

# **Draft Principles for Public and Local Community Relations and Communications Regarding a National Research Resource**

**NIH Blue Ribbon Panel on  
Risk Assessment of the BUMC National Emerging  
Infectious Diseases Laboratories**



**Hibernian Hall  
Dudley Square, Roxbury  
October 14, 2008  
6:30 – 10:00 PM**





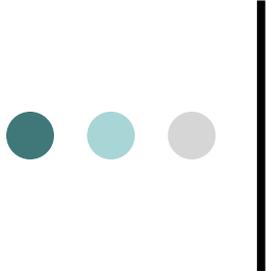
# Topics for Discussion

- **Charge of the Blue Ribbon Panel**
- **Update on Risk Assessment**
- **Boston Prohibition on rDNA BSL-4 Research**
- **Community Engagement**
  - **Draft Principles**
  - **Draft Strategies**



# NIH Blue Ribbon Panel

- To provide scientific and technical advice to the NIH regarding the construction and operation of a national biocontainment laboratory at Boston University Medical Center
  - **Comments and concerns have been voiced by:**
    - **Courts**
    - **Local community**
    - **General public**

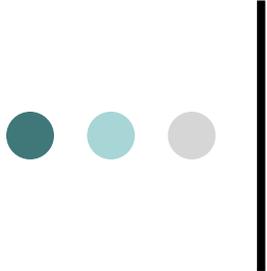


# Two-Fold Charge to the Panel

- Advise on:

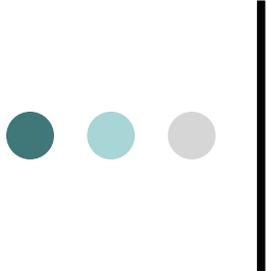
-  **Studies to assess any potential public health risks associated with the operation of the NEIDL and assess strategies for mitigating these risks**

-  **Strategies to enhance local community relations and communications regarding national and regional biocontainment laboratories**



# Update on Supplementary Risk Assessment

- Broad range of infectious agents and scenarios (<http://acd.od.nih.gov/>)
- Ongoing oversight of study by Blue Ribbon Panel
- Public comment on draft study: late 2009
- Interim status of BUMC NEIDL operation
  - No BSL 3 or 4 operations during this time – pending outcome of court decision
  - BUMC has 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 Agency 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 prohibition**



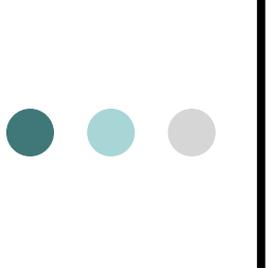
**Development of Principles and Best Practices for Public and Local Community Relations and Communications Regarding a National Research Resource**

*Mary E. Northridge, Ph.D., M.P.H.  
Member, NIH Blue Ribbon Panel  
Professor of Clinical Sociomedical Sciences  
Mailman School of Public Health  
Columbia University*



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

- 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 and court cases point to the acceptability of conducting high- and maximum-containment research conditions***
- Implementation of principles will be left up to local jurisdiction



# Applicability to Other Facilities

- Draft principles are generally applicable to other high- and maximum-containment labs
  - **Consulting with the Regional and National Biocontainment Laboratories Funded through the NIAID/NIH Emerging Infectious Diseases and Biodefense Program**



# Draft Principles

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



# **Draft Principles for Public and Local Community Relations and Communications Regarding a National Research Resource**

*Johnnye Lewis, Ph.D., D.A.B.T.*

*Member, NIH Blue Ribbon Panel*

*Director, Community Environmental Health Program*

*College of Pharmacy, Health Sciences Center*

*University of New Mexico*



# 1. Local Biosafety Review

- **All high- and maximum-containment research requires a rigorous process of local biosafety review**
  - **Scope extends beyond current requirements for biosafety review , which apply only to research with select agents or recombinant DNA at institutions funded by NIH for that type of research**
- **Community representation**
  - **Foster better understanding by the community regarding the nature and goals of biocontainment research and help ensure that concerns about public health and safety are adequately addressed**
- **Intellectually independent**
  - **Reviewers are free of conflicts of interest**



