# Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 1

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Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL; National Research Council

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Board on Life Sciences

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
*OF THE NATIONAL ACADEMIES*

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April 20, 2010

Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
Building 1
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

At your request, the National Research Council (NRC)[1] reconvened its Committee on Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory (NEIDL), Boston University[2] to provide you and your Blue Ribbon Panel with further technical input on the scope and design of any additional studies that may be needed to assess the risks associated with the siting and operation of the NEIDL.

In particular, you asked the NRC committee to meet with the NIH Blue Ribbon Panel in public at key milestones in the development of the draft risk assessment. To this end, the NRC committee met in open session with the Blue Ribbon Panel on March 19, 2010 to hear presentations by NIH's contractors on the approaches they intend to take in conducting the risk assessment. Following the open meeting, the NRC committee met in closed session to prepare this brief letter report on the plan for the supplementary risk analyses, focusing on whether the analyses are scientifically and technically sound in general and whether they address the concerns raised by the NRC in its first two letter reports. The committee's full statement of task, as developed with your office, is provided in the main body of this report.

The committee heard plans, but not yet results. In general, the NRC committee finds the proposed approaches to conducting the risk assessment suitable and well planned. The agents selected for analysis are appropriate and comprehensive, and the expertise available on and to the assessment team is strong. NIH and its contractor (Tetra Tech) appear to recognize data

[1] The principal operating arm of the National Academy of Sciences and the National Academy of Engineering.
[2] A list of committee members and their biographies is included as Attachment A.

limitations and the need for flexibility in study design. The committee encourages NIH and Tetra Tech to develop qualitative analyses (an explanation of the safety and risk profile) of all 13 pathogens on the list in a manner that is clear and accessible to the public. For example, the qualitative analyses in the body of the assessment could be supplemented with results of quantitative modeling planned for five pathogens, with details provided in appendices. Further, the committee encourages NIH and Tetra Tech to rely on data that are available from existing case studies, public health surveillance of the surrounding communities, and incidents, not only to support its models but also to provide a complete and understandable picture for the public. The final risk assessment must also be able to serve as an effective risk communication tool. More detailed observations on these points appear in the body of the report.

This report reflects the consensus of the committee and has been reviewed in accordance with standard NRC procedures. The work was supported by Frances Sharples, Director of the NRC's Board on Life Sciences, Panola Golson of the Board on Environmental Studies and Toxicology, and Kathi Hanna, our professional science writer.

The committee thanks NIH for seeking its input as it works to develop resources for advancing the national capacity to protect and improve health. The committee hopes that its suggestions will be useful in this regard.

Sincerely,

John F. Ahearne, Chair
Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL

cc: Amy Patterson, M.D.

# BACKGROUND AND INTRODUCTION

In 2003, the Boston University Medical Center (BUMC) was awarded a $128 million grant from the National Institutes of Health (NIH) to build one of two national high- and maximum-containment laboratory facilities for research on biological pathogens. The National Emerging Infectious Diseases Laboratories (NEIDL) are meant to support the National Institute of Allergy and Infectious Diseases' biodefense research agenda, conducting research to develop new approaches to treating, preventing, and diagnosing a variety of bacterial and viral diseases. Diseases and agents to be studied include viruses (e.g., Ebola, Marburg, dengue fever, Lassa fever, and highly pathogenic influenza) and bacteria (e.g., *Shigella* and plague) that occur naturally and cause infections or that could be used in deliberate attacks. The facility includes a biosafety level 4 (BSL-4) containment laboratory housed in a 192,000 square foot building. Although the NEIDL BSL-4 laboratory space accounts for only 13 percent of the building's total space, it has been the source of virtually all of the community concern surrounding this project. The location of the facility on Albany Street in Boston's South End (an environmental justice community) has been controversial, and there have been numerous public meetings over the plans for the facility as well as three legal actions that challenge the project. Construction of the laboratory building is now complete although commissioning of the laboratory facilities has not been completed. A remaining issue is whether the BSL-4 component will become operational.

