BioSquare Phase II

Boston, Massachusetts

Supplemental Final Environmental Impact Report

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submitted to **Executive Office of Energy and Environmental Affairs**
submitted by **Trustees of Boston University**
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TABLE OF CONTENTS

TABLE OF CONTENTS

VOLUME I

TABLES

FIGURES

VOLUME II

APPENDICES

VOLUME III

EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES

Trustees of Boston University Medical Center constructed the National Emerging Infectious Diseases Laboratories (NEIDL) at BioSquare Research Park in Boston, Massachusetts. The project was awarded funding in 2003 by the National Institutes of Health (NIH) through a competitive process which considered proposals from across the country. The NEIDL includes biological laboratories, clinical research space, offices and support space. The biological laboratories are designed to accommodate research at four increasing levels of safety and biocontainment, which are classified as "Biosafety Levels (BSL)". In addition to BSL-2 and BSL-3 laboratories, the NEIDL includes a Biosafety Level-4 (BSL-4) laboratory. The purpose of the NEIDL is to develop diagnostics, therapeutics, and vaccines for emerging and re-emerging infectious diseases, and for agents that could possibly be used for bioterrorism. When it is fully operational, the NEIDL facility will be in a unique position to reinforce the nation's ability to protect public health as one of only a handful of facilities allowed to conduct research at BSL-4 levels within the United States.

This project underwent Massachusetts Environmental Policy Act (MEPA) review as part of the BioSquare Phase II project (EOEA #12021). A Final Environmental Impact Report (FEIR) was filed in July 2004. On November 15, 2004, the Secretary of the Executive Office of Environmental Affairs issued a Certificate on the FEIR, determining that it adequately and properly complied with MEPA. Subsequent to the issuance of that certificate, litigation was commenced in Superior Court challenging the adequacy of the FEIR. In July 2006, the Superior Court vacated the Certificate and remanded the matter to the Secretary for further administrative action. The Secretary issued a Certificate following Remand ("Remand Certificate") in September 2006 which requested the filing of a Supplemental Final Environmental Impact Report (SFEIR). The Remand Certificate requires a risk assessment of at least one scenario involving an accidental or malevolent release of a contagious pathogen, an evaluation of whether the consequences of such a release would be materially different if the laboratory were located in a less densely populated area, and evidence that "such impacts" have been avoided to the maximum extent feasible, minimized where unavoidable and mitigated as appropriate.

Construction of the NEIDL facility began on March 6, 2006 and was fully completed in the first quarter of 2011. In August 2011 Boston University submitted a request to the Secretary for a Phase One Waiver as well as a Notice of Project Change (NPC) to allow research activity at the BSL-2 and BSL-3 levels only to commence. In December 2011, the Secretary issued a Final Record of Decision on the Phase One Waiver request, and a Certificate on the Notice of Project Change. The result of these filings and subsequent decisions was that the NEIDL was approved to undertake

research activities at only BSL-2 levels. The Secretary's decision did not allow for research to proceed at BSL-3 levels prior to completion of the SFEIR.

The Secretary determined that "The NPC presented a description of the uses proposed for the NEIDL Building. Because the NEIDL Building is completed, the proponent has identified few environmental impacts. Traffic and parking impacts, drainage and permitting issues were fully evaluated in the DEIR and FEIR. The remaining issues to be reviewed, such as the risk assessment, will be addressed in the SFEIR."

In response to the Secretary's decision and additional legal challenges in the Federal courts, the NIH has undertaken an unprecedented effort to perform a supplementary risk assessment to further analyze and determine what, if any, adverse human health effects would occur from an accidental or malevolent release of a pathogen from the NEIDL. The Final Supplementary Risk Assessment (FSRA), which is far more detailed and extensive than required by the Secretary's Remand Certificate, is summarized in this SFEIR and included in its entirety in this document as Appendix 11. A Supplemental Record of Decision (SROD) was issued by the NIH and noticed in the Federal Register on January 2, 2013. The Supplemental Record of Decision approves the construction and operation of the NEIDL, and 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 in Boston, MA. The SROD is also included in this document as Appendix 9.

FINAL SUPPLEMENTARY RISK ASSESSMENT

The Final Supplementary Risk Assessment examined a variety of possible scenarios, including those that posed the maximum realistic risk that might result in primary or secondary infections in laboratory workers or the general public resulting from release of pathogens being 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 small amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into everyday practice at the NEIDL. The FSRA concluded that the greatest risk of infection is to individuals conducting research in the building. The risk to the general public is extremely low, or beyond reasonably foreseeable, with the exception of secondary infections involving 1918 H1N1 influenza and SARS-associated corona virus (SARS CoV). Infections from a release of 1918 H1N1 influenza or SARS CoV might occur once in over 500–5,000 years of operation, far beyond the facility lifetime of 50 years.

