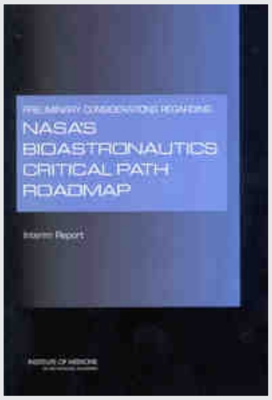

PRELIMINARY CONSIDERATIONS REGARDING
NASA'S
BIOASTRONAUTICS
CRITICAL PATH
ROADMAP

Interim Report

Preliminary Considerations Regarding NASA's Bioastronautics Critical Path Roadmap: Interim Report

DETAILS

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Committee on Review of NASA's Bioastronautics Critical Path Roadmap; Board on Health Sciences Policy; Institute of Medicine

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Board on Health Sciences Policy

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> *Willing is not enough; we must do."*
> —Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions nor did they see the final draft of the report before its release. The review of this report was overseen by Mary Jane Osborn, University of Connecticut Health Center. Appointed by the National Research Council and the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Preliminary Considerations Regarding NASA's Bioastronautics Critical Path Roadmap: Interim Report of the Committee on Review of NASA's Bioastronautics Critical Path Roadmap

SUMMARY

Extending the spatial and temporal boundaries of human space flight are important goals for the National Aeronautics and Space Administration (NASA), yet human space flight remains an endeavor with substantial risks. NASA's Bioastronautics Critical Path Roadmap (BCPR) defines risk as "the conditional probability of an adverse event occurring, or a system performance-related inefficiency." Potential hazards include exposure of the crew to space radiation, degraded crew performance related to human behavioral and other health changes, failure of life support systems, and the adverse effects of space flight on human biological systems including the musculoskeletal, cardiovascular, neurovestibular, endocrine, neuropsychiatric, and immune systems. Human factors are critically important in risk assessment and countermeasure development, including engineering design for human space flight. The BCPR is designed to provide summary assessments of the importance of each risk, and the current state of science and technology with respect to minimizing them.

In 2003, NASA asked the Institute of Medicine (IOM), in collaboration with the Division on Engineering and Physical Sciences of the National Academies, to conduct a review of the BCPR (see Appendix B for the version of the BCPR that the committee reviewed). Specifically, NASA asked the committee to (1) conduct a comprehensive assessment and report of the strengths and weaknesses of the content and processes of the BCPR as applied to the missions described in the President's exploration initiative

and (2) identify the unique challenges for accomplishing its goals and objectives. Specific questions for the committee to answer included but were not limited to the following:

1. How can the BCPR better capture and describe the critical risks and key research and technology issues for risk reduction and management so as to provide a framework for informed decisions regarding resource allocation?
2. Does the BCPR use an appropriate method of risk assessment and expression of risk assessment? Does it adequately communicate the methods underlying risk assessment and the resulting activities for different mission scenarios?
3. How well does the BCPR address different types of risk (e.g., health, engineering) and their impact?
4. Are the categories of critical research issues and the metrics used to analyze them appropriate (risk assessment and characterization, mechanistic/process research, countermeasure development, and medical diagnosis and treatment)?
5. Are efficiency and technology issues properly and adequately addressed?

This is the interim report of the IOM committee's review of NASA's BCPR. The purpose of this report is to provide NASA with preliminary conclusions regarding the strengths and weakness of the BCPR. Over the next several months, the committee will continue to gather data and information and meet with NASA personnel, including senior leadership, other NASA decision makers, and those in operational areas related to the human space flight program. The committee's final report, due in August 2005, will elaborate on these preliminary conclusions and provide NASA with recommendations about how to address the issues that are identified by the committee.

The BCPR was developed collaboratively by NASA's Office of Biological and Physical Research, the Office of Space Flight, and the Office of the Chief Health and Medical Officer. NASA describes the BCPR as a framework for identifying and assessing the risks to crews that are exposed to the hazardous environments of space.[1] The roadmap identifies risks

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[1] Bioastronautics spans research, technological, medical/operational, and policy issues related to understanding and managing the human consequences of space flight.

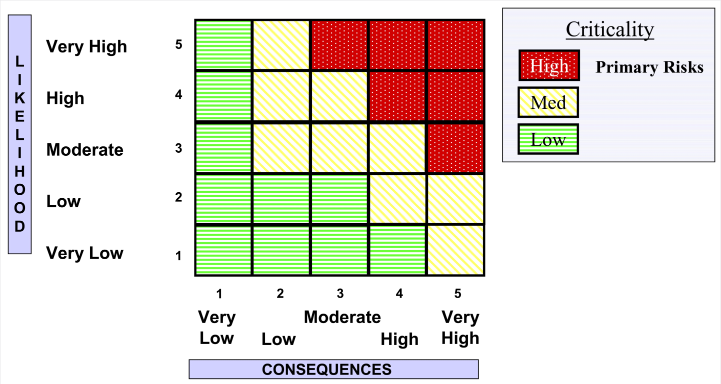
and associated research questions related to human space flight. The goal of the BCPR is to obtain empirical evidence and systematic data for risk reduction and management. The roadmap represents a comprehensive and thoughtful approach to meeting the challenges of the President's space initiative, specifically, a 1-year mission to the International Space Station, a month-long stay on the lunar surface, and a 30-month round-trip journey to Mars. Currently, the BCPR identifies 35 human health–related risks and 15 risks related to systems performance and efficiency clustered in five cross-cutting areas (human health and countermeasures, radiation health, behavioral health and performance, autonomous medical care, and advanced human life support technologies).

Efforts to understand and manage the risks associated with human space flight have been ongoing at NASA for many years, and specific activities related to the development of a roadmap began in the early 1990s. The process of risk identification that resulted in the BCPR commenced in 1997, in brainstorming sessions involving NASA and non-NASA experts who rated risks within their own discipline areas. With guidance from NAS and other advisory reports (see Appendix C), 150 risks were identified. More recently, and after several iterations, the list was culled to the 50 risks that are the focus of the current BCPR.

The final risks and related critical questions were identified by the discipline teams using the advisory committee reports as well as other recent research findings. The Bioastronautics Science Management Team, which includes NASA scientists, managers, and flight surgeons, and the National Space Biomedical Research Institute (NSBRI) Director, reviewed and discussed the risks and provided oversight for the project. The current set of 50 risks is the product of those deliberations. For communication and decision-making regarding these risks, the BCPR uses a visual metaphor called a stoplight chart in which red/yellow/green categories replace the NASA standard 5 × 5 model of risk assessment (see Box 1).