The building, including the BSL-4 laboratory, is part of the BioSquare Phase II project. Under the Massachusetts Environmental Policy Act (MEPA), the Secretary of the Commonwealth of Massachusetts's Executive Office of Environmental Affairs issued a certificate stating that the BioSquare II project required the preparation of an Environmental Impact Report. In August 2004, the Massachusetts Secretary of Environmental Affairs issued a certificate stating that the final Environmental Impact Report adequately and properly complied with MEPA. This determination was challenged in court, and in July 2006 the Superior Court of Massachusetts vacated Massachusetts' certification of the Environmental Impact Report and remanded the matter to the Secretary of Environmental Affairs for further administrative action.

NIH prepared a document, "Draft Supplementary Risk Assessment and Site Suitability Analyses" (DSRASSA), regarding the siting and operation of the NEIDL in response to comments from the federal court presiding over another lawsuit under the National Environmental Policy Act (NEPA) and to supplement NIH's previous assessments of the potential risks posed by the NEIDL at its current location in Boston.

## 2007 NRC Letter Report

In 2007, the Massachusetts Executive Office of Energy and Environmental Affairs (MEOEEA) asked the National Research Council (NRC) to establish a committee to provide technical input to the MEOEEA on the NIH DSRASSA. Although the DSRASSA was prepared in response to comments that arose in federal litigation pursuant to the NEPA process, the MEOEEA requested a review because it expected the DSRASSA to be an integral part of the material that would be submitted to it by Boston University in fulfillment of MEPA requirements.

NRC's Committee on Technical Input on the NIH Draft Supplementary Risk Assessment and Site Suitability Analyses was convened to review the DSRASSA and discuss its methods and analyses in response to specific questions posed by the MEOEEA. In November 2007, the committee released its letter report answering these questions.[3] The committee's assessment was critical of the DSRASSA, finding that it was not sound and credible, did not adequately identify and thoroughly develop worst-case scenarios, and did not contain the appropriate level of information to compare the risks associated with alternative locations. The report also raised specific concerns about agent selection, scenario development, modeling methodology, environmental justice issues, and risk communication.

In March 2008, NIH announced that additional steps would be taken to address the NRC committee's comments on the DSRASSA as well as the comments and concerns expressed by the courts, the local community, and the general public regarding the construction and operation of the NEIDL. Specifically, NIH established an independent Blue Ribbon Panel (BRP) to advise the agency in responding to these comments and concerns. The BRP was established as a Working Group of the Advisory Committee to the NIH Director and is comprised of experts in infectious diseases, public health and epidemiology, risk assessment, environmental justice, risk communication, biodefense, biosafety, and infectious disease modeling.[4] NIH initiated the development of a draft supplementary risk assessment and sought additional input from the NRC committee on this project. The MEOEEA informed NIH that it views the NRC's additional input on the supplemental assessment being conducted by NIH as an important part of the review process.

**2008 NRC Letter Report**

In 2008, the reconvened NRC committee released its second letter report.[5] As in its first report, in addressing its charge from NIH, the committee did not review the content of previous documents (such as the original environmental impact statement or environmental impact report) or the scope of what had already been done to address risk and community concerns. The committee restricted its comments to suggestions based only on its review of the DSRASSA and on improving the risk assessments presented therein as input to any additional studies that may be needed to assess risk associated with the siting and operation of the NEIDL. The committee prepared its second letter report largely on the basis of the analysis and discussions that went into the preparation of its November 2007 report and discussions that were expanded by a series of conference calls held in April 2008. As noted in its 2007 report, the committee acknowledged and emphasized the need for biocontainment laboratories, including BSL-4 laboratories. The committee also recognized that BSL-4 facilities are being operated safely in both urban and rural areas. However, the committee's view remained that the selection of sites for high-containment laboratories should be supported by detailed analyses and transparent communication of the

[3] NRC. Technical Input on the National Institutes of Health's Draft Supplemental Risk Assessments and Site Suitability Analyses for the National Emerging Infectious Diseases Laboratory, Boston University: A Letter Report (2007). Available at: http://www.nap.edu/catalog/12073.html.
[4] See http://nihblueribbonpanel-bumc-neidl.od.nih.gov/roster.htm.
[5] NRC. Technical Input on Any Additional Studies to Assess Risk Associated with Operation of the National Emerging Infectious Diseases Laboratory, Boston University: A Letter Report (2008). Available at: http://www.nap.edu/catalog/12208.html.

available scientific information regarding possible risks.

