Fundamental Principles and Best Practices for Public and Local Community Engagement and Communications for High- and Maximum-Containment Regional and National Biocontainment Laboratories Funded through the NIAID/NIH Emerging Infectious Diseases and Biodefense Program

Principles and Best Practices Proposed by the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center

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Preface

The NIH Blue Ribbon Panel was established to provide independent and scientifically based advice to the NIH Director on supplementary risk assessment studies to be performed regarding the planning and oversight of the Boston University Medical Center (BUMC) National Emerging Infectious Diseases Laboratories (NEIDL), as well as to advise on principles of engaging and sustaining communication with the community regarding the NEIDL. The concepts offered in this paper were developed to assist NIH and BUMC in their endeavor to further develop plans for community engagement. These concepts will be applicable to the NEIDL if the outcome of ongoing supplementary risk assessment studies and court cases leads to a decision to conduct research at this particular facility under high- or maximum-containment conditions. The Panel views these principles and best practices as broadly applicable to other Regional and National Biocontainment Laboratories funded through the NIAID/NIH Emerging Infectious Diseases and Biodefense Program, and they are thus articulated for that broader audience.

Background

Infectious diseases continue to be a major cause of morbidity and mortality worldwide, causing at least a quarter of the annual estimated 57 million deaths globally. In addition, infectious disease outbreaks can be a major source of public fears and concerns. More than 200 previously unknown infectious disease agents have been identified since the 1970s, including HIV, Ebola virus, hepatitis C virus, and Nipah virus, for which no cures are available. Furthermore, in our modern society, infectious agents that once were endemic to only certain geographic regions are now a potential threat to public health internationally. This fact is attributable to rapid global travel, the growing rural-urban wildlife interface, climate change, and the potential for deliberate release of biological agents.

As part of efforts to ensure our national readiness to address these threats, NIH has provided partial funding for the construction of Regional and National Biocontainment Laboratories (RBLs and NBLs), which provide scientifically valuable high-containment (biosafety level 3) and maximum-containment (biosafety level 4 at NBLs only) research laboratory facilities. These facilities are important elements in the national and international infrastructure of research resources to address these pressing public health concerns regarding emerging infectious diseases, whether these diseases occur naturally or are deliberately introduced. These laboratories not only provide the resources for basic research critical to understanding these infectious agents, but also serve as a critical component of the public health response to infectious diseases outbreaks by providing the means for scientists to develop new diagnostic, therapeutic, and preventive tools and strategies.

Of paramount importance is the safe operation of these facilities, which is supported by long-standing, widely accepted, and proven biosafety practices and containment standards, as well as by more recent technological advances in facilities design and scientific understanding about infectious agents. Also key is public trust in and understanding of the nature of these facilities and the research to be carried out in them. Toward that end, these facilities must be conceptualized, planned, constructed, and operated in a manner that promotes understanding of how they function, offers transparency of their research agendas, and fosters community engagement, particularly with respect to the potential impact of these facilities on local communities. In the same vein, institutions must be publicly accountable for upholding the highest standards of safety and security and for being responsible stewards of publicly funded resources.

With those aims in mind, the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center proposes the following principles and best practices for community relations and communications of RBLs and NBLs funded in part through the NIAID/NIH Emerging Infectious Diseases and Biodefense Program.

Principles

- **Community engagement.** NIH-funded National and Regional Biocontainment Laboratories have the potential for significant day-to-day impact on the surrounding communities in terms of traffic, aesthetics, consumption of public resources, and so forth. In addition, the nature of the research conducted in a biocontainment facility can engender fears and concerns about the health and safety of those who live in close proximity to the facility in the event of an accidental or deliberate release of a pathogen. Consequently, communities surrounding the biocontainment facility should have a means to learn about and convey any concerns about the planning, operation, and oversight of the facility. Institutions should periodically revisit and evaluate, through a transparent and public process, the ongoing effectiveness of their community engagement activities with an eye toward optimizing the value of these programs to the community and the institution.

- **Engagement of local public health authorities.** To promote public health and safety, institutions have a responsibility to apprise public health authorities of the agents under study at the laboratory and to assist them, as appropriate, with developing public health response plans and in addressing questions from the local health care providers.

- **Rigorous, balanced, and transparent local biosafety review of proposed biocontainment research.** In addition to meticulous scientific merit peer review, which all NIH-funded research undergoes, all high- and maximum-containment research at NIH-funded RBLs and NBLs should undergo a rigorous process of local biosafety review to ensure that the research performed in the biocontainment facility will be conducted as safely and securely as possible. Review should occur not only at the proposal stage, but also be ongoing to ensure continued adherence to biosafety standards. This review should encompass all high- and maximum-containment infectious agent research in these facilities, and thus exceeds current requirements, which are limited to recombinant DNA research at institutions funded by NIH for such research. Local review should include an appropriate breadth of scientific, medical, and technical expertise, drawing from outside the institution, as necessary. Local review should also provide for community representation. This can promote better understanding by the community as to the nature and goals of the research and can help to ensure that concerns about public health and safety and the health of the environment are adequately addressed. Finally, local review should also be "intellectually independent" in that the reviewers are free of conflicts of interest and, as important, of influences that may dampen the expression of views that may be perceived as controversial or unpopular.