In the spring of 2004, NASA held several consensus workshops that included the research community and NASA operations communities (flight surgeons, astronauts, and the medical office) to address the sample size needed for research related to the risks identified, the use of animal models, and the ranking of the 35 biomedical risks in the BCPR from the point of view of the astronauts and flight surgeons. Of note, the Workshop on Requirements for Human Subjects for Exploration Research, held on June 9, 2004, concluded that although 10 research subjects per flight experiment (astronauts may participate in more than 1 research project per

BOX 1
NASA 5 × 5 Matrix Model



LIKELIHOOD	1 Very Low	2 Low	3 Moderate	4 High	5 Very High
5 Very High	Low	Med	High	High	High
4 High	Low	Med	Med	High	High
3 Moderate	Low	Med	Med	Med	High
2 Low	Low	Low	Low	Med	Med
1 Very Low	Low	Low	Low	Low	Med

SOURCE: Connley, Warren. *Code 300 All Hands: NASA-wide risk reporting.* NASA. November 7, 2002.

flight) would serve as a feasible minimum sample, it would still place limits on the statistical power of the data from in-flight research.

Since its creation in January 2004, the Committee on Review of NASA's Bioastronautics Critical Path Roadmap has held three meetings (see Appendix A for details). Each meeting included a data-gathering session where testimony from NASA officials and space science experts was heard. At each meeting, the committee also held closed sessions where it deliberated and developed conclusions. This interim report presents the committee's preliminary assessment of the strengths and weaknesses of the BCPR in terms of risk identification, inclusion of operational priorities, sample size considerations, understanding about the interactions among risks, and risk-assessment and communication methods. The report outlines areas in the BCPR that merit more attention from NASA and provides the committee's preliminary conclusions concerning

- the need for users of the BCPR to be able to assess the quality of the science that forms the basis for decision making reflected in the document;

- the potential impact of the President's space initiative on the organizational-level risk that NASA faces;
- the importance of time as a dimension of risk analysis, especially in the context of long-term missions;
- the problems associated with very small sample size, which characterizes in-flight, health-related studies;
- the need for incorporating results of ongoing research into the calibration of risk in the BCPR to help ensure that the roadmap is a dynamic document that is used throughout the agency;
- the importance of human factors in space engineering design; and
- the relevance of data from analog environments for understanding the risk of human space flight.

INTRODUCTION

As the boundaries of distance and flight duration are extended, demands on the crew change and increase. The nature and severity of the risks also change as the duration of space flight increases, and time becomes an important element in assessing the risks associated with human space flight. On a 30-month Mars mission, for example, abort modes and opportunities for early return do not exist, demanding greater commitment from NASA and the crew. The need for the crew to function autonomously becomes imperative. Social tensions, lack of privacy, noise, disrupted sleep patterns, and lack of leisure time can produce mounting stress on the crew. Expectations for autonomous performance of the crew include diverse skills such as the delivery of medical care, including self-care; provision of food and water; maintenance of vehicle systems; and performance of independent research.

In the President's space initiative, NASA has a proposed schedule that demands considerable resources, notably time and funding. Crew safety and mission success require an understanding of the effects of long-duration space flight, which entails, for example, prolonged isolation, exposure to microgravity, and the potential of technology failure. As flight duration increases, the cumulative impact of risks and their sequencing may change. Unfortunately, the number of astronaut-days remaining on the International Space Station (ISS) is very limited relative to the time needed for carrying out critical research and testing countermeasure readiness.

The President's Initiative

On January 14, 2004, President Bush announced his vision for space exploration. The President's plan for continued human and robotic space exploration is summarized in Box 2. The BCPR refers to three scenarios in the plan as "design reference missions" and describes them as follows: (1) a 1-year mission to the ISS; (2) a 1-month stay on the lunar surface; and (3) a 30-month journey to Mars and back.

Overview of the BCPR

NASA describes the BCPR as a framework for identifying and assessing the risks to crews that are exposed to the hazardous environments of

BOX 2
President Bush's Vision for U.S. Space Exploration

The President's plan for steady human and robotic space exploration is based on the following goals:

- First, America will complete its work on the International Space Station by 2010, fulfilling our commitment to our 15 partner countries. The United States will launch a re-focused research effort on board the International Space Station to better understand and overcome the effects of human space flight on astronaut health, increasing the safety of future space missions. To accomplish this goal, NASA will return the Space Shuttle to flight consistent with safety concerns and the recommendations of the Columbia Accident Investigation Board. The Shuttle's chief purpose over the next several years will be to help finish assembly of the Station, and the Shuttle will be retired by the end of this decade after nearly 30 years of service.
- Second, the United States will begin developing a new manned exploration vehicle to explore beyond our orbit to other worlds—the first of its kind since the Apollo Command Module. The new spacecraft, the Crew Exploration Vehicle, will be developed and tested by 2008 and will conduct its first manned mission no later than 2014. The Crew Exploration Vehicle will also be capable of transporting astronauts and scientists to the International Space Station after the Shuttle is retired.

space. The roadmap identifies risks and associated research questions related to human space flight. The goal of the BCPR is to obtain empirical evidence and systematic data for risk reduction and management. Some risks (see Table 1) are specific to traditional space life science disciplines, whereas others are of a cross-cutting nature and require an integrated approach, for example, human response to stress, which may include psychological, neurological, and immunological change. Examples of discipline-specific risks include the acceleration of age-related osteoporosis, decompression sickness, and cardiac dysrhythmias. All of the risks in the BCPR were initially identified and assessed through the deliberation of expert panels that included extramural scientists, NASA intramural scientists, and operational and management staff.

- Third, America will return to the Moon as early as 2015 and no later than 2020 and use it as a stepping stone for more ambitious missions. A series of robotic missions to the Moon, similar to the Spirit Rover that is sending remarkable images back to Earth from Mars, will explore the lunar surface beginning no later than 2008 to research and prepare for future human exploration. Using the Crew Exploration Vehicle, humans will conduct extended lunar missions as early as 2015, with the goal of living and working there for increasingly extended periods. The extended human presence on the Moon will enable astronauts to develop new technologies and harness the Moon's abundant resources to allow manned exploration of more challenging environments. An extended human presence on the Moon could reduce the costs of further exploration, since lunar-based spacecraft could escape the Moon's lower gravity using less energy at less cost than Earth-based vehicles. The experience and knowledge gained on the Moon will serve as a foundation for human missions beyond the Moon, beginning with Mars. NASA will increase the use of robotic exploration to maximize our understanding of the solar system and pave the way for more ambitious manned missions. Probes, landers, and similar unmanned vehicles will serve as trailblazers and send vast amounts of knowledge back to scientists on Earth.

SOURCE: http://www.whitehouse.gov/infocus/space/vision.html.