The committee refrained from prescribing specific methods and other details, electing instead to structure its suggestions to the NIH BRP around a few overarching questions that should be addressed in future impact reports about the risks associated with operating the NEIDL. The NRC committee offered a series of suggestions and recommendations to NIH and the BRP for consideration in its development of any additional risk assessment studies, loosely organized around the following three domains:

- What Could Go Wrong?
  - Scenarios of Release of an Infectious Agent
  - Agents to Consider for Risk Assessment
- What Are the Probabilities?
- What Would Be the Consequences?

Finally, the committee also recommended that NIH use the accumulated wisdom in the published literature on how to achieve effective risk communication.

**Statement of Task for This Letter Report**

This report again involved reconvening the NRC committee, consistent with NIH's intention to engage the committee at key milestones during the development of a draft supplementary risk assessment. The statement of task is as follows:

> The NIH will engage the Committee on Technical Input on the NIH's DSRASSA for the Boston University NEIDL at key milestones during the development of a draft supplementary risk assessment. The NRC and the NIH Blue Ribbon Panel (BRP) will meet together in public to discuss the developing draft report. Information contained in the draft risk assessment may include data on agents, models, and scenarios; preliminary modeling results; and quantitative and qualitative assessments. Documents reviewed and discussed at these meetings will be made available to the public. Following each meeting with the BRP, the NRC Committee in closed session will prepare brief letter reports on the preliminary results of the supplementary risk analyses, focusing on whether the analyses are scientifically and technically sound in general and whether they address the public health concerns previously raised by the NRC in its review of the July 2007 DSRASSA. These letter reports will be made available to the public. The committee will also provide written comments on the draft supplementary risk assessment when that document is made available for formal public comment. The Committee will submit their findings in the form of a final letter report that will also be made available to the public.

The NRC committee and the BRP met by conference call (which was open to the public) in April 2009 and in person in March 2010 to discuss the developing draft report. At the March 19, 2010 joint meeting of the NIH BRP and the NRC committee, the two groups selected by NIH to complete the supplemental risk assessment—Tetra Tech and its subcontractors from the

University of Utah—made presentations on the proposed approach for the supplemental risk assessment. At NIH's request, the committee focused its discussions of the proposed approach on the following questions:

1. Is the range of agents being studied appropriate?
2. Is the approach to event sequence analysis appropriate?
   - Will the method result in an adequate range of scenarios being considered and selected for analysis?
   - Are the plans for analysis and expression of results appropriate?
3. Is the modeling approach appropriate?
   - Is the approach to initial infection sound?
   - Are the criteria for and selection of models sound?
   - Are the uses of the hybrid branching-compartment models and the extreme values analysis sound?

This letter report is a response to the committee's charge to provide input on key milestones (as presented at the March 2010 meeting) in the development of the supplementary risk assessment.

## COMMITTEE RESPONSE AND RECOMMENDATIONS

In reviewing the proposed risk assessment plan, the committee took into account the discussions with the BRP in evaluating whether the proposed risk assessment is proceeding in the right direction, with appropriate choices being made regarding agents to be assessed, scenarios, event sequence analysis, and qualitative and quantitative methodologies. The committee was pleased to see that NIH and its contractors seriously considered and responded to the NRC committee's findings and the suggestions presented in its second letter report. The material presented provides a range of scenarios that meet the criteria the committee recommended be examined. The contractor appears to be cognizant of data limitations and has accommodated those limits in its proposed methodology. In addition, the contractor appears to have followed the three classic risk triplet questions: What can go wrong? How likely is that? And what would be the consequences? This was recommended in the committee's 2008 letter report.

