

NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory at Boston University Medical Center

Working Group of the Advisory Committee to the Director

Summary of Public Meeting October 14, 2008

The NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory (NEIDL) at Boston University Medical Center (BUMC) (Blue Ribbon Panel [BRP or “the Panel”]), a working group of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH), was convened for its fifth meeting at 6:30 p.m. on October 14, 2008, at the Roxbury Center for the Arts, Hibernian Hall, 184 Dudley Street, Roxbury, Massachusetts. Dr. Adel Mahmoud (Chair) presided. In accordance with Public Law 92-463, the meeting was open to the public from 6:30 p.m. until 10:30 p.m. on October 14, 2008. Notice of this meeting was published in the *Federal Register* on September 23, 2008 (73 FR 54841). The purpose of this meeting was to discuss draft principles and draft strategies for effective community engagement, with time allotted for public comment.

Panel Members Present

Stephen Eubank, Ph.D., Virginia Polytechnic Institute and State University
Vicki S. Freimuth, Ph.D., University of Georgia
George Friedman-Jiménez, M.D., Bellevue Hospital Center
Dennis L. Kasper, M.D., Harvard Medical School and Brigham and Women’s Hospital
Johnnye Lewis, Ph.D., DABT, University of New Mexico
W. Ian Lipkin, M.D., Northeast Biodefense Center and Columbia University
Adel Mahmoud, M.D., Ph.D., Princeton University (Chair)
Thomas H. Murray, Ph.D., The Hastings Center
Mary E. Northridge, Ph.D., M.P.H., Columbia University and *American Journal of Public Health*
Jean Patterson, Ph.D., Southwest Foundation for Biomedical Research
Samuel L. Stanley, Jr., M.D., Midwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research and Washington University in St. Louis
Wayne Thomann, Dr.P.H., Duke University/Duke University Medical Center

NIH Staff Members Present

Amy P. Patterson, M.D., Office of the Director (OD), NIH

Moderators for the Public Comment Sessions

John T. Burklow, OD, NIH
Alfred C. Johnson, Ph.D., Director, Office of Research Services (ORS), OD, NIH

Others

Approximately 350 people attended this BRP meeting.

I. Welcome and Introduction of Blue Ribbon Panel Members/Dr. Mahmoud

Dr. Mahmoud, BRP Chair, called the BRP's second meeting in Boston to order at 6:30 p.m. on October 14, 2008. BRP members introduced themselves with name, professional affiliation, and primary area of professional activity.

Dr. Mahmoud reviewed the purpose of this meeting, which was to discuss draft principles and draft strategies for effective community engagement, with significant time allotted for public comment. Other topics to be covered were the charge of the BRP, an update on the risk assessment, and Boston's prohibition on recombinant deoxyribonucleic acid (rDNA) research. He thanked Klare Allen, Ruth Barkley, Elmer Freeman, and Carmen Nazario-Vega for their assistance in obtaining the meeting site and in publicizing the meeting. Translators were available for Spanish, Mandarin, Haitian Creole, and Sign Language for anyone who notified the registration desk staff of such need.

II. NIH Blue Ribbon Panel: Background, Charge, and Progress Update/Dr. Mahmoud

Dr. Mahmoud provided background information about the BRP. Established by NIH Director Dr. Elias Zerhouni, the BRP was tasked with providing scientific and technical advice to the NIH regarding the construction and operation of a national biocontainment laboratory at the BUMC, known as the NEIDL. The two-part charge to the BRP is to advise on (1) studies to assess any potential public health risks associated with the operation of the NEIDL and strategies for mitigating these risks and (2) strategies to enhance local community relations and communications regarding national and regional biocontainment laboratories.

Regarding the ongoing supplementary risk assessment study, Dr. Mahmoud explained that the assessment is being conducted with a broad range of infectious agents and scenarios and with ongoing oversight of this supplementary risk assessment study by the BRP. Public comment in the draft study will occur in late 2009. In the meantime, the interim status of the NEIDL's operation is that no biosafety level (BSL) 3 (BSL-3) or BSL-4 research will be conducted at least until the courts have made their decisions; BUMC has proposed to use the empty space in that building to conduct public safety, health, and operations training in partnership with public health authorities.

Regarding the prohibition by the City of Boston on the use of rDNA at the BSL-4 level, Dr. Mahmoud explained that NIH grants include a stipulation that NIH-funded research and construction must comply with all applicable laws and requirements at the Federal, State, and local levels. On the basis of this provision, Boston University (BU) and other grantees must abide by Boston's prohibition on rDNA research. BU has affirmed that all activities will be in compliance with this prohibition.