TABLE 1 BCPR Discipline Teams and Cross-Cutting Areas (Table 4-2 of the BCPR)

Discipline Teams	Cross-Cutting Areas
• Bone Loss • Muscle Alterations & Atrophy • Neurovestibular Adaptation • Cardiovascular Alterations • Immunology, Infection & Hematology • Environmental Effects	Human Health and Countermeasures (HH&C): *Focuses on understanding, characterizing, and counteracting the whole body's adaptation to microgravity, enabling healthy astronauts to accomplish mission objectives and return to normal life following a mission.*
• Radiation Health	Radiation Health: *Defines the research strategy and sets radiation shielding and monitoring requirements, thus increasing allowable crew time in space and reducing uncertainty for cancer and other radiation risks.*
• Psychosocial Adaptation • Sleep & Circadian Rhythm Problems • Neurobehavioral Problems • Cognitive Abilities	Behavioral Health and Performance (BH&P): *Focuses on maintaining the psychosocial and psycho-physiological functions of the crew throughout space flight missions and providing an optimal set of countermeasures.*
• Clinical Capabilities	Autonomous Medical Care (AMC): *The capability to provide medical care during a mission with little or no real-time support from Earth. Crew medical officers or other crew members provide routine or emergency medical care using available resources. The local resources in an autonomous system augment and support the caregiver. Additionally, part of creating an autonomous medical care system includes preventing or reducing the likelihood of conditions before a mission starts, thus reducing the capabilities and consumables needed in the medical system.*
• Advanced Food Technology (AFT) • Advanced Life Support (ALS) • Advanced Environmental Monitoring & Control (AEMC)	Advanced Human Support Technologies (AHST): *Focuses on developing efficient, reliable, and autonomous technologies and systems to support human habitation in*

TABLE 1 Continued

Discipline Teams	Cross-Cutting Areas
• Advanced Extravehicular Activity (AEVA) • Space Human Factors Engineering (SHFE) • Advanced Integration Matrix (AIM)	*spacecraft and planetary dwellings. These technologies include food and life support systems, environmental monitoring and control systems, extravehicular activity technologies, and human factors solutions through integrated testing in appropriate facilities.*

SOURCE: NASA, 2004.

Risk assessment criteria included the determination of the likelihood of occurrence and the severity of consequences of each risk in terms of crew health and safety, and performance of mission objectives. Relative risk priorities were derived from that assessment. Each risk has a set of critical questions whose answers are intended to lead to (1) risk assessment and quantification, (2) the development of countermeasures to prevent or mitigate the deleterious effects of space flight, (3) an improved basic understanding of underlying processes, and (4) medical diagnostic and treatment capabilities. This risk-based approach was devised to enable the development of a more rigorous decision-making process for the allocation and implementation of resources, risk prioritization, access to facilities, operational requirement implementation, and crew time, as well as for the development of cost-effective countermeasures, and the design and implementation of effective advanced life support technology.

The determination of risk always involves an element of uncertainty. To fully communicate the likelihood of occurrence of an event, it is necessary to communicate the extent of uncertainty in the assessment. For risk communication, the uncertainty associated with a risk may be represented by objective measures such as statistical confidence intervals or by subjective measures based on narrative descriptions of the risk (e.g., expert opinion obtained in focus group settings). The version of the BCPR reviewed by this committee does not include any expression of uncertainty either in terms of reported confidence intervals or in narrative discussion. The committee was informed that NASA is working at this time to establish confidence bands and acceptable levels of risk so that it can communicate such information to the research and operations communities.

The committee has observed that the risks identified in the BCPR occur within the context of a larger set of risks to the human space flight program and to NASA as an organization. Highly visible failures, such as the loss of the space shuttles Challenger and Columbia, have the potential to erode public confidence in, and congressional support for, human space flight and for NASA as an agency. Under certain circumstances, the presidential initiative announced in January 2004 could add an additional risk: that of pressure being applied to achieve the goals of the initiative without sufficient time or resources for adequate preparation, which could compromise mission safety. Pressure can increase when critical biomedical research is delayed by a disaster-related response, such as the one that occurred after the loss of the Challenger. The single most substantial organizational risk that NASA faces may be the possibility that a thoughtfully conceived critical path roadmap could be pre-empted or abandoned as a result of such pressures or of an abrupt change in policy direction.

STRENGTHS AND WEAKNESSES OF THE BCPR

The BCPR is a broad and complex document, one that has been developed with care and thought. NASA has sought internal and external expert opinion to evaluate and refine the risks and the critical research questions that are associated with those risks. One of the strengths of the BCPR is its breadth of coverage. The discipline areas identified in the roadmap are broad—for example, the area of human health and countermeasures includes bone and muscle loss, neurovestibular adaptation, cardiovascular and immunological changes, and environmental effects. Advanced human life support comprises food and life support systems, environmental monitoring and control systems, and extravehicular activity technologies and the human factors related to these technologies. However, grouping risks into broad discipline areas can result in uneven attention being focused across topics. For example, some areas, such as bone loss in the Human Health and Countermeasures area, have received considerable attention and investigation, whereas others, such as the psychological and physical impacts of stress on crew performance in the Behavioral Health and Performance area, have not been adequately addressed.

In the area of Advanced Human Support Technologies (AHST), NASA faces challenges that may be divided into two areas: (1) the determination of optimal technology and (2) the engineering development and qualification of the hardware, software, and operational procedures required to realize the systems performance of the selected technology. Determining the optimal technology involves interrelated studies within the physical, chemical, and biological sciences, and frequently builds on accumulated experience. Reliance on mechanical systems that are subject to degradation and breakdown underscores the need for engineering to effectively engage with other disciplines to ensure that all relevant human factors are properly evaluated.

In the context of long-duration missions, ensuring highly reliable performance of technologies will depend on two principal means of verification: stress testing and full duration life testing. In the first approach, relevant environmental factors are made more stressful (e.g., hotter/colder than normal) to permit evaluation of long-term performance in a short period of time. The "full duration" approach is to build the apparatus and operate it within normal limits for an extended period of time—preferably several times the actual requirement. Coupled with failure analysis and remediation, the full duration approach gives the greatest confidence. To accomplish this sort of qualification with advanced life support systems, accumulated operational experience with such systems or their immediate predecessors is necessary.[2]

To respond to these and other challenges, NASA has sought feedback from scientific researchers, operational managers, and administrators; examined the value and implications of research involving crews in analogous environments, such as the Antarctic or submarines; and explored the applicability of findings from animal models. NASA also has initiated efforts to understand the implications of small sample size on space-related research. Such efforts are appropriate for the efficient design of a research program that supports long-term, long-distance space flight. NASA's commitment to external review and expert advice is evidenced by its request for the current study as well as other related reviews by the National Academies (see Appendix C). The committee's final report will include a summary of the recommendations from these previous reports that remain relevant to the current study.

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[2] The Russian-built Elektron oxygen generator is a case in point. A U.S.-designed and built system using more advanced technology awaits launch in mid-2008. The United States is engaged in adapting the Russian system rather than using the intervening time to qualify the U.S. apparatus.

Risk Identification

NASA's decision to rely on expert opinion in identifying and ranking risks is a reasonable strategy, given the broad array of topics addressed in the BCPR. Expert opinion in health care and the life sciences is influenced both by systematically derived data and by heuristics, or "rules of thumb," that are derived from personal and group experience. In a cautionary note, the committee observes that several factors contribute to the complexity of the issues that the BCPR addresses, including the number of identified risks, the heterogeneity of risk types, and the interdependence among risks. Risks range from theoretical concerns, such as virus-induced lymphomas and leukemias, to practical issues, including nutrition, motion sickness, and bone and muscle loss. In addition, some risks are specific (e.g., renal stone formation), whereas others are general (e.g., ambulatory care). Further external review may assist NASA in evaluating and prioritizing risks.

Inclusion of Operational Priorities

Many stakeholders with diverse points of view have contributed to the BCPR. To scientists, it is a research agenda for investigator-initiated projects that will advance the knowledge base of science. To NASA's line managers, it is a set of operational challenges to be addressed to support the proposed missions to the International Space Station, the Moon, and Mars. The committee concludes that in order to further refine and focus the goals of the BCPR, NASA should label risks according to their relevance to operational requirements and according to temporal urgency—or the timeliness of countermeasure development—notably as related to medical operations. To be included meaningfully in the decision making process, biomedical countermeasures and life support technologies must be validated well in advance of the final integrated mission architecture. The committee further concludes that the identification of operational priorities requires the active and ongoing collaboration and exchange of perspectives among the key stakeholders (e.g., line managers, clinicians, researchers, and astronauts) in the human exploration of space.

Sample Size Considerations

A subject sample size of 10 imposes significant limitations on the information that can be obtained from the resulting data sets. Specifically, very small sample size makes it impossible to state findings within reasonable confidence intervals, or to compare alternatives using tests of statistical significance. The committee recognizes that health-related studies based on observations of space mission crews will, for the foreseeable future, suffer from small sample size, and consequently inferences based on single missions will have inadequate statistical power. Hence, the committee does not propose that crew size be dictated by the requirements for statistical power.

The committee proposes that, rather than rely on data from a single mission for inference, NASA could use two techniques to analyze data pooled from several missions. Drawing on the findings of the 2001 NAS report, *Small Clinical Trials*,[3] the committee suggests the following: (1) a Bayesian sequential trials approach[4] and (2) hierarchical random or fixed effects methods to account for variation across missions.[5]

Specifically, for the Bayesian sequence of studies approach, the committee proposes that studies be designed to incorporate as many missions as possible, somewhat in the manner of sequential clinical trials, and also that they incorporate prior information from archival data and ground-based studies to the extent practicable. In a Bayesian framework, a prior uncertainty distribution for degree of mineral bone mass loss as a function of age, sex, and time in space, for example, would be incrementally modified by new information gained from, and incidental to, a series of missions. The goal would be to develop a sequence of posterior distributions about the quantity of interest, the latest of which would always summarize the current accumulated information.

For effective pooling, at least in terms of the hierarchical modeling analysis, a number of consistency issues need to be addressed. For example, consistency is needed across the pooled missions in terms of what is measured and the frequency of longitudinal measurements. *Small Clinical Trials* provides a discussion of such modeling (IOM, 2001: 67–70). With good planning and execution and some consideration of these issues, the resulting data should be suitable for such hierarchical methods.

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[3] See page 14 of *Small Clinical Trials* for an example of pooling of data across missions.

[4] See pages 72–73 of *Small Clinical Trials* for a discussion of Bayesian methods in this context.

[5] See pages 67–70 of *Small Clinical Trials* for a discussion of hierarchical methods in this context.

Understanding the Interactions Among Risks

The committee notes with approval that NASA has identified five cross-cutting risk areas (human health and countermeasures, radiation health, behavioral health and performance, autonomous medical care, and advanced human life-support technologies) and suggests that these cross-cutting areas deserve further attention. Notably, the committee suggests that crew health is an important driver of engineering design requirements. For risk reduction and management in human space flight, important factors include the interactions and interrelationships among risks, the sequence of risks, and the resultant cumulative risk.

Design reference missions are used by many groups within NASA for planning and operations. To be most useful to NASA, design reference missions could be better defined by inclusion of additional relevant information to help the BCPR's intended audience assess the overall system design and biomedical countermeasure requirements. An example for the ISS mission might be the estimated evacuation time for medical emergencies; for a month-long lunar mission, knowing the availability of powered surface locomotion, or whether the base is mobile or "buried" for radiation shielding would be important. For the 30-month mission to Mars, the ratio of orbital period to surface stay time, the cultural diversity of the crew, and the level of electrical power available are relevant considerations. To better understand interactions among risks, the design reference missions could be developed using "straw man" techniques, for example, to compare a Mars mission that orbits the planet affording no "real" gravity to a Mars mission wherein the crew lived on the surface for several months in one-third "g" (gravity). The former mission description would more strongly indicate the need for centrifugally induced "artificial gravity" than the latter. Importantly, up-to-date human factors engineering requirements could be applied to straw man missions, facilitating assessment of the nature and location of shortcomings.

Under the rubric of human behavior and performance issues, NASA could examine interactions among risks by focusing on the full dimensions of human performance failure, including (1) intrapersonal factors, such as personality and coping styles; (2) interpersonal factors, such as attitudes toward cooperation and conflict; and (3) organizational factors, including the cultural and value systems of the participating national space agencies and contractors. The physiological response to stress also includes hormonal changes that influence human performance and affect cardiovascular health, immune system function, and other risk areas identified in the BCPR. Attention to the complexities of human behavior and performance issues would strengthen the BCPR.

Risk Assessment and Communication

The committee has identified aspects of risk reduction and management that require further attention in the BCPR, including methods of communication that would support the full range of BCPR stakeholders, notably NASA medical operations personnel, investigators, and astronauts, and the need for a more comprehensive analysis of risk, including its identification, assessment, estimation, and evaluation. Communication of risk, including the response to accidents and disaster, is an important element of the BCPR. Methods of information communication that could enhance the usefulness of the BCPR include the following:

- levels of supporting evidence for each risk;
- evidence supporting the selection of enabling questions for each risk;
- information about the interaction and interrelations among risks;
- confidence intervals for quantitative data, and narrative comments about the strength of qualitative conclusions;
- information about how both qualitative and quantitative data were derived; and
- a glossary.

Although final policy decisions about risk must be simple—for example, “go” or “no-go”—and the visual metaphor of stoplight colors in the BCPR is appealing in this context, the committee concludes that the assignment of risks to red, yellow, or green status has pushed this simplification down to a point that occurs too early in the risk-analysis process. Final, simplistic decisions should be made only after a thorough analysis of the risk factors has been conducted at the more fundamental levels. Specific problems associated with the stoplight chart include the following:

- a given color designation has numerous possible (disparate) paths;
- multiple and varying dimensions are reflected in each color designation, including the severity and probability of occurrence;
- there is an absence of threshold values and consistent information

about confidence intervals or the robustness of the data that support specific risk considerations;

- the dimension of time is not factored properly into risk assessment in the BCPR. This prohibits analysis of the impacts of long-distance space flight on crew health and life support systems, prioritization of risks, and assessment of countermeasure readiness; and
- the design reference missions (DRMs) are inadequately defined in terms of data and information that are relevant to the diverse users of DRMs.

The committee observes that risks are not expressed in the BCPR in the format of the NASA-wide Continuous Risk Management system,[6] even though the systemwide use of this format is well understood by NASA personnel and would be an effective way of communicating the elements of the BCPR throughout the organization. NASA developed the Continuous Risk Management System in 1996 to help project managers continuously identify, analyze, and manage risk throughout the life-cycle of a project and for use as a proactive tool for managers to monitor resource allocation and ensure that critical project milestones are achieved within acceptable levels of risk. The use of the Continuous Risk Management system results in a set of actionable risks that can be assessed with regard to the probability and consequences of occurrence. This information can be used to plan mitigation measures indicating that all risks have been reduced to "green" by the projected launch date, to inform cost–benefit analyses and prioritization efforts, and to help NASA obtain adequate resources (funding, time, expertise) to carry out these measures.

The importance of evaluating the timeliness of research and countermeasure and system development is illustrated by the needs of the Mars Design Reference Mission, for which the lack of a qualified life support system will be more critical in 2020 than it is today. Risks could be formulated using the straw man techniques described above to evaluate the selection of habitat and pressure suit atmospheres. This would eliminate the need for testing new and optimum pre-breathe protocols and allow NASA

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[6] For more information on NASA's Continuous Risk Management system, see http://satc.gsfc.nasa.gov/support/ASM_FEB99/crm_at_nasa.html.

to address more tractable questions about the effects of prolonged living in selected cabin atmospheres. Because design and countermeasure readiness milestones must significantly precede mission launch milestones, acknowledgment that time is an important dimension of risk implies recognition of the specific link between the date that a validated countermeasure is needed and the actual mission launch target date.

Risk Areas Meriting More Attention

The committee has identified risk areas in the BCPR that deserve further attention from NASA, including the following:

- psychological and physical impacts on the ability to perform, including crew selection criteria (social, demographic, and pre-existing health status of astronauts and their response to stress), especially in the context of longer term missions;
- radiation effects;
- nutrition;
- autonomous medical care and self-care, including telerobotic surgery, especially in the context of longer term missions; and
- environmental factors associated with long-term missions, such as analyses of air and water quality and cabin and extravehicular activities pressure.

PRELIMINARY CONCLUSIONS

- To assess the quality of the science that forms the basis for decision making in the BCPR, users of the document must be able to distinguish risks and countermeasures that have been identified using (1) heuristics (rules of thumb) versus scientific investigation (evidence based), (2) data derived from analog environments versus those obtained from in-flight experience, and (3) data derived from human versus animal studies.
- As a result of the President's space exploration initiative, NASA has proposed a schedule that requires considerable resources, notably time and upfront funding. Safety and mission effectiveness may be compromised if the necessary resources are not authorized or allocated promptly. To the technical risks of space flight the President's initiative has added the organizational risk that elements of the BCPR might be compromised in an effort to meet a societal goal.

- Time is an important dimension of risk, particularly in the context of long-duration space flight, such as the 30-month Mars mission outlined in the President's initiative. Lack of attention to the dimension of time makes it difficult to identify risk priorities and determine countermeasure readiness, predict the maintainability of systems and equipment, and understand the impact of space flight on crew health over time.
- Health-related studies based on observations of crew members always will suffer from small sample size. Consequently, any inferences based on single missions will have inadequate statistical power. Methods are available to address this problem, including the pooling of data from multiple studies or missions in the manner of sequential clinical trials and Bayesian sequential trials.
- Standard procedures are needed for incorporating the results of ongoing research into the calibration of risk, including the development of mechanisms for updating risk assessment and the establishment of exit criteria for risks for which adequate mitigation measures have been developed. The long time frame of the space initiative makes it likely that new knowledge and technologies will need to be incorporated into the BCPR. A structure that provides focus and attention throughout the agency and at the same time clearly identifies the "owner and manager" of the BCPR will help assure that it remains a dynamic document over the coming decades.
- Human factors are a high priority in space engineering design, especially in an era of planetary exploration. Linking human factors with engineering perspectives in the BCPR is important for the development of countermeasures, for example, for musculoskeletal weakness upon arrival in a gravitational environment after long-duration space flight, control of radiation exposure, and identification of coping skills and preventive measures to respond to the stresses of prolonged space flight.
- Analog environments, notably polar expeditions in the Arctic and Antarctic, high-altitude exploration, undersea exploration, and space simulation studies, provide a wealth of data and information that could be further incorporated into the BCPR to make the current analyses more robust.

In summary, the current BCPR is a solid beginning for the further understanding, management, and mitigation of the risks associated with longer duration space flight. However, additional refinement and development is required to take full advantage of current evidence regarding these risks and to develop a focused and prioritized plan for their mitigation to the crew, the mission, the program, the agency, and the national image associated with space flight. This could lead to the development of a management tool that will guide NASA leadership in assigning the operational and research priorities that will be required prior to future lunar and Mars missions.

NEXT STEPS

The IOM committee plans to engage in information collection efforts over the next 11 months in order to provide NASA with recommendations about risk communication and about the assessment, management, and implementation of the BCPR with respect to bioastronautics research for the missions contemplated in the President's exploration initiative. The committee's work will include a visit to the Johnson Space Center, other meetings with NASA personnel, other NASA decision makers, and those in operational areas related to the human space flight program, and analysis of testimony from a wide range of experts in the areas of bioastronautics and risk assessment. The final report will be issued in August 2005.

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IOM (Institute of Medicine). 2001. *Small Clinical Trials.* Evans, C.H., Ilstad, S.T., eds. Washington, DC: National Academy Press.

NASA (National Aeronautics and Space Administration). 2004. *Bioastronautics Critical Path Roadmap: An Approach to Risk Reduction and Management for Human Space Flight.* Houston, TX: Lyndon B. Johnson Space Center.

Appendix A

Methods

The committee developed this interim report and arrived at preliminary conclusions about the strengths and weaknesses of the BCPR during a five-month period from April 2004 to September 2004. During this time, the committee held three data-gathering sessions and met in closed session three times to deliberate. Agendas for the open, data-gathering sessions of these meetings are included in this appendix. The committee's final report will provide a full list of meeting participants and contributors to the study process.