SUPPLEMENTAL FINAL ENVIRONMENTAL IMPACT REPORT

This Supplemental Final Environmental Impact Report (SFEIR) includes additional information on matters specifically requested in the Secretary's Certificate on Remand of the FEIR. Those matters include: the identification and evaluation of alternative locations for siting the laboratory in less densely populated areas; the evaluation of at least one "worst-case" scenario involving the release of a contagious pathogen from the laboratory, as summarized above; the identification of any material differences in public health impacts from a worst-case release scenario between the proposed site and two alternative sites; responses to all comments submitted on the FEIR that fall within the scope of the SFEIR; draft Section 61 findings on outstanding state permits or actions; and identification of mitigation measures associated with the project. The mitigation measures include detailed discussions of the mitigation measures which are built into the NEIDL design and operations to ensure a "culture of safety" through biosafety, and biocontainment, transportation safety measures and emergency response plans in place for the NEIDL and Boston University Medical Center (BUMC). BUMC's Community Relations plans as well as the extensive public outreach undertaken through community relations venues and an extensive NEIDL website are also described. The FSRA, as well as the SFEIR are available for review on the NEIDL website: www.bu/edu/NEIDL.

Chapter 1

PROJECT SUMMARY

1.0 PROJECT SUMMARY

1.1 PROJECT DEVELOPMENT

Trustees of Boston University (hereinafter referred to as "the Proponent") has constructed a 7-story, 192,000 square foot (sf) national biocontainment laboratory facility, called the National Emerging Infectious Diseases Laboratory (hereinafter referred to as "NEIDL"). This facility is located within the BioSquare Research Park, at 620 Albany Street in Boston's South End. The NEIDL has been designed to perform research at Biosafety (BSL) Levels 2 through 4. The facility is currently operational and permitted to perform research at Biosafety Level 2 only.

This Supplemental Final Environmental Impact Report (hereinafter referred to as "the SFEIR") provides supplemental information about the NEIDL as required by the Secretary's of Energy and Environmental Affairs ("the Secretary") Certificate Following Remand on the Final Impact Report (hereinafter referred to as "the Remand Certificate") as well as the Secretary's Final Record of Decision on the Phase One Waiver Request, (hereinafter referred to as "the EOEEA FROD") and the Secretary's Certificate on the Notice of Project Change, (hereinafter referred to as "the NPC Certificate").

The NEIDL was initially reviewed as part of the BioSquare Phase II Project (EOEEA #12021). That project, developed by University Associates Limited Partnership, includes the NEIDL, another medical research building, and an above-grade parking garage. Those buildings, in conjunction with BioSquare Phase I program, constitute BioSquare Research Park, a 14.5-acre biomedical research campus located along Albany Street west of the Boston Flower Exchange and Southbound Frontage Road, north of the Massachusetts Avenue Connector, and south of the Boston University Medical Center complex. See Figure 1-1, Locus Map, and Figure 1-2, BioSquare Research Park.

Trustees of Boston University and Boston Medical Center Corporation each originally held a 50% equity interest in the NEIDL at the time it was constructed with the right to share equally in the future operating activities of the NEIDL. The University managed the initial NIH construction award and subsequent NIH operating grant awards, and Boston Medical Center held a non-controlling interest. In May 2010, in accordance with the terms of the agreement between the University and Boston Medical Center, Boston Medical Center notified the University of its

intent to withdraw from further participation in the NEIDL as of May 1, 2011. The hospital made the decision to exercise this right as part of an overall review of its long-range financial investments and how best to continue to support its core mission. This action has not caused any change in the NEIDL leadership team, and there are no changes in the approvals and oversight required for the research that takes place in the NEIDL. Boston Medical Center will continue to be available as needed to provide emergency medical care.

In addition to the NEIDL, the BioSquare Phase II project includes Building G, a 234,700 sf medical research facility, and Building H, an 8-level parking garage that provides 1,400 parking spaces. The NEIDL and the parking garage (Building H) have been constructed. The parking garage is currently in operation. Construction of Building G is anticipated to commence at a later date.

The NEIDL is one of two National Biocontainment Laboratories (NBL) operating within university environments which were funded by the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID) in 2003. The facility, which is owned, operated, and managed by the Proponent, contains state-of-the-art, highly contained laboratories designed to conduct research in a safe and secure environment. The purpose of the NEIDL is to conduct basic research in the understanding of the mechanism by which the agents cause disease, their pathogenesis and to develop diagnostics, therapeutics, and vaccines for emerging and re-emerging infectious diseases, and for agents that could possibly be used for bioterrorism.

The NEIDL building includes four stories of biomedical research space and three stories of mechanical and building support space. The NEIDL also contains office space, clinical research space and support spaces for laboratories and offices. A description of Laboratory Biocontainment Safety levels follows.