- **Transparency regarding laboratory operations, research, and oversight.** To the extent possible, details about the operation of the biocontainment facility, the research conducted in the facility, and the processes for oversight of the facility and its associated research should be shared with the public. Examples of relevant details may include those related to risk (or perceived risk) of loss of containment of pathogenic organisms into the local or larger community, results of risk-related evaluations done by oversight committees, and status of and changes in the oversight process itself.

  The open exchange of information enhances education efforts and, moreover, helps to address and dispel concerns about the purpose and operation of biocontainment facilities and to develop and maintain public trust regarding them. Of note, transparency does not mean disclosing specific details that could compromise biosecurity, e.g., locations of particular pathogens or mechanisms for securing pathogens or for controlling access to pathogens.

- **Appropriate scientific and technical expertise.** All of these biocontainment facilities must have appropriately trained scientific and technical staff to ensure that the facility is operating as designed. These individuals provide valuable oversight of

biosafety practices and ensure proper functioning of systems to maintain safe operations. Their efforts help support public safety and, consequently, are essential in establishing and maintaining trust of local residents and the public at large.

- **Ongoing operations oversight at the local level.** Rigorous oversight of the operation of these biocontainment facilities at the local level is essential to ensure the safe and optimal operation of the facility as well as to facilitate and maintain public trust. These activities will include periodic review of protocols and all untoward events with potential public health implications by the Institutional Biosafety Committee (IBC), annual biosafety inspections, and Select Agent inspections.

Recommended Best Practices

These concepts and measures build on existing approaches with the goal of achieving best practices.

- **Ongoing community liaison activities.** National and Regional Biocontainment Laboratories should develop community liaison activities to promote openness and transparency with respect to the research agenda and biosafety record of the institution. These activities should be both integrative and interactive and offer opportunity for
    - Input from the community about the impact of the laboratory on the community;
    - Communication to the community about the operations of the laboratory; and
    - Education targeted at adults and children about the research programs and the public health benefits of the laboratory's research.

  Many NIH-funded high- and maximum-containment laboratories develop, or build on, existing programs of community outreach to ensure an institutional appreciation of the impact of the facility on the surrounding neighborhoods and adjacent communities. Such liaison and other outreach activities yield benefits to all parties concerned and allow productive partnerships to develop.

- **Engagement of local public health authorities.** Institutions should engage local public health authorities early on in the process of planning and constructing maximum-containment NBL facilities, in particular. The public health authorities should be informed of the research agenda of these maximum-containment facilities and the kind of organisms that will be used there, and must be immediately notified of any untoward events with potential public health implications. Furthermore, lines of communication should be established and maintained between the IBC at the institution and the public health authority to include information about research under way in the maximum-containment laboratories of the NBL and any pertinent significant safety issues that may arise.

Institutions also have the responsibility to provide expertise and information to public health authorities to help address questions and concerns from the local health care provider community regarding laboratory activities that may arise from the local health care provider community and, as appropriate, assist public health authorities in the development of public health preparedness plans.

- **Transparent and rigorous assessment by a local review committee of research requiring high or maximum containment.** All high- and maximum-containment infectious disease research conducted in NIH-funded RBLs and NBLs should be reviewed, approved, and overseen by an institutional body (such as the IBC) that
    - Has collective expertise in infectious disease research and biosafety principles and procedures;
    - Includes at least one member representing the laboratory technical staff experienced in the implementation of biosafety practices;
    - Has at least two non-institutional members who can represent the interests of the local community; and
    - Is transparent by virtue of making its meeting minutes publicly available (albeit with provisions to avoid compromising information that is proprietary, private, or essential to biosecurity, e.g., locations of particular pathogens or mechanisms for securing pathogens or for controlling access to pathogens).

  Although existing IBCs are only mandated to review recombinant DNA research, many institutions have their IBCs review all infectious agent research, whether recombinant DNA technologies are employed or not. In those instances, the IBC likely already has the various characteristics described in the best practice articulated above and may represent an appropriate model for this type of research.

- **Communications about phase-in of operations.** To assure the local community of the institution's aims to uphold and maintain the highest safety standards possible, institutions with RBLs and NBLs should include as part of their communications activities specific information regarding the safeguards and precautions that are utilized in phasing in research operations. Phase-in of research operations may include the conduct of low-containment research in maximum containment facilities as part of personnel training in biosafety practices, testing of containment measures, and verification of building systems. These phase-in procedures permit validation of the readiness of the facility and the establishment of a safety record before higher containment research is undertaken.