**Selection of Agents**: The committee finds the range of the 13 agents to be studied appropriate and comprehensive. Although Ebola virus has relatively low transmissibility, its inclusion in the assessment is appropriate given its associated high case fatality rate, public concern about this agent, and its status as a BSL-4 agent. The risk assessment, however, should take special care in explaining that Ebola virus has limited transmissibility (by contact with blood or body fluids of infected people, not by aerosol transmission). In general, NIH and its contractors should not attempt to push modeling further than data for the agents being studied allow. For example, although the Rift Valley Fever (RVF) literature contains good examples of forecasting models in which the incidence of RVF is rendered as a function of weather indices, these are not the kind of data needed for the NEIDL risk assessment. The combination of compartmental and vector borne models outlined by Tetra Tech will require estimating coefficients for both horizontal

transmission (animal-human, animal-animal) and, in the vector borne component (animal-animal), biting rates, and insect abundance for the Boston area. This is a challenge even when describing what happens in those countries where RVF is endemic, and is not likely to be less challenging here. Also, the likelihood of asymptomatic infections and incubation period variability should be acknowledged as important epidemiological characteristics directly associated with the success of containment strategies. Finally, the committee strongly supports conducting a qualitative assessment for all 13 pathogens and quantitative analyses for five of the pathogens.

**Modeling**: The committee finds that the proposed use of both the branching process and compartmental modeling approaches is appropriate, rational, and straightforward. These strategies individually and sequentially can facilitate the modeling of both small and large transmission events, accommodate common laboratory events, and can most likely be completed within the project's timeframe (i.e., by the end of calendar year 2010). There is evidence that well-designed models—even those for which there are limited datasets—have significant value. Such models contribute information to support decision making, policy development, and designing intervention options to mitigate risk (e.g., training, security issues, vaccination strategy), and to identify areas of uncertainty or data gaps. Nevertheless, modeling results should be augmented by case studies based on actual occurrences of laboratory or natural infections (e.g., *Burkholderia mallei*, Sabia virus, *Francisella tularensis, Yersinia pestis*). For this reason, the committee cautions that it will be critical to complement transmission modeling with the qualitative methodologies being used in the assessment. Such case studies can serve to illustrate actual risks and minimize misconceptions and misinformation. To the extent possible, the models should take into account environmental justice issues as well as health disparities in terms of access to and quality of care. The committee recognizes that much of the required data will be difficult to find but notes that the compartmental models proposed by the contractors can easily accommodate demographic characteristics such as age, pre-existing conditions, and even access to care should such data be available.

Finally, the committee is skeptical about the plans for using extreme value analysis. The statistical methods of extreme value analysis require great care about underlying assumptions (e.g., the assumptions underlying the use of a Gaussian [normal] probability distribution) in the estimation of parameters and selection of probabilities to be used in the risk analysis. Without such care, the risk analysis could ignore important issues of dependence versus independence in the sequence of events leading to exposure and subsequent infection. Rather, it is the committee's view that the emphasis should be on sensitivity analysis and carefully examining scenarios (e.g., event sequences) with low probability (rare occurrence) but high consequence, using data when available and well-documented judgment from experts when data are not available to estimate event probabilities. While statistical techniques in extreme value analysis may be helpful, these methods must be checked to be consistent with expert judgment regarding the probabilities of unlikely, but possible, high-consequence events. In addition, uncertainty analyses, which differ from sensitivity analyses and are generally more qualitative, should be included. Some input data may be highly uncertain, yet this uncertainty may have minimal impact on overall risk.

**Expertise and Capabilities**: The committee was critical of the previous team contracted by NIH. The committee was encouraged to see the inclusion of personnel with experience in hospital infection control and infectious disease research, theory, and public health on the new team, as well as personnel who are already in touch with the Boston area public health surveillance system. The new team is also well connected to other networks of expertise that can be consulted if needed and has been working with NIH on developing a plan for identifying additional expertise should this be required. The presentations of the new team suggested that they understand the issues. However, the committee is concerned that the project staff is small and the schedule is tight. It will be important to provide the contractors with adequate resources to complete their work in the time proposed.

**Qualitative Issues**: The committee identified a few issues that it urges be considered in the qualitative assessments, and to the extent possible, in the models. The first is the need to focus on vulnerable populations where transmissibility and/or susceptibility may be higher, for example, among immunocompromised individuals. The second is the benefit of using a curve for infectious dose-response relationships, rather than relying solely on $ID_{50}$ calculations. The limitations of use of points on the dose-response curve (e.g., $ID_{50,}$ $ID_{10}$, $ID_1$) should be clearly articulated.

**Risk Communication**: The committee continues to urge that the supplemental risk assessment be developed in recognition of the inevitable use of the document as a risk communication tool. To this end, it should be clear, accessible, and transparent to non-scientists, or be accompanied by a summary version that is comprehensive and easily accessible to the lay reader. In addition, the committee recommends that whenever possible, the final risk assessment clarify which findings are generalizable to other high-containment laboratories and those findings that are specific to the NEIDL, and why. Doing so could be valuable in informing future risk assessments for other facilities.

While pleased that the plans presented are consistent with the committee's recommendations, the committee notes that these are plans. We await the results.

Finally, although the plans for analysis look appropriate, it is important that the assessors are flexible in applying and modifying their methods as any new information as well as analytical results become available.

Attachments:

A Committee Membership and Biographies

B March 19, 2010 Open Session Public Agenda

# Attachment A

## Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL

**JOHN AHEARNE** *(Chair)*, The Scientific Research Society, Research Triangle Park, NC
**THOMAS ARMSTRONG**, TWA8HR Occupational Hygiene Consulting, LLC, Branchburg, NJ
**GERARDO CHOWELL**, Arizona State University, Tempe, AZ
**MARGARET COLEMAN**, Consultant, Cicero, NY
**GIGI KWIK GRONVALL**, University of Pittsburgh, Baltimore, MD
**ERIC HARVILL**, Pennsylvania State University, University Park, PA
**BARBARA JOHNSON**, Barbara Johnson & Associates, LLC, Herndon, VA
**PAUL LOCKE**, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
**WARNER NORTH**, NorthWorks, Inc., Belmont, CA
**JONATHAN RICHMOND**, Jonathan Richmond & Associates, Southport, NC
**GARY SMITH**, University of Pennsylvania School of Veterinary Medicine, Kenneth Square, PA

### Staff

**FRANCES SHARPLES**, Project Director
**KATHI E. HANNA**, Consultant Writer
**PANOLA GOLSON**, Program Associate

### Biographies

**John Ahearne** (chair) is Executive Director Emeritus of Sigma Xi, the Scientific Research Society, and Emeritus Director of the Sigma Xi Ethics Program. Prior to working at Sigma Xi, Dr. Ahearne served as Vice President and Senior Fellow at Resources for the Future and as Commissioner and Chair of the U.S. Nuclear Regulatory Commission. He worked in the White House Energy Office and as Deputy Assistant Secretary of Energy. He also worked on weapons systems analysis, force structure, and personnel policy as Deputy and Principal Deputy Assistant Secretary of Defense. Serving in the U.S. Air Force (USAF), he worked on nuclear weapons effects and taught at the USAF Academy. Dr. Ahearne's research interests include risk analysis, risk communication, energy analysis, reactor safety, radioactive waste, nuclear weapons, materials disposition, science policy, and environmental management. He was elected to the National Academy of Engineering in 1996 for his leadership in energy policy and the safety and regulation of nuclear power. Dr. Ahearne has served on many NRC Committees in the past twenty years, and has chaired a number of these, including the current Committee on Evaluation of Quantification of Margins and Uncertainty Methodology Applied to the Certification of the Nation's Nuclear Weapons Stockpile and the Committee on the Internationalization of the Civil Nuclear Fuel Cycle. He is a Fellow of the American Academy of Arts and Sciences, the

American Physical Society, the Society for Risk Analysis, and the AAAS. In 1966, Dr. Ahearne earned his Ph.D. in Physics from Princeton University.

**Thomas W. Armstrong** retired in 2008 from his position as Senior Scientific Associate in the Exposure Sciences Section of ExxonMobil Biomedical Sciences, Inc., where he worked since 1989. Dr. Armstrong also worked with the University of Colorado Health Sciences Center as the lead investigator on exposure assessment for epidemiological investigations of potentially benzene-related or other occupational exposure-related hematopoietic diseases in Shanghai, China. Dr. Armstrong also spent nine years working for the Linde Group, as both the manager of loss control in the gases division and as a manager of safety and industrial hygiene. Dr. Armstrong conducted research on quantitative risk assessment models for inhalation exposure to Legionella, and remains professionally active on that topic. He has recently contributed to publications on mathematical models to estimate exposures to hazardous materials, and methods for exposure reconstruction. He was a member of the Society for Risk Analysis and remains an active member of the American Industrial Hygiene Association. The American Board of Industrial Hygiene certifies him as an Industrial Hygienist. Dr. Armstrong has an M.S. in Environmental Health and a Ph.D. in Environmental Engineering from Drexel University.

**Gerardo Chowell** is an Assistant Professor at the School of Human Evolution and Social Change at Arizona State University. Prior to joining ASU, Dr. Chowell was a Director's postdoctoral fellow with the Mathematical Modeling and Analysis group (Theoretical Division) at the Los Alamos National Laboratory. He performs mathematical modeling of emergent and re-emergent infectious diseases (including SARS, influenza, Ebola, and Foot-and-Mouth Disease) with an emphasis in quantifying the effects of public health interventions. His research interests include agent-based modeling, model validation, and social network analysis. Dr. Chowell received his Ph.D. in Biometry from Cornell University and his engineering degree in telematics from the Universidad de Colima, Mexico.

**Margaret E. Coleman** is a medical microbiologist, risk analyst, and sole proprietor of Coleman Scientific Consulting. She serves as Councilor of Upstate NY Society for Risk Analysis and various leadership roles, including her appointment to the Editorial Board for the journal *Risk Analysis*. Also an active member of the American Society for Microbiology (ASM), she recently contributed an article to ASM's *Microbe* (*Microbial Risk Assessment Scenarios, Causality, and Uncertainty*). Ms. Coleman contributes to peer review processes for several journals, including SRA's journal *Risk Analysis*. She was selected as an expert in European Food Safety Authority database, as an expert reviewer for two NRC Reports (*Reopening Public Facilities After a Biological Attack; Evaluation of the Health and Safety Risks of the New USAMRIID High Containment Facilities),* and as a committee member on the *Review of Testing and Evaluation Methodology for Biological Point Detectors*. Ms. Coleman contributed extensively to the published literature on quantitative microbial risk assessment for infectious agents in air, food, and water. She recently developed freelance work on health risks from dermal exposure to *Bacillus* spores for a new client. Ms. Coleman earned her B.S. degree from SUNY College of Environmental Science and Forestry at Syracuse and M.S. degrees from Utah State University and the University of Georgia in Biology/Biochemistry and Medical Microbiology.

**Gigi Kwik Gronvall** is a Senior Associate at the Center for Biosecurity of University of Pittsburgh Medical Center (UPMC) and Assistant Professor of Medicine at the University of Pittsburgh. An immunologist by training, Dr. Gronvall's work addresses how scientists can diminish the threat of biological weapons and how they can contribute to an effective response against a biological weapon or a natural epidemic. She is a term member of the Council on Foreign Relations and also serves on the American Association for the Advancement of Science (AAAS) Committee on Scientific Freedom and Responsibility. Dr. Gronvall is a founding member of the Center for Biosecurity of UPMC and, prior to joining the faculty in 2003, she worked at the Johns Hopkins University Center for Civilian Biodefense Strategies. From 2000-2001 she was a National Research Council Postdoctoral Associate at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland. Dr. Gronvall earned a Ph.D. from Johns Hopkins University for her work on T-cell receptor/MHC I interactions.