1.1.1 LABORATORY BIOCONTAINMENT SAFETY LEVELS

The Centers for Disease Control and Prevention (CDC) have established standards for the classification of containment levels for biological research laboratories, known as biosafety levels 1-4 (BSL-1 through BSL-4). These levels have been established to ensure safety and security in laboratory operations appropriate for the type of research to be performed. The recommended biosafety level will vary with the type of agent being studied, the form of the agent (dry, liquid or aerosol) and the nature of the research to be performed. Section 5.2 includes a technical description of the biosafety levels and a table comparing the characteristics of biosafety

laboratories. Photographs of representative of typical biosafety laboratories can be found in Appendix 8, Representative Publications From the NEIDL Website. Detailed descriptions of biosafety levels as well as biocontainment procedures which have been incorporated in the NEIDL are included in Appendix 11, Supplementary Final Risk Assessment (SFRA).

1.2 PUBLIC REVIEW PROCESS

The Project has undergone environmental review by the City of Boston (Boston Redevelopment Authority), the Commonwealth of Massachusetts (Massachusetts Environmental Policy Act Office), and the federal government (National Environmental Policy Act review under the National Institutes of Health).

1.2.1 STATE ENVIRONMENTAL REVIEW

Executive Office of Environmental Affairs (now the Executive Office of Energy and Environmental Affairs) Massachusetts Environmental Policy Act Office (MEPA) review of the BioSquare Phase II Project began with an Environmental Notification Form (ENF), which was submitted by the Proponent in August 1999. The Secretary issued a Certificate on the ENF requiring the preparation of an Environmental Impact Report on October 9, 1999.

Boston University received a grant award from the NIH for the construction and operation of the NEIDL on the BioSquare II campus on September 30, 2003. Following that award, the University prepared and filed a Draft Environmental Impact Report (DEIR) with the MEPA Office for the BioSquare Phase II project, which included the new laboratory building. The Secretary issued a Certificate on the DEIR on December 1, 2003, along with a scope for additional issues to be addressed in the Final Environmental Impact Report (FEIR). The Proponent filed the FEIR with the MEPA Office on July 30, 2004. On November 15, 2004, the Secretary issued a Certificate finding that the BioSquare Phase II project, including the NEIDL, adequately and properly complied with MEPA.

Based on concerns regarding the potential community health impacts of a high containment research laboratory, a ten-citizen group appealed the Secretary's decision to the State Superior Court. Superior Court Justice Gants issued a Memorandum and Order dated July 31, 2006 vacating the certification of the FEIR and remanding the matter back to the Secretary for

further administrative action. Judge Gants' Order was affirmed by the Supreme Judicial Court in a decision dated December 13, 2007.

On September 5, 2006, the Secretary issued a Certificate (Remand Certificate) requiring the preparation of a Supplemental FEIR (SFEIR) addressing the Court's concerns. Specifically, the Certificate requires the evaluation of "an additional 'worst case' scenario" that involves the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The Remand Certificate also requires an evaluation of whether the consequences of such a release would be materially different if the laboratory were located in a less densely populated area, and that impacts have been avoided to the maximum extent feasible, minimized where unavoidable and mitigated as appropriate.

Boston University had commenced construction of the laboratory building prior to the Supreme Judicial Court's decision and by September 2008 the building was substantially complete. The NEIDL construction was completed, and the systems made ready for occupancy in the first quarter of 2011.

A detailed description of the Project History is included in the Secretary's Certificate on the NPC request, which is included in Appendix 1, MEPA Certificates.

In August of 2011, Boston University submitted a request for a Phase One Waiver as well as a Notice of Project Change to allow for research activity at BSL-2 and BSL-3 to commence. In December of 2011, the Secretary issued a Final Record of Decision on the Phase One Waiver request, and a Certificate on the Notice of Project Change. The result of these filings and subsequent decisions was that the NEIDL was approved to undertake research activity at BSL-2 levels only. The Secretary determined that "The NPC presented a description of the uses proposed for the NEIDL Building. Because the NEIDL Building is completed, the proponent has identified few environmental impacts. Traffic and parking impacts, drainage and permitting issues were fully evaluated in the DEIR and FEIR. The remaining issues to be reviewed, such as the risk assessment, will be addressed in the SFEIR."

Following the completion of the MEPA review process on the NPC and the Phase One Waiver request, the Proponent initiated BSL-2 research in April 2012.

This SFEIR has been prepared in order to comply with the Court decisions and to respond to the requirements of the Remand Certificate. Once the Certificate on the SFEIR is issued, research at BSL-3 and BSL-4 will be allowed to proceed only following the receipt of all required Federal, State and local approvals.

This Supplemental Final Environmental Impact Report (SFEIR) includes additional information about matters specifically requested in the Remand Certificate. Those matters include: the identification and evaluation of alternative locations for siting the laboