

**NIH Blue Ribbon Panel to
Advise on Risk Assessment for the BU
National Emerging Infectious Diseases Laboratories**

Progress Update

**Advisory Committee to Director, NIH
December 5, 2008**



Phase I Recommendations Regarding Supplementary Risk Assessment

- **Briefed ACD in June 2008 regarding proposed scope and analytic approach for supplementary risk assessment**
 - **ACD voted to accept BRP recommendations and noted the following elements should be explicitly included:**
 - **Assessment of probability of detection of pathogen release;**
 - **Availability of vaccines and characteristics of communities, including the range of healthcare providers utilized by community members**
 - **Alternative site analyses of urban, suburban and rural areas**
 - **Community input in formulation of recommendations**
- **NIH Director approved the recommendations regarding studies to assess risk of operating the NEIDL and authorized initiation of the studies**

Update on Supplementary Risk Assessment

- **Contract awarded in September 2008**
- **Broad range of infectious agents and scenarios as recommended by the ACD**
- **Ongoing oversight of study by the Blue Ribbon Panel**
- **Public engagement during conduct of study and public comment on draft written report in 2009**
- **BRP will provide ACD with an update on status of studies in June 2009**

Interim Status of BUMC NEIDL Operation

- **No BSL 3 or 4 operations during this time – pending outcome of court decisions**
- **BUMC proposed public safety, health, and operations training in partnership with public health authorities**

Boston Prohibition on the Use of Recombinant DNA at BSL-4

- The City of Boston has a regulation that prohibits the use of recombinant DNA technology requiring BSL-4 containment
- The Panel and the NIH emphasize that the research will fully comply with any and all Boston City regulations, including the current prohibition on recombinant DNA use at BSL-4
 - Boston University has affirmed that all research at their institution will be in compliance with this City of Boston regulation

Phase II Tasks

- **Advise NIH on strategies to address local community relations and communications regarding the BUMC NEIDL as part of the supplemental risk assessment**
 - **Develop principles and identify best practices in the context of a national research resource**

Panel Approach

- **NIH Blue Ribbon Panel Meetings devoted to community engagement topics**
- **Briefings regarding local oversight frameworks and community engagement**
 - **Regional and National Biocontainment Laboratories funded through the NIAID/NIH Emerging Infectious Diseases and Biodefense Program**
 - **Boston University**
 - **Boston Public Health Commission**

BRP Meetings with the Community

- **May 16, 2008 (Boston)**
 - Present the BRP charge and proposed approach to supplementary risk assessment
- **July 16, 2008 (Bethesda)**
 - Invited members of Boston community, Boston city officials, community researchers, and social justice advocates
 - Explored case studies on community engagements and environmental justice
 - Roundtable discussion of how to effectively engage communities
- **October 14, 2008 (Boston)**
 - Engaged community members in planning of meeting and outreach efforts
 - Evening meeting in local community hall to:
 - Present and seek community input on draft principles and best practices for community engagement
 - Hear general comments and perspectives from community members

Principles and Best Practices for Public and Local Community Relations and Communications

- Build on existing measures with the goal of achieving best practices
- Apply to Regional and National Biocontainment Laboratories funded by the NIH
 - ***NOTE: These principles will apply to the NEIDL only if ongoing supplementary risk assessment studies, court cases, and Massachusetts state authorities point to the acceptability of conducting high- and maximum-containment research conditions***
- Draft principles are generally applicable to other high- and maximum-containment labs
- Implementation of principles will be left up to individual institutions

Draft Principles

- 1. Rigorous, balanced, and transparent local institutional 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 the local public health authorities**
- 6. Ongoing operations oversight**

Best Practices

- 1. Rigorous, balanced, transparent local institutional biosafety review and oversight of high- and maximum-containment research**
- 2. Community liaison activities to promote openness and transparency with respect to the research agenda of the institution**
- 3. Communications plan regarding phase-in of research operations**

Best Practices

1. **Rigorous, balanced, and transparent local institutional review and oversight of high- and maximum-containment research should embody the following principles:**
 - **Appropriate technical expertise**
 - **Periodic review of research**
 - **Ongoing operations oversight, including laboratory inspections and systems testing**
 - **Maximal transparency regarding facility operation and the nature and oversight of research**
 - **Community engagement**

Rigorous, Balanced, Transparent Local Institutional Review

- **BRP recommends that all high- and maximum-containment infectious disease research conducted in Regional and National Biocontainment Laboratories funded by the NIH be reviewed, approved, and overseen by an institutional body**
 - **At least two non-institutional members who can represent the interests of the local community**
- **Institutional Biosafety Committees offer an example of such an institutional review bodies**

Rigorous, Balanced, Transparent Local Institutional Review

- **Currently, IBC review mandated only for recombinant DNA research**
 - Review includes:
 - Community representatives
 - Biosafety and scientific expertise
 - Authority to approve/disapprove rDNA protocols
 - Ongoing oversight throughout life of research project
 - Minutes publicly available
- **Many institutions nonetheless have established local review and oversight mechanisms for work with non-recombinant infectious agents**

Best Practices

2. **Community liaison activities to promote openness and transparency with respect to the research agenda of the institution**
 - **These activities should be integrative and offer opportunities for:**
 - **Input from community about impact of lab**
 - **Communication to the community regarding lab operations**
 - **Community education about research programs and public health benefits of research**

Best Practices

3. **Communications plan regarding phase-in of research operations**

- **Regional and National Biocontainment Laboratories funded by the NIH should communicate specific information regarding safeguards and precautions often utilized in phasing in research operations**
 - **Conduct of low-containment research under maximum containment conditions for training**
 - **Ample technical expertise to assess performance of building systems and readiness for operation**
- **Institutions should inform their communities and local public health authorities about plans for transitioning to a fully operational high – and maximum-containment laboratory**

Discussion