III. Development of Principles and Best Practices for Public and Local Community Relations and Communications/Dr. Northridge

Dr. Northridge discussed briefly the BRP's proposed principles and best practices for public and local community relations and communications. These recommendations were considered because of the issues that arose as a result of the NEIDL, but they apply to all regional and national laboratories funded by the NIH. Whether these principles are applicable to BU and the NEIDL will be determined by whether the ongoing supplementary risk assessment study and court cases point to the acceptability of conducting high- and maximum-containment research conditions at this location. These principles are performance standards that will be implemented by local jurisdictions and that allow some latitude in reaching the desired outcomes.

In a meeting at the end of October 2008, discussion of these principles and best practices will occur with other regional biocontainment laboratories (RBLs) and national biocontainment laboratories (NBLs), which are funded through the NIH's National Institute of Allergy and Infectious Diseases' Emerging Infectious Diseases and Biodefense Program.

The draft principles are:

1. Rigorous, balanced, and transparent local biosafety review of proposed biocontainment research at high- and maximum-containment research at NIH-funded RBLs and NBLs
2. Maximal transparency regarding facility operation, nature of research, and oversight of research
3. Community engagement
4. Appropriate technical expertise
5. Engagement of local public health authorities
6. Ongoing operations oversight

IV. Draft Principles for Public and Local Community Relations and Communications Regarding a National Research Resource/Dr. Lewis

Dr. Lewis elaborated on the six draft principles introduced by Dr. Northridge, for the purpose of stimulating ideas about how to implement these principles:

1. *Local biosafety review.* All high- and maximum-containment research requires a rigorous process of local biosafety review that extends beyond the current requirements for biosafety review that apply only to research with select agents or rDNA at institutions funded by the NIH for that type of research. Community representation should foster better understanding by the community regarding the nature and goals of biocontainment research and should help ensure that concerns about public health and safety are addressed adequately. To keep these reviews intellectually independent, reviewers should be free of conflicts of interest.
2. *Maximal transparency.* Information should be shared as appropriate with the public to educate the public and develop and maintain public trust with regard to facility operations, the types and outcome of the research being conducted, and the oversight process.
3. *Ongoing pattern of community engagement.* Community engagement affords community members the opportunity to become informed about and familiar with the facility and its research activities, and provides a mechanism or venue for expressing concerns. When activities are directed toward addressing community concerns, community members should be invited to play key roles in such activities.
4. *Technical expertise.* All biocontainment facilities must have sufficient numbers of appropriately trained resident technical experts to ensure safe operation and safe access. In addition, experts in public health and infectious diseases are necessary for protocol review and day-to-day operations, as well as for the development and review of plans for responding effectively to accidents and emergencies. Ongoing training programs for facility staff members, provided by the NIH, will optimize the safety of laboratory workers as well as the public.
5. *Engagement of local public health authorities.* Because rigorous oversight of the operation of biocontainment facilities is essential, institutions should engage local public health authorities early in the process. In addition, regular communication should be established and maintained by the institutional biosafety committee (IBC) at the institution and the public health authority regarding protocols, types of research, and hazards of the agents.
6. *Ongoing operations oversight.* Rigorous ongoing oversight of the operation of biocontainment facilities is essential to ensuring the safe and optimal operation of the facility as well as to facilitate and maintain public trust. Ongoing monitoring and transparency will protect public health and safety.

V. Strategies for Carrying Out Principles for Public and Local Community Relations and Communications Regarding a National Research Resource/Dr. Stanley

Dr. Stanley reviewed the three draft recommended strategies: mechanisms for transparent local review and oversight of high- and maximum-containment research, community liaison activities, and a communications plan regarding phase-in of research operations.

Currently, IBC review is mandated only for rDNA research that is funded by the NIH. Such review comprises including community representatives and experts in biosafety and related science, obtaining the authority to approve or disapprove rDNA protocols, providing ongoing oversight in the form of inspection and auditing throughout the life of the research project, and ensuring transparency by making the minutes of IBC meetings available to the public. Although IBC review currently is mandated for rDNA research only, almost all institutions have established local review and oversight mechanisms for any biohazardous research. The BRP recommends that all high- and maximum-containment infectious disease research conducted in RBLs and NBLs and funded by the NIH be reviewed, approved, and overseen by an institutional body, of which IBCs are one example.

Because community liaison activities are vital ways to enhance openness and transparency with respect to the research agenda of the institution, the BRP recommends that these activities should be integrative and should offer opportunities for (1) input from the community about the impact of the laboratory and the kind of research to be conducted there, (2) communication to the community regarding laboratory operations, and (3) community education about research programs and the public health benefits of research.