**Eric Harvill** is an Associate Professor of Microbiology and Infectious Diseases at the Pennsylvania State University. His primary research interest is in the interactions between bacterial pathogens and the host immune system, and his group investigates both bacterial virulence factors and host immune functions at the molecular level using the tools of bacterial genetics and mouse molecular immunology. These studies investigate the effects these molecular-level activities may have on the population-level behavior of infectious diseases. Dr. Harvill has served on several NRC committees, including the Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis. He has reviewed for more than 20 scientific journals and serves on the Editorial Board for *Infection and Immunity*. Dr. Harvill has reviewed proposals for six different National Institutes of Health study sections, the U.S. Department of Agriculture and multiple international funding organizations. He has organized international and local meetings and chaired sessions at annual meetings of both the American Association of Immunologists and the American Society for Microbiology. He earned his Ph.D. at the University of California, Los Angeles.

**Barbara Johnson** has over 15 years of experience in the U.S. Government in the area of biosafety, biocontainment and biosecurity, and currently owns the consulting company Barbara Johnson & Associates, LLC. Dr. Johnson has managed the design, construction and commissioning of a BSL-3 Aerosol Pathogen Test Facility, and she launched the U.S. Government's first chemical and biological counterterrorism training facility. Research areas include biological risk assessment and mitigation, testing the efficiency of respiratory protective devices, and testing novel decontamination methods against biological threat agents. In the private sector she pioneered the development of the first joint biosafety and biosecurity programs between the United States and institutes in the former Soviet Union, and founded and directed a Center for Biosecurity in association with this work. She has served as the President of the American Biological Safety Association, and is the Co-editor of the journal Applied Biosafety.

**Paul A. Locke** is an Associate Professor in the Department of Environmental Health Sciences (EHS) at the Johns Hopkins Bloomberg School of Public Health. He is a public health scientist and attorney with expertise in risk assessment and risk management, radiation protection law and policy, and alternatives to animals in biomedical testing. Dr. Locke is a member of the Board of Directors of the National Council on Radiation Protection and Measurements (NCRP) and

chaired the NCRP's 2010 annual meeting program committee. From 2004 until 2009 he was a member of the NRC Nuclear and Radiation Study Board, and has participated on two NRC Committees that evaluated the risks associated with the disposal of high-level radioactive waste. Dr. Locke has received several awards, including the Yale School of Public Health Alumni Service Award, and the American Public Health Association Environment Section Distinguished Service Award. He holds an M.P.H. from Yale University School of Medicine, a J.D. from Vanderbilt University School of Law, and a Dr.P.H .from the Johns Hopkins Bloomberg School of Public Health. He directs the EHS doctoral program in Public Health.

**Warner North** is President of NorthWorks, Inc., a consulting firm in Belmont, California. Dr. North is also a consulting professor in the Department of Management Science and Engineering at Stanford University. Over the past 30 years, Dr. North has carried out applications of decision analysis and risk analysis for electric utilities in the United States and Mexico, for petroleum and chemical industries, and for government agencies with responsibility for energy and environmental protection. He has served as a member and consultant to the Science Advisory Board of the Environmental Protection Agency since 1978, and as a presidentially appointed member of the U.S. Nuclear Waste Technical Review Board. Dr. North recently served as a member on the NRC's Panel on Public Participation in Environmental Assessment and Decision Making and has chaired NRC Committees. Dr. North is a past president of the International Society for Risk Analysis, a recipient of the Frank P. Ramsey Medal from the Decision Analysis Society for lifetime contributions to the field of decision analysis, and a recipient of the Outstanding Risk Practitioner Award from the Society for Risk Analysis.