## 2. Maximal Transparency

- Information should be shared as appropriate with the public in order to educate and to develop and maintain public trust
  - Facility operations
  - Research being conducted
  - Oversight process



## **3. Community Engagement**

- **Afford community members the opportunity to become informed about and familiar with the facility and research activities**
- **Provide a mechanism for expressing concerns**
- **Participate in the activities directed toward addressing community concerns**



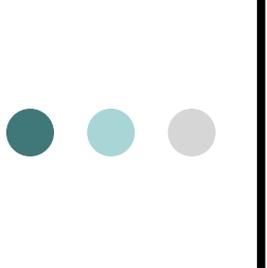
## 4. Technical Expertise

- All biocontainment facilities must have sufficient numbers of appropriately trained resident technical experts
  - 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 staff will optimize the safety of laboratory workers and members of the general public



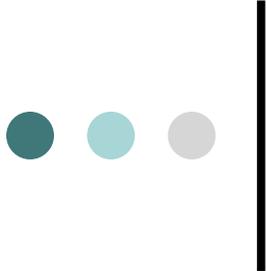
## **5. Engagement of Local Public Health Authorities**

- **Rigorous oversight of the operation of biocontainment facilities is essential**
  - **Institutions should engage local public health authorities early on in the process**
  - **Communication should be established and maintained by the IBC at the institution and the public health authority**



## 6. Ongoing Operations Oversight

- **Rigorous oversight of the operation of biocontainment facilities**
  - **Essential to ensuring the safe and optimal operation of the facility**
  - **Facilitate and maintain public trust**



**Strategies for Carrying Out  
Principles for Public and Local  
Community Relations and  
Communications Regarding a  
National Research Resource**

***Samuel Stanley, M.D.***

***Member, NIH Blue Ribbon Panel***

***Vice Chancellor for Research, and Professor of  
Medicine and Molecular Microbiology  
Washington University in St. Louis***



# Strategies



**Mechanisms for transparent local review and oversight of high- and maximum-containment research**



**Community liaison activities**



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

# Current Requirements for Local 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



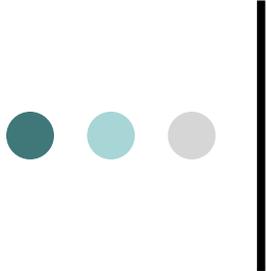
# Expanded Scope of Local Review

- **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**
- **Institutional Biosafety Committees offer an example of such an institutional review body**



## **Community Liaison Activities at Regional and National Biocontainment Laboratories**

- **Community liaison activities are vital ways to enhance 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**



# Communication About Phase-in of Research Operations

- **Regional and National Biocontainment Laboratories funded by the NIH should communicate specific information regarding safeguards and precautions that are customary practice in phasing in research operations**
  - **Conduct of low-containment research under maximum containment conditions for training**
  - **Assess readiness of the operation**
- **Institutions should inform their communities on plans for transitioning to a fully operational high – and maximum-containment laboratory**



# Questions for Discussion

-  **How can institutions most effectively reach out to local communities and educate about these laboratories?**
-  **What kind of information regarding the planning, operation and oversight of biocontainment research facilities should community members know?**
-  **What are the best ways for institutions to seek out the views of community members about the operation and oversight of biocontainment research facilities?**



# Questions for Discussion



**How can institutions most effectively reach out to local communities and educate about these laboratories?**



# Questions for Discussion

 What kind of information regarding the planning, operation and oversight of biocontainment research facilities should community members know?



# Questions for Discussion

 **What are the best ways for institutions to seek out the views of community members about the operation and oversight of biocontainment research facilities?**



# General Discussion



# Written Comments

- **Email:** [NIH\\_BRP@od.nih.gov](mailto:NIH_BRP@od.nih.gov)

- **Mail to:**

**NIH Blue Ribbon Panel**

**National Institutes of Health**

**6705 Rockledge Drive, Suite 700**

**MSC 7985**

**Bethesda, Maryland 20892**