The BRP's third recommendation is that RBLs and NBLs funded by the NIH should communicate specific information regarding safeguards and precautions that are customary practice in phasing in research operations, including conducting low-containment research under maximum-containment conditions for training and assessing the readiness of the operation. Institutions should inform their communities about plans for transitioning to a fully operational high- and/or maximum-containment laboratory.

VI. Questions for Public Consideration and Discussion

Facilitators: John T. Burklow, Office of Communications (OC), Office of the Director (OD), NIH; and Elmer R. Freeman, M.S.W., Center for Community Health, Education, Research and Service and Northeastern University

Dr. Mahmoud explained that the BRP is seeking community input on the following three questions related to its charge. Oral remarks were limited to 3 minutes in order to maximize the number of speakers. Longer and additional comments were invited in writing, by e-mail to NIH_BRP@od.nih.gov, and via the U.S. Postal Services (USPS) to NIH Blue Ribbon Panel, National Institutes of Health, 6705 Rockledge Drive, Suite 700, MSC 7985, Bethesda, MD 20892-7985.

Question 1: How can institutions most effectively reach out to local communities and educate them about these laboratories?

Question 2: What kind of information regarding the planning and oversight of biocontainment research facilities should community members know?

Question 3: What are appropriate ways for institutions to seek out community perspectives on the oversight of biocontainment research facilities?

The following individuals commented on Question 1 or remarked on other issues related to the NEIDL:

- James L. Fox, Upton Street resident, Vice President, Union Park Neighborhood Association
- Lillian Greeley, Cambridge resident

- Amy Hendrickson, Brookline resident
- Pat Hines, BU School of Public Health
- William Lynch, registered sanitarian
- Grace Ross, citizen
- Richard Trevino, Worcester Square resident
- Donovan Walker, Developmental Neighborhood Coalition, Roxbury
- Plus one other who did not identify himself

The following individuals commented on Question 2 or remarked on other issues related to the NEIDL:

- Walter Depena, BU student and community resident
- Carmen Nazario-Vega, Safety Net
- Mark Pelletier, local resident and biomedical researcher
- Elizabeth Tobin, Roslindale resident
- Vicky Steinitz, Cambridge United for Peace
- Plus three others who did not identify themselves

The following individuals commented on Question 3 or remarked on other issues related to the NEIDL:

- Ruth Barkley, Cathedral United Tenants Organization
- Eloise Lawrence, private citizen
- Mark Pelletier, local resident and biomedical researcher
- Carmen Pola, resident
- Charles C. Yancey, Boston City Councilor
- Plus four others who did not identify themselves

The following clarification of fact was offered by Michael G. Kurilla, an NIH representative: Regarding classified research, the NIH does not support or fund classified research of any type. BU has affirmed it will not engage in any form of classified research whatsoever.

Dr. Mahmoud offered the following clarifications and additional information:

- The BRP has advised the NIH to conduct a comprehensive risk assessment study that includes risk mitigation and emergency responses to any possible accident. The NIH approved the BRP's recommendation, and the community will have an opportunity to critique the risk assessment after it has been completed in late 2009.
- Development of bioweapons is forbidden by U.S. law and international law. Anyone who develops bioweapons can be prosecuted criminally.
- Bioweapons research is different from biodefense research. Biodefense research is conducted to develop protective interventions; one such example was the 2001 anthrax attacks, against which the United States had at the time only one (weak) defense.

Dr. Lewis asked for attendees to raise their hands for a poll as follows:

- Attending a meeting about the NEIDL for the first time—approximately 35% of attendees
- Supporters of the NEIDL—about 20 people
- Against the NEIDL—most attendees
- Undecided about the NEIDL—5 to 10 people

VII. General Discussion

Facilitators: John T. Burklow, OC, OD, NIH, and Alfred C. Johnson, Ph.D., Director, ORS, OD, NIH

Mr. Burklow and Dr. Johnson reviewed the procedures for the public input portion of the meeting, which was approximately 2 hours long. Individuals who wished to speak had been asked to sign up at the table outside the room starting approximately 1 hour before the meeting began, and additional comments were noted as possible if all the registered remarks were completed within the allotted timeframe.

Oral statements were limited to 3 minutes to allow enough time for all individuals to speak, and individuals were encouraged to submit their remarks in writing if more time was needed. Written comments were invited by e-mail to NIH_BRP@od.nih.gov and via the USPS to NIH Blue Ribbon Panel, National Institutes of Health, 6705 Rockledge Drive, Suite 700, MSC 7985, Bethesda, MD 20892-7985. Envelopes and paper were available at the registration desk.