  Also important is providing information to the community – including employees as key stakeholders – about the various measures institutions take to ensure safety. For example, institutions should provide information about their occupational health plans for surveilling and promptly recognizing laboratory-acquired infections. Institutions should explain how those plans enable prompt detection, treatment, and containment with the goal of minimizing the possibility of secondary transmission. Institutions should educate their communities about these kinds of phase-in operations planned for the RBLs and NBLs and the safeguards they offer. Such educational efforts

should include information on the various facets of these activities, their progress, and plans for transitioning to a fully operational high- or maximum-containment laboratory.

- **Communications about the body of scientific and technical expertise applied to the operations of high- and maximum-containment laboratories.** As noted previously, all of these biocontainment facilities employ a multidisciplinary team of resident experts to help the laboratories run safely and effectively. Engineers, containment specialists, and tradesmen ensure that the facility is operating as designed and maintain the functionality of the facility. Staff competent in biosafety policies and procedures ensure that the principles and practices of laboratory biosafety are adhered to on a daily basis by those involved in the performance of research. In addition, experts in public health and infectious disease develop and review plans for responding effectively to accidents and emergencies. Such individuals also collaborate with local public health authorities in incident response planning and as, needed, in the development of educational resources for local health care providers. Because scientific and technical experts play a major role in ensuring the safe operations of biocontainment facilities, it is advisable that institutions share information with the public about the efforts of these highly trained staff members.

  As a special observation, the Panel noted that, given the need for individuals with expertise in biosafety and biocontainment, NIH should foster the professional development and continued training of a cadre of individuals with these specialized skills. These efforts will optimize the safety of laboratory workers and members of the general public, including those who live in close proximity to the facility.

Conclusion

The successful operation of RBLs and NBLs relies not only on an ongoing commitment to the highest standards of biosafety and biosecurity, but also on the implementation and regular reassessment of plans for community engagement and sustained communications, designed to promote transparency, mutual trust, and public collaboration. The Blue Ribbon Panel acknowledges the dedicated outreach efforts that are already under way in laboratories nationwide and hopes that this document may prompt further reflection and conversation among institutions about principles, best practices, and lessons learned regarding biocontainment laboratories and community engagement.

Glossary of Terms

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – A document describing standards and special microbiological, safety equipment, and facilities appropriate for work with infectious agents. The *BMBL* is developed by the CDC and the NIH and can be obtained at:
http://www.cdc.gov/OD/OHS/biosfty/bmbl5/BMBL_5th_Edition.pdf

Biosafety level (BSL) – The BSL designation of a laboratory corresponds to a set of biosafety practices, containment measures, and other precautions that are used in keeping with the risk of the research taking place in that laboratory. BSL designations range from the lowest designation of "1" to the highest designation of "4," corresponding to conditions suitable for the lowest risk to highest risk research, respectively. The *BMBL* describes the four biological safety levels in detail (see Section IV, BMBL 5th edition). The *NIH Guidelines for Research Involving Recombinant DNA Research* (see below) similarly describe four biosafety levels that correspond to those of the *BMBL*, but they use the abbreviation "BL" (see Appendix G of the *NIH Guidelines* at:
http://oba/oba/rac/guidelines_02/Appendix_G.htm).

High-containment laboratory – A laboratory that conforms to BSL-3 or BL-3 biosafety measures, as described in *Biosafety in Microbiological and Biomedical Laboratories* and the *NIH Guidelines for Research with Recombinant DNA Molecules*, respectively. This is the second highest level of containment out of four levels.

Institutional Biosafety Committee – A local biosafety review committee required under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to provide local review and oversight of nearly all forms of research utilizing recombinant DNA. Over time, many institutions have chosen to assign their IBCs the responsibility for reviewing a variety of experiments that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). The roles and responsibilities of IBCs are described in Section IV-B-2 of the *NIH Guidelines*
(http://oba/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm#_Toc7261582)

Maximum-containment laboratory – A laboratory that conforms to BSL-4 or BL-4 biosafety measures, as described in *Biosafety in Microbiological and Biomedical Laboratories* and the *NIH Guidelines for Research with Recombinant DNA Molecules*, respectively. This is the highest level of containment out of four levels.

***NIH Guidelines for Research with Recombinant DNA Molecules* (*NIH Guidelines*)** – A document that details safety practices and containment procedures for basic and clinical research involving recombinant DNA, including the creation and use of organisms and viruses containing recombinant DNA. The *NIH Guidelines* are a "living" document that was first drafted in 1976 as an outcome of a meeting of scientists

concerned about addressing the potential public health and environmental risks associated with this developing technology. Since that time, the *NIH Guidelines* have been frequently amended to reflect evolving scientific understanding of recombinant DNA and its applications. Institutions receiving funding from the NIH for recombinant DNA research must follow the *NIH Guidelines*. The NIH Guidelines can be obtained at: http://oba/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm