

*Name of Committee:* Cell Biology Integrated Review Group Cellular Signaling and Regulatory Systems Study Section.

*Date:* January 31–February 1, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

*Contact Person:* Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, [smirnov@csr.nih.gov](mailto:smirnov@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group Clinical Neuroplasticity and Neurotransmitters Study Section.

*Date:* January 31–February 1, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

*Contact Person:* Suzan Nadi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, [nadis@csr.nih.gov](mailto:nadis@csr.nih.gov).

*Name of Committee:* Oncology 1-Basic Translational Integrated Review Group Cancer Etiology Study Section.

*Date:* January 31, 2013.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Riverwalk, 420 W. Market Street, San Antonio, TX 78205.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Bioengineering Sciences and Technology.

*Date:* January 31, 2013.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, [pyonkh2@csr.nih.gov](mailto:pyonkh2@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 26, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012–31451 Filed 12–31–12; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Supplemental Record of Decision; Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories

*Responsible Official:* Daniel G. Wheeland, Director, Office of Research Facilities Development and Operations, National Institutes of Health.

**SUMMARY:** The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Supplementary Risk Assessment and a thorough consideration of public comments on the Draft and Final Supplementary Risk Assessment, to implement the Proposed Action, which is identified as the Preferred Alternative in the Final Environmental Impact Statement (EIS). This action reaffirms the NIH's previous decision to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts.

**FOR FURTHER INFORMATION CONTACT:** For further information on the Record of Decision: Valerie Nottingham, Chief, Environmental Quality Branch, Office of Research Facilities, National Institutes of Health, 9000 Rockville Pike, Bld. 13/2S11, Bethesda, MD 20892 [nihnepa@mail.nih.gov](mailto:nihnepa@mail.nih.gov).

For further information on the Supplementary Risk Assessment: Kelly Fenington, Senior Health Policy Analyst, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838 [NIH\\_BRP@od.nih.gov](mailto:NIH_BRP@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The National Institutes of Health (NIH), an operating division of the Department of Health and Human Services (HHS), has decided, after completion of a Final Supplementary Risk Assessment for the Boston University (BU) National Emerging Infectious Diseases Laboratories (NEIDL) and a thorough consideration of the public comments on the Draft and Final Supplementary Risk Assessments, that the NEIDL, in its current location in the BioSquare Research Park, poses minimal risk to the community surrounding the facility. The Final Supplementary Risk Assessment extensively evaluated scenarios involving the potential human health consequences of an exposure to

laboratory workers and members of the general public as a result of unintentional or malevolent events. The Final Supplementary Risk Assessment also analyzed the potential human health impacts of siting the NEIDL at two alternate locations from the current site in Boston. The Final Supplementary Risk Assessment concluded that the risk to the public was generally low, regardless of where the facility was located. The analysis also showed there was no disproportionate impact to the residents living in the environmental justice communities adjacent to the NEIDL's current location or to any environmental justice communities at either of the two alternative locations analyzed. Based on the results of the Final Supplementary Risk Assessment, NIH is reaffirming its prior Record of Decision of January 26, 2006, published in the **Federal Register** on February 2, 2006.

On January 26, 2006, the NIH signed the Record of Decision (ROD) to partially fund the construction of a state-of-the-art National Biocontainment Laboratory, which is now known as the NEIDL, on the Boston University Medical Campus in Boston, Massachusetts. The NEIDL is a research facility that was designed to include high- and maximum-containment laboratories for research on emerging and re-emerging infectious diseases. The ROD was posted in the **Federal Register** on February 2, 2006, and described the Proposed Action and alternatives considered in the NIH's Environmental Impact Statement for the NEIDL. The ROD also described many of the physical characteristics of the NEIDL and the safeguards that would be in place for research conducted in the building.

After the ROD was released, some members of the public continued to have concerns about the safety and environmental impact of the facility. Several citizens and public interest groups filed lawsuits in Federal court to stop the NIH's partial funding of the NEIDL's construction. Opponents also filed a lawsuit in Massachusetts state court challenging the state's approval of the project. Both lawsuits alleged failure to adequately assess the potential impacts of the NEIDL on public health in alternative locations. In the Federal court proceedings, questions were raised specifically about the potential risks of the biosafety level 4 (BSL–4) laboratory. To address the concerns raised in these lawsuits, NIH established an independent Blue Ribbon Panel to advise the agency on comprehensively responding to the concerns raised by members of the community and by the

courts. The Blue Ribbon Panel was established as a working group of the Advisory Committee to the NIH Director and was comprised of experts in infectious diseases, public health and epidemiology, risk assessment, environmental justice, risk communications, biosafety, and infectious disease modeling. At multiple points during the preparation of the Supplementary Risk Assessment, the NIH also consulted the National Research Council (NRC) Committee on Technical Input that had been critical of a previous draft NIH risk assessment for the NEIDL. With the technical and scientific guidance of the Blue Ribbon Panel and the NRC Committee on Technical Input as well as extensive public input, NIH prepared a Draft Supplementary Risk Assessment, which was published in the **Federal Register** on February 24, 2012. The publication of the Draft Supplementary Risk Assessment in the **Federal Register** began a 67-day public comment period. After a thorough consideration of comments received on the Draft Supplementary Risk Assessment, including those comments received during a public meeting held in Boston on April 19, 2012, NIH prepared a Final Supplementary Risk Assessment, notice of which was published in the **Federal Register** on July 6, 2012.

#### Decision

After careful consideration of the information and analyses presented in the Final Supplementary Risk Assessment, including the potential impacts on public health and safety arising from research involving infectious agents, as well as all public comments received during and after the assessment's preparation, the NIH has decided to reaffirm the decision reached in the agency's initial Record of Decision to implement the Selected Alternative, to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), the National Emerging Infectious Diseases Laboratories (NEIDL), at the Boston University Medical Campus (BUMC) in Boston, Massachusetts described in the December 2005 Final EIS. The additional information provided from the Final Supplementary Risk Assessment results has reinforced the agency's original decision. The NIH's decision to reaffirm the ROD does not commit the NIH to support any specific research in the NEIDL in the future.

#### Alternatives Considered

The Final Supplementary Risk Assessment considered and compared

the potential public health impacts of a biocontainment failure at three separate, proposed locations for the NEIDL. Those locations included an urban (the current BUMC site), a suburban (Tyngsborough, MA), and a rural (Peterborough, NH) setting. The results of the Supplementary Risk Assessment showed minimal differences in the risks of infections or fatalities to lab workers at the three different sites because the laboratory and its operations would be the same at all three sites. There are differences in the three sites with regard to population density and other features of the environment, such as availability of medical care. The possible effects of these differences on risks to the public were evaluated. The results show that no statistically significant differences can be concluded at the suburban and rural sites (Peterborough and Tyngsborough) compared to the urban site (Boston).

#### Factors Involved in the Decision

Throughout the course of the project, NIH engaged in extensive consultations with the Boston community. During the development of the Supplementary Risk Assessment for the NEIDL, public input was sought and considered multiple times before the report was finalized. In preparing its advice to the NIH for the Supplementary Risk Assessment, the Blue Ribbon Panel held multiple public meetings, including several in Boston at locations suggested by community members, to hear the concerns of the community and to solicit input on what scenarios and agents the community wished to see analyzed in the document. The approach taken to perform the Supplementary Risk Assessment, as well as the types of scenarios and agents studied in the Supplementary Risk Assessment, were thoroughly discussed and publicly vetted through the Blue Ribbon Panel and the NRC Committee on Technical Input. These two independent bodies provided technical advice that was then used to guide NIH through the risk assessment process. In order to help ensure that the Supplementary Risk Assessment was as comprehensive and technically and scientifically sound as possible, the NIH contracted with a leading consulting firm to perform the assessment. This firm engaged outside experts in infectious diseases and modeling to assist in preparing the assessment.

After extensive consultations with the Blue Ribbon Panel, the NRC Committee on Technical Input, and the public, the contractor preparing the Supplementary Risk Assessment identified and considered approximately 300 events

that could potentially lead to loss of containment. The contractor grouped these 300 events initially into 30 categories of related events. Based on their likely risk, several of these events were selected to represent the overall group. The selected events include higher- and lower-risk events that occur in a variety of ways and expose different groups of people or the environment. Taking these factors into account, the possible events selected for detailed analysis in the Final Supplementary Risk Assessment were a needlestick accident, a centrifuge aerosol release, an earthquake, and transportation accidents.

To ensure examination of consequences with the most negative possible outcomes, mitigating features of the building systems, fully functional personal protective equipment, and standard operating procedures were not taken into account in the Supplementary Risk Assessment, which increased the risk by posing failures without taking into account mitigating features. For example, for purposes of the risk assessment, it was assumed that a needlestick would not be recognized and reported. Similarly, the risk assessment considered what would happen if a centrifuge release went undetected and unreported. In reality, lab personnel are trained to recognize and report such incidents, thus mitigating the consequences should such a lab accident occur.

The Final Supplementary Risk Assessment examined a variety of possible situations—including those that posed the maximum realistically expected risk that might expose laboratory workers and the general public to disease-causing microbes that will be studied in the NEIDL. While there is no such thing as “no risk”, the results of the analysis showed that the risk of infections or fatalities resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. The risk assessment evaluated the NEIDL and proposed activities in its laboratories as well as the potential impacts to site-specific populations in the three alternative geographic locations.

#### Practicable Means To Avoid or Minimize Potential Environmental Harm From the Selected Alternative

All practicable means to avoid or minimize adverse environmental effects from the selected action have been identified and adopted. The NEIDL will be subject to oversight by numerous federal, state, and local entities including, but not limited to, the Centers for Disease Control (CDC) and

Prevention, the NIH, and the Boston Public Health Commission. The NEIDL will also be subject to federal, state, and local pollution prevention, waste management, and environmental regulations. This level of oversight and regulation, in addition to NEIDL-specific laboratory standard operating procedures and researcher training should greatly minimize any chance of a pathogen being released into the environment.

### Monitoring and Enforcement Program for Mitigation Measures

Boston University has established policies and procedures to ensure that the NEIDL complies with all applicable Federal, state, and local regulations. In addition, trained biosafety staff at Boston University will perform periodic laboratory inspections to ensure safety standards are rigorously upheld. Laboratory inspections will also be performed by the Boston Public Health Commission. The CDC will also perform inspections for those laboratories performing research with Select Agents. Projects requiring the use of BSL-3 and BSL-4 containment must be reviewed and approved by the Boston University Institutional Biosafety Committee (IBC). The Boston University IBC includes at least two members from the public who are not affiliated with Boston University. The Boston Public Health Commission will also review and approve projects requiring BL3 or BL4 containment. Finally, as an NIH grantee, Boston University is required to comply with the grant terms and conditions. These terms and conditions require Boston University to file an annual progress report with NIH that describes the use of any highly pathogenic agents or Select Agents in the past year.

### Conclusion

The Final Supplementary Risk Assessment examined a variety of possible scenarios, including those that posed the maximum realistic risk that might result in laboratory workers or the general public having primary or secondary infections resulting from release of pathogens that might be studied in the NEIDL. While there can be no such thing as “no risk,” the results of this analysis show that the risk of infections resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. This is largely due to the safeguards built into the facility, the low amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into everyday practice at the NEIDL and as well as due to oversight of the NEIDL by

regulatory authorities, like the Boston Public Health Commission and the Centers for Disease Control and Prevention. The greatest risk posed by research in the NEIDL is to individuals conducting research in the building, not to the general public. The analysis did not show any statistically significant increase in risk to medically vulnerable populations when analyzed as a group or individually, as compared to what those risks would be at alternate sites. Based on these factors, NIH is reaffirming its prior Record of Decision, dated January 26, 2006, and concludes that high and maximum containment research could be conducted safely at the NEIDL based upon the current safeguards and engineering controls in place at the facility.

Dated: December 18, 2012.

**Daniel G. Wheeland,**

*Director, Office of Research Facilities Development and Operations, National Institutes of Health.*

[FR Doc. 2012-31509 Filed 12-31-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-HQ-IA-2012-N304;  
FXIA16710900000P5-123-FF09A30000]

### Endangered Species; Receipt of Applications for Permit

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

**DATES:** We must receive comments or requests for documents on or before February 1, 2013.

**ADDRESSES:** Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358-2280; or email [DMAFR@fws.gov](mailto:DMAFR@fws.gov).

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2280 (fax); [DMAFR@fws.gov](mailto:DMAFR@fws.gov) (email).

**SUPPLEMENTARY INFORMATION:**

## I. Public Comment Procedures

### A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

### B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

## II. Background

To help us carry out our conservation responsibilities for affected species, and