Public Commenters

Although this list of commenters includes the affiliations of most of the speakers, in most cases it was not clear whether the individual was speaking for herself/himself or for her/his organization. Names are listed alphabetically within each of two groups.

Speaking *in support* of the NEIDL were the following individuals:

- Carlos Benitez, Dorchester resident and biotech worker
- Chris Brayton, Community Liaison Committee
- Jane Bryant, South End resident
- Deborah Cochever, Tufts University, Grafton
- Robert Fineberg, University of Massachusetts, Worcester
- Jeffrey Gelfand, Massachusetts General Hospital/Harvard University
- Ken Lopez, Heat and Frost Insulators Local 6
- Steven Maloney, Massachusetts Biotech Council
- Robert McCarron, Association of Independent Colleges and Universities of Massachusetts
- Scott Sherman, South End, Dorchester/Fenway resident
- Roger Smith, Broad Institute of MIT and Harvard
- Michael Spillane, Massachusetts Association for Nonprofit Schools
- Roger Wellington, South End resident
- Bob Wells, Dover Neighborhood Association

Speaking *in opposition* to the NEIDL were the following individuals:

- Laura Armand, Lawyers' Committee for Civil Rights (attorneys for those opposing the location of the NEIDL in Boston)
- Ruth Barkley, Cathedral Tenants United
- Glen Berkowitz, resident
- Mary Crotty, Massachusetts Nurses Association
- Sandy Eaton, Massachusetts Nurses Association
- Joan Ecklein, Newton and Women's International League for Peace and Freedom
- Michael Flaherty, At-Large City Councilor
- James L. Fox, Northeastern University
- Mel King, activist and former State representative
- Phoebe Knopf, resident
- Ernesta Krackiewicz, Watertown Citizens for Environmental Safety
- William Leonard, Socialist Workers Party candidate for State Senate

- David Mundel, South End resident
- Mae Riggs, resident
- Grace Ross, 2006 gubernatorial candidate and Worcester resident
- Howie Rotman, Service Employees International Union Local 1199
- Sandra Silver, South End resident
- Tillyruth Teixeira, Massachusetts Senior Action Council
- Chuck Turner, District 7 City Council member
- Donovan Walker, Developmental Neighborhood Coalition
- Sam Yoon, Boston City Council

The following clarifications of fact were offered by Dr. Kurilla:

- The approximate cost of the NEIDL project is \$200 million. Three-fourths of that money came from the NIH and the remainder from BU. No U.S. Department of Defense funding is associated with this project.
- There are not 15 BSL-4 laboratories currently in operation; that figure was derived from incorrect counting methodology by a U.S. General Accounting Office (GAO) report. Currently, four BSL-4 laboratories are under construction by the NIH; none of those four is operating at this time. Some laboratories in the GAO report were double-counted. At present there is a maximum of 12 BSL-4 laboratories, 4 of which are not yet operational (1 is the NEIDL).
- BSL-4 laboratories supported by the NIH are not studying new diseases; they are only studying naturally occurring diseases.
- There is no military involvement in the BU NEIDL laboratory.

Dr. Mahmoud offered the following clarification: Experts are conducting the risk assessment, and their results will be brought back to the community for public debate.

VIII. Closing Remarks/Dr. Mahmoud

Dr. Mahmoud encouraged anyone who did not have a chance to offer comments to do so via e-mail or USPS mail. He reiterated that the BRP's work products will come back to this community for evaluation, and that all community input will be reflected in the minutes of the meeting and will be considered carefully by the BRP.

Dr. Mahmoud thanked all of the public participants at this meeting, with specific thanks to Klare Allen, Ruth Barkley, and Carmen Nazario-Vega who met with the BRP in July 2008 in Bethesda, Maryland, and who urged the BRP to convene a second meeting in Boston.

VII. Adjournment

Dr. Mahmoud adjourned the meeting at 10:30 p.m. on October 14, 2008.

[Note: This summary is based on notes taken at the meeting by a science writer and NIH staff members. More detailed information will be available in the minutes of this meeting. Actions approved by the BRP are considered recommendations to the ACD; therefore, actions are not considered final until approved by the ACD.]

Additional information about this Blue Ribbon Panel can be found at: <http://nihblueribbonpanel-bumc-neidl.od.nih.gov/index.htm>.

Attachment: Roster NIH Blue Ribbon Panel

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