INSTITUTE OF MEDICINE
AGENDA
Committee on Aerospace Medicine and Medicine in Extreme Environments
and
Committee on Review of NASA's Bioastronautics Critical Path Roadmap

Keck Building
500 5th Street, NW
Washington, DC
Room 110

MONDAY, APRIL 12, 2004

CLOSED SESSION (committee and staff only)
8:00 a.m. – 12:00 p.m.

OPEN SESSION

12:00 p.m.	**Lunch**
1:15 p.m.	**Request for a review of the Bioastronautics Critical Path Roadmap** *Richard Williams, M.D., Chief Health and Medical Officer, NASA*
2:00 p.m.	**Overview of the Bioastronautics Critical Path Roadmap** *NASA presenters: Guy Fogleman, Director of Bioastronautics Research, Office of Biological and Physical Research; Howard Ross, Acting Deputy Associate Administrator for Science, Office of Biological and Physical Research; Mark Shepanik, Aerospace Medicine Specialist, NASA; Frank Sulzman, Manager, Space Radiation Health Project*
3:00 p.m.	**Break**
3:30 p.m.	**Categories of critical research issues and metrics used in the Bioastronautics Critical Path Roadmap**
4:10 p.m.	**Efficiency and technology issues in the Bioastronautics Critical Path Roadmap**
4:50 p.m.	**Plenary discussion** Led by *David Longnecker, M.D.*
5:30 p.m.	**Adjourn to reception and dinner with invited guests** *Location: third floor atrium*

INSTITUTE OF MEDICINE
AGENDA
Committee on Aerospace Medicine and Medicine in Extreme Environments
and
Committee on Review of NASA's Bioastronautics Critical Path Roadmap

Keck Building
500 5th Street, NW
Washington, DC
Room 110

TUESDAY, APRIL 13, 2004

OPEN SESSION

8:00 a.m.	**Continental breakfast**
8:30 a.m.	**Welcoming remarks** *David Longnecker, M.D.*
8:45 a.m.	**Overview of related work by the National Academies**
9:00 a.m.	**Space Studies Board/Aeronautics and Space Engineering Board**
9:30 a.m.	**Committee on Aerospace Medicine and Medicine in Extreme Environments**
10:00 a.m.	**Break**

CLOSED SESSION (committee and staff only)

10:15 a.m. – 3:30 p.m.

INSTITUTE OF MEDICINE
AGENDA
Committee on Review of NASA's Bioastronautics Critical Path Roadmap

Keck Building
500 5th Street, NW
Washington, DC
Room 204

WEDNESDAY, JUNE 9, 2004

OPEN SESSION

9:00 a.m.	**Welcome and overview of day's agenda** *David Longnecker, M.D., and Lisa Vandemark, Ph.D.*
9:15 a.m.	**Briefings related to the review of the Bioastronautics Critical Path Roadmap** *NASA presenters: Lauren Leveton, Bioastronautics Science Management Team, NASA; Holly Patton, Aerospace Technologist, NASA; David Tomko, Lead Scientist, Biomedical Program, NASA Bioastronautics Research Division; Guy Fogleman, Director of Bioastronautics Research, Office of Biological and Physical Research; Frank Sulzman, Manager, Space Radiation Health Project*
12:00 p.m.	**Lunch**
1:00 p.m.	**Bone loss and countermeasures: historical perspectives and new in-flight clinical studies** *Jay Shapiro, M.D., Uniformed Services University*
2:00 p.m	**Harmonization of crew living module and extra-vehicular pressure suit atmospheric constituents and pressures** *Bruce McCandless, M.S., M.B.A., Lockheed Martin*
3:00 p.m.	**Break**
3:30 p.m.	**An overview of space biology from cells to humans** *David Klaus, Ph.D., University of Colorado, Boulder*
4:30 p.m.	**Plenary discussion** Led by *David Longnecker, M.D.*
5:30 p.m.	**Adjourn**

THURSDAY, JUNE 10, 2004

CLOSED SESSION (committee and staff only)

8:30 a.m. – 3:00 p.m.

INSTITUTE OF MEDICINE
AGENDA

Committee on Review of NASA's Bioastronautics
Critical Path Roadmap
Keck Building
500 5th Street, NW
Washington, DC
Room 201

MONDAY, AUGUST 2, 2004

OPEN SESSION

9:00 a.m.	**Welcome, introductions, and overview of day's agenda** *David Longnecker, M.D., and Lisa Vandemark, Ph.D.*
9:20 a.m.	**Briefings related to the review of the Bioastronautics Critical Path Roadmap** *Richard Williams, M.D.*
10:30 a.m.	**Break**
11:00 a.m.	**Briefings related to the review of the Bioastronautics Critical Path Roadmap** *NASA presenters via videoconference from JSC: Guy Fogleman, Director of Bioastronautics Research, Office of Biological and Physical Research; Mark Shepanik, Aerospace Medicine Specialist, NASA; Desmond Lugg, Chief, Medicine of Extreme Environments, Office of the Chief Medical Officer*
11:30 a.m.	**Question and answer discussion** *David Longnecker, M.D., moderator*
12:00 p.m.	**Lunch**
1:00 p.m.	**Advanced life support issues** *Brian Dunaway, Boeing Corporation*

CLOSED SESSION (committee and staff only)
2:30 p.m. – 5:30 p.m.

TUESDAY, AUGUST 3, 2004

CLOSED SESSION (committee and staff only)
8:30 a.m. – 3:00 p.m.

Appendix B

NASA. 2004. *Bioastronautics Critical Path Roadmap (BCPR): An Approach to Risk Reduction and Management for Human Space Flight.* Houston, TX: Lyndon B. Johnson Space Center

An electronic copy of the BCPR is included on the CD-ROM located in the back cover sleeve.

Appendix C

Bibliography of Related National Academies Reports

IOM (Institute of Medicine). 2001. *Safe Passage: Astronaut Care for Exploration Missions.* Washington, DC: National Academy Press.

IOM (Institute of Medicine). 2001. *Small Clinical Trials.* Evans CH, Ilstad ST, Eds. Washington, DC: National Academy Press.

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Appendix D

Committee and Staff Biographical Information

DAVID E. LONGNECKER, M.D., *Chair,* is Professor of Anesthesia at the University of Pennsylvania. He has received numerous NIH research grants and a Research Career Development Award for research involving the effects of anesthetics on the microcirculation, oxygen delivery to tissue, oxygen therapeutics, endothelium-dependent circulatory control, and health services research. Dr. Longnecker is a member of IOM and Chair of the IOM's Committee on Aerospace Medicine and the Medicine of Extreme Environments.