**Jonathan Richmond** is CEO of Jonathan Richmond and Associates, a biosafety consulting firm with a global clientele. Prior to starting his own firm, Dr. Richmond was the director of the Office of Health and Safety at the Centers for Disease Control and Prevention in Atlanta, Georgia. He is an international authority on biosafety and laboratory containment design. Dr. Richmond was trained as a geneticist, worked for ten years as a research virologist, and has been involved in the field of biosafety for the past 25 years. He has authored many scientific publications in microbiology, chaired many national symposia, edited numerous books, and is an international consultant to ministries of health on laboratory safety and training. He served as President of the American Biological Safety Association.

**Gary Smith** is Chief of the Section of Epidemiology and Public Health in the School of Veterinary Medicine at University of Pennsylvania. He has a secondary appointment in the Department of Biostatistics and Epidemiology at the University of Pennsylvania's School of Medicine and is an Associate Scholar in the Center for Clinical Epidemiology and Biostatistics. He is also an affiliated faculty member of Penn's Institute for Strategic Threat Analysis and Response. His research deals with the epidemiology and population dynamics of infectious disease in humans as well as wild and domestic animal species. He has extensive experience of mathematical modeling in the context of infectious and parasitic disease control strategies (including the evolution of drug resistance) and has published case-control studies on a range of infectious diseases of animals and humans. Dr. Smith served on an FAO/WHO Expert Committee on the implementation of farm models in the developing world; he served on the Pennsylvania Food Quality Assurance Committee, and he was a member of a European Union Expert Committee on Bovine Spongiform Encephalopathy risk. He has served on the editorial

boards of *Parasitology Today*, *The International Journal of Parasitology*, *The Veterinary Quarterly*, and *Frontiers in Ecology and the Environment*. Dr. Smith earned Bachelors degrees in Zoology and Education from the Universities of Oxford and Cambridge respectively and a D.Phil. in Ecology from the University of York.

# Attachment B

## MARCH 19, 2010 OPEN SESSION PUBLIC AGENDA

**NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center**

**March 19, 2010**

**NIH Campus**
**Building 31, 6th Floor Conference Center, Conference Room 6**
**Bethesda, Maryland**

## DRAFT AGENDA

8:30 AM **Welcome and Purpose of Today's Meeting**
*Adel Mahmoud, M.D., Ph.D.*
*Chair, NIH Blue Ribbon Panel*
*Professor, Department of Molecular Biology, Princeton University*

8:35 AM **Opening Remarks**
*John F. Ahearne, Ph.D., Committee Chair, National Research Council*

8:40 AM **Roundtable Introduction of Blue Ribbon Panel and National Research Council Members**

8:50 AM **Development of the Supplementary Risk Assessment: Recap of Past Activities and Charting the Course Forward**
*Adel Mahmoud, M.D., Ph.D.*
*Amy P. Patterson, M.D., Acting Director, Office of Science Policy, Office of the Director, National Institutes of Health*
*Karen A. Holbrook, Ph.D., Vice President for Research and Innovation, Office of Research, University of South Florida*
*Wayne Thomann, Ph.D., Director, Occupational and Environmental Safety and Assistant Research Professor, Duke University/Duke University Medical Center, Nicholas School of the Environment and Earth Sciences*

9:40 AM **Accident Sequence Analyses**
*Ken Bulmahn, Tetra Tech Risk Assessment Team*

10:45 AM **Break**

11:00 AM **Health Effects and Transmission Modeling**
*Adi Gundlapalli, M.D., Ph.D., M.S., Assistant Professor, Departments of Internal Medicine, Pathology and Biomedical Informatics, University of Utah School of Medicine*
*Damon Toth, Ph.D., Research Assistant Professor, Department of Mathematics, University of Utah*

12:30 PM **Break**

12:45 PM **Working Lunch and Group Discussion**

1:45 PM **Public Comment**

2:00 PM **Adjourn**