	Dean of SOM
Librarian (represented)	See Memorandum of Understanding with UC-AFT
Librarian (unrepresented)	University Librarian
Undergraduate Student	Vice Chancellor, Undergraduate Affairs

E. Application

The disciplinary procedures to be applied are indicated below for each category of appointee who may engage in research.

1. Academic Senate Members. The Academic Senate has agreed to allow the investigation by the Ad Hoc Investigative Committee to stand in lieu of the appointment of the administrative officer called for in Academic Senate Bylaw 230. The Academic Senate has also agreed to extend coverage of Bylaw 230 to the following: Adjunct Professor

Series, the Clinical Professor Series, Acting Assistant Professors, and Supervisor of Physical Education Series.

2. Non-Senate Academic Appointees. Discipline of unrepresented appointees in this category must conform to the requirements of APM 140 and PPM 230-5. Included in this category are Academic Administrators, Academic Coordinators, Program Coordinators, Continuing Education Specialists, CME Fellows, Postgraduate Researchers, Professional Research Series, Research Associates, Research Fellows, Specialist Series, Visiting Researchers, Clinical Affiliates, Visiting Professor Series, Language Assistants, Readers, Research Assistants, Teaching Assistants, Teaching Fellows, Visiting Scholars, and Librarians excluded from the bargaining unit because of their supervisorial status.

   Discipline and dismissal actions involving exclusively represented non-Senate academic appointees must conform to the requirements of Article XXXI of the Memorandum of Understanding between the University of California and the University Council-American Federation of Teachers.

3. Staff Appointees. Appointees in this category are either (a) exclusively represented by a union, in which case the Memorandum of Understanding applies to disciplinary actions taken against them, or (b) covered by staff personnel policies, specifically Staff Personnel Policy 740, *Dismissal of Regular Status Employees*.
4. Postdoctoral Scholars, Fellows, and Trainees. (Grievance and disciplinary procedures for this classification are under development.)
5. Students. Charges of misconduct by a student will be processed in accordance with existing procedures for disciplining students.
6. House Staff. Section J, *Personnel Records, Discipline, Dismissal, Due Process* of the *House Officer Policy and Procedure Document*, approved by the chancellor on June 13, 1985, governs the discipline and dismissal of House Staff.
7. Librarians. Librarians are exclusively represented by the University Council-American Federation of Teachers, and discipline and dismissal actions involving non-excluded Librarians must conform to the requirements of Article XXIV, *Corrective Action, Dismissal, Release*. Discipline and dismissal of excluded librarians (those excluded from the bargaining unit because of their supervisorial status) are covered in Category 2.

APPENDIX

Policies Which Pertain to Integrity in Research at the University of California, San Diego

1. University Policy on Integrity of Research (June 19, 1990).
2. University Policy on Faculty Conduct and the Administration of Discipline (June 14, 1974), including the faculty Code of Conduct (August 26, 1988).
3. Any policies or regulations concerning research fraud and unethical conduct issued by federal, state, and private agencies from which the University has accepted research funding. Such regulations include, but are not limited to, "Responsibilities of Public Health Service Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science" (42 CFR, Part 50, Subpart A) and the National Science Foundation's final regulations on misconduct in science and engineering research (45 CFR, Part 689).
4. University Policy on Disclosure of Financial Interest in Private Sponsors of Research (April 26, 1984).
5. Policy on Outside Professional Activities of Faculty Members (April 13, 1979).
6. Standing Order of the Regents of the University of California 103.1(b), Special Provisions Concerning Officers, Faculty Members, and Employees of the University, Service Obligations.
7. University Policy on the Use of Animals in Research and Teaching (October 15, 1984).
8. University Policy on the Protection of Human Subjects in Research (September 2, 1981).
9. Guidelines on University-Industry Relations (May 17, 1989).
10. University Regulation No. 4, Special Services to Individuals and Organizations, Academic Personnel Manual, Section 020 (June 23, 1958).
11. University Policies Applying to Campus Activities, Organizations, and Students—Part A, Student Conduct and Discipline (October 31, 1983).
12. Business and Finance Bulletins G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest (revised April 15, 1986, and June 15, 1989).
13. Guidelines for Disclosure and Review of Principal Investigators' Financial Interest in Private Sponsors of Research (April 27, 1984).
14. University of California Patent Policy (November 18, 1985, and revised in part on April 16, 1990).

15. University Copyright Policy (August 1, 1975).
16. University Policy and Procedures for Reporting Improper Governmental Activities and Protection Against Retaliation for Reporting Improper Activities (January 1, 1990).
17. Statements of professional ethics and responsibility. In considering allegations of scientific or ethical misconduct, the University will, if it deems it to be appropriate, consider the statements of professional ethics and responsibility of the professional society of which the accused is a member.