JAMES P. BAGIAN, M.D., P.E., is Director, Department of Veterans Affairs National Center for Patient Safety. From 1980 to 1995, Dr. Bagian served as a NASA astronaut. He is a veteran of two Shuttle missions, including the first dedicated Space and Life Sciences Spacelab mission. He was also a lead investigator for both the Challenger and Columbia accidents. Dr. Bagian focuses on applications in aerospace systems, notably crew survival and physiological adaptation issues that affect aviation and space flight operations, as well as environmental technology. He has also developed and implemented, on a national and international basis, systems-based solutions to improve patient safety. Dr. Bagian is a member of IOM and NAE and has served on or chaired numerous committees of the National Academies.

ELIZABETH CANTWELL, Ph.D., is Section Leader in the Micro and Nanotechnology Center of the Lawrence Livermore National Laboratory. Dr. Cantwell works with issues involving technology transfer, strategic planning for new programs, technology assessment for microtechnology and biotechnology, the development of new applications and clients, environmental monitoring and sensors, and drinking water security. Previously, Dr. Cantwell was a program manager in the Life Sciences Division at NASA Headquarters. Her main responsibility at NASA was the Advanced Environmental Monitoring and Control Program. Dr. Cantwell was a member of the previous NRC Committee on Human Support in Space.

VALERIE GAWRON, Ph.D., is Chief Scientist, Human Factors, Flight and Aerospace Research Group, Veridian Corporation, Buffalo, New York. Dr. Gawron is a fellow of the Human Factors and Ergonomics Society and associate fellow of the American Institute of Aeronautics and Astronautics, with previous NRC service. Currently, her research focuses on the cognitive and environmental effects of human performance, with a specialization in situational awareness, testing, and evaluation. She is also currently the Chair of the Science and Technology Working Group of NASA's Space-Human Factors Engineering Group.

CHRISTOPHER HART, J.D., M.S., is Assistant Administrator for System Safety, Federal Aviation Administration (FAA). Mr. Hart holds a bachelor's degree and master's degree in aerospace and mechanical science from Princeton University, as well as a law degree from Harvard University. He holds a commercial pilot's license with multi-engine and instrument ratings. He has served as a member of the National Transportation Safety Board (1990–1993), where he had specialized interests in human factors and the impact of automation on transportation systems.

CHARLES LAND, Ph.D., is a Senior Investigator with the National Cancer Institute, specializing in studies of cancer risk in populations exposed to ionizing radiation from medical, occupational, and environmental sources, including the survivors of the atomic bombings of Hiroshima and Nagasaki and populations exposed to radioactive fallout from nuclear weapons testing in Kazakhstan. A related area of interest is accounting for subjective and statistical uncertainty in the expression of information on risk. Dr. Land is a member of the National Council on Radiological Protection and Measurements, and of Committee 1, on Risk, of the International Commission on Radiological Protection. He is a fellow of the American Statistical Association.

THOMAS TEN HAVE, Ph.D., is Professor of Biostatistics, Department of Biostatistics and Epidemiology, School of Medicine, and Senior Fellow, Institute on Aging, at the University of Pennsylvania. Dr. Ten Have's methodological interests focus on effectiveness research in the context of multisite randomized and observational studies in psychiatry, geriatrics, family medicine, addiction research, and disparities research. In particular, he has received funding to develop new methods for adjusting for patient and physician noncompliance in randomized trials, group-randomized trials, and confounding due to clinics, centers, or practices. Dr. Ten Have is associate editor of *Biometrics and Statistics in Medicine.*

DANIEL R. MASYS, M.D., is Director of Biomedical Informatics and Professor of Medicine, University of California, San Diego, School of Medicine. He was Chief of the International Cancer Research Data Bank of the National Cancer Institute, NIH, and from 1986 through 1994 was Director of the Lister Hill National Center for Biomedical Communications. Dr. Masys is a diplomate of the American Board of Internal Medicine in Medicine, Hematology, and Medical Oncology. He is a fellow of the American College of Physicians, fellow of the American College of Medical Informatics, and member of IOM. He has served as a consultant to the NASA Life Science Informatics program and is an active instrument-rated pilot.

BRUCE McCANDLESS II, M.S., is an aerospace engineer and Research Scientist in Advance Space Transportation Systems at Lockheed Martin. He is a former NASA astronaut. Mr. McCandless has directed numerous space technology risk assessment efforts including the first phase of the Jupiter Icy Moons Orbiter nuclear-fission powered space craft studies, analysis of acoustical properties of the International Space Center, Bride-to-Space and other tether technology programs, and fuel and power-related studies for space travel.

TOM S. NEUMAN, M.D., is Professor of Medicine and Surgery and Associate Director, Department of Emergency Medicine, University of California, San Diego, San Diego Medical Center. Dr. Neuman is board certified in internal medicine, pulmonary disease, occupational medicine, undersea and hyperbaric medicine, and emergency medicine. He is a fellow of the American College of Physicians and the American College of Preventive Medicine. Dr. Neuman has been a leader in the field of the physiology and medicine of diving throughout his career and was the editor-in-chief of *Undersea and Hyperbaric Medicine* until July 2002. He is the co-editor of the most widely used textbook of diving medicine and physiology. He previously served on the IOM Committee on Space Medicine.

THOMAS F. OLTMANNS, Ph.D., is Edgar James Swift Professor of Arts and Sciences in the Department of Psychology at Washington University in St. Louis, Missouri. He previously served as a Professor of Psychology and Psychiatric Medicine and Director of Clinical Training in Psychology at the University of Virginia and as a Professor of Psychology at Indiana University. Dr. Oltmanns is past president of the Society for a Science of Clinical Psychology and is a consulting editor for the *Journal of Abnormal Psychology* and member of the editorial board for *Psychological Bulletin* and the *Journal of Personality Disorders*. His research has included peer assessment of personality traits and pathology. He has served on two different grant review committees for the National Institute of Mental Health and is a member of NASA's Astronaut Selection Psychiatric Standards Working Group.

LAWRENCE A. PALINKAS, Ph.D., is Professor and Vice Chair, Department of Family and Preventive Medicine, University of California, San Diego. Dr. Palinkas serves as the Deputy Chief Officer of the Life Sciences Standing Scientific Committee of the Scientific Committee on Antarctic Research. He has more than 15 years of experience in studying behavioral adaptation in the Antarctic. He also has been active in translating Antarctic research for use in developing effective countermeasures to long-duration missions in space. Dr. Palinkas served as a member of the NAS Committee on Space Biology and Medicine from 1997 to 2000. He currently serves as Chair of the External Advisory Council of the National Space Biomedical Research Institute and as a member of the Behavior and Performance Integrated Product Team at NASA's Johnson Space Center.

JAMES PAWELCZYK, Ph.D., is a physiologist at the Noll Physiological Research Center of Pennsylvania State University. He was Payload Specialist on STS-90 (Neurolab) and flew in 1998 with a focus on neuroscience. Dr. Pawelczyk has been a member of the NASA Life Sciences Advisory Subcommittee, Office of Biological and Physical Research since 1998, and was a member of the ReMaP Task Force in 2002, which was charged with reprioritizing research on the Space Station. He has held various NASA funding as an individual principal investigator and as a project leader on center grants and for contracts (including those involving international collaboration) since 1993. Dr. Pawelczyk's research areas include central neural control of the cardiovascular system and compensatory mechanisms to conditioning and deconditioning.

BRUCE S. RABIN, M.D., Ph.D., is Professor of Pathology and Psychology, University of Pittsburgh Medical Center, and Director of the Clinical Immunopathology Laboratory. A main focus of his interest is in the interrelationship among stress, immune function, and health. Dr. Rabin is Past President of the Psycho-neuro-immunology Research Society. He has served on a number of government panels to promote research in mind-body interactions. Dr. Rabin's research includes interdisciplinary investigations into the effects of stress on human body systems, including several disciplines germane to this study, such as immunology and human behavior changes.

KARLENE ROBERTS, Ph.D., is a Professor in the Haas School of Business of the University of California, Berkeley, and a research psychologist at Berkeley's Institute of Industrial Relations. Dr. Roberts has expertise in the design and management of organizations and systems of organizations for which errors can have catastrophic consequences. The results of her research have been applied to the medical industry and to programs in numerous organizations including the U.S. Navy and Coast Guard, the FAA's Air Traffic Control System, and NASA. Dr. Roberts is a fellow of the American Psychological Association and the American Psychological Society.

CAROL SCOTT-CONNER, M.D., Ph.D., is Professor of Surgery at the University of Iowa Carver College of Medicine, Iowa City. From 1995 to 2004, she was Professor and Head of Surgery at the same institution. Dr. Scott-Conner has been active on 22 editorial boards and has authored more than 200 original papers, abstracts, reviews, and book chapters. She holds memberships in many elected surgical societies and has frequently served in leadership positions. She previously served as a member of the IOM Committee on Space Medicine.

MARGARET RHEA SEDDON, M.D., is Assistant Chief Medical Officer, Vanderbilt Medical Group, Nashville, Tennessee, and a former three-flight veteran astronaut for NASA. As an astronaut, she logged more than 722 hours in space. She was a mission specialist on STS-51D and STS-40 and was Payload Commander on STS-58. Dr. Seddon also served in several other capacities at NASA, namely as technical assistant to the Director of Flight Crew Operations, as special adviser for Shuttle/Mir scientific payloads, and as a member of NASA's Aerospace Medical Advisory Committee and the International Bioethics Task Force. Dr. Seddon's areas of interest are emergency medicine and nutrition.

JAY R. SHAPIRO, M.D., is the Director, Interdepartmental Center for Space Medicine, Uniformed Services University and Director of the Osteogenesis Imperfecta Program at the Kennedy-Krieger Institute. Dr. Shapiro has many years of direct experience with NASA research and clinical countermeasures related to bone and muscle loss in a microgravity environment. As such, he has a critical historical perspective on NASA risk management of bone loss and expertise in a wide range of clinical countermeasures, including exercise and in-flight drug trials.

STAFF

ANDREW M. POPE, Ph.D., is Director of the Board on Health Sciences Policy at the Institute of Medicine. With expertise in physiology and biochemistry, his primary interests focus on environmental and occupational influences on human health. Dr. Pope's previous research activities focused on the neuroendocrine and reproductive effects of various environmental substances on food-producing animals. During his tenure at the National Academy of Sciences and since 1989 at the Institute of Medicine, Dr. Pope has directed numerous studies on topics that include injury control, disability prevention, biologic markers, neurotoxicology, indoor allergens, and the enhancement of environmental and occupational health content in medical and nursing school curricula. Most recently, Dr. Pope directed studies on priority-setting processes at the National Institutes of Health, fluid resuscitation practices in combat casualties, and organ procurement and transplantation.

LISA M. VANDEMARK, Ph.D., has a Ph.D. in Geography from Rutgers University and an M.S. in Human Ecology from the University of Brussels, Belgium. She is a registered nurse with a B.S. from Rutgers University.

Since 2000 Dr. Vandemark has been a Program Officer at the NRC's Board on Earth Sciences and Resources, and in 2003 she served as a consultant to NOAA on geospatial capacity-building in Africa. Prior to joining the NRC, she was a research associate at the Institute of Marine and Coastal Sciences, Rutgers University; a policy intern at the National Science Resources Center at the Smithsonian Institution; and a psychiatric nurse at McLean Hospital and the Quincy (Massachusetts) Mental Health Center. Her research interests include environmental perception and decision making, international development, natural resource management, and interdisciplinary approaches to policy analysis.

MELVIN H. WORTH, JR., M.D., is a Scholar-in-Residence at the Institute of Medicine. Dr. Worth completed his surgery residency at New York University–Bellevue in 1961 and remained on that faculty for 18 years. He founded the Bellevue Trauma Service in 1966 and continued as Director until 1979, when he left to become director of surgery at Staten Island University Hospital. He served for 15 years with the New York State Office of Professional Medical Conduct and 8 years as a member of the New York State Hospital Review and Planning Council (for which he was chair in 1993). He is a fellow of the American College of Surgeons, American College of Gastroenterology, and International Society for Surgery and holds memberships in the American Association for the Surgery of Trauma, Society for Critical Care Medicine, Association for Academic Surgery, New York Surgical Society (of which he was president in 1979), and other academic and professional organizations. Dr. Worth retains his appointment at New York University and is Clinical Professor of Surgery at the State University of New York Downstate (Brooklyn) and the Uniformed Services University of the Health Sciences. Dr. Worth most recently served as an IOM study staff member to the Committee on Fluid Resuscitation for Combat Casualties and is the senior adviser to the Committee on Creating a Vision for Space Medicine During Travel Beyond Earth Orbit.

BENJAMIN N. HAMLIN, B.A., Research Associate at the Institute of Medicine, received his bachelor's degree in biology from the College of Wooster in 1993 and a degree in health sciences from the University of Akron in 1996. He then worked as a surgeon's assistant in the fields of vascular, thoracic, and general surgery for several years before joining the National Academies staff in 2000. As a Research Assistant for the Division on Earth and Life Studies at the National Academies, he worked with the

Board on Radiation Effects Research on projects studying the health effects of ionizing and non-ionizing radiations on the human body. He has worked on a number of Institute of Medicine studies, including *Testosterone and Aging: Clinical Research Directions; Review of NASA's Longitudinal Study of Astronaut Health; Health Literacy: A Prescription to End Confusion; Improving Medical Education: Enhancing the Behavioral and Social Science Content in Medical School Curricula;* and *NIH Extramural Center Programs: Criteria for Initiation and Evaluation.* Mr. Hamlin is currently pursuing graduate work in the sociomedical sciences. He is also involved with the U.S.–Bangladesh Advisory Council, an organization that promotes governmental cooperation between the United States and Bangladesh on matters of trade and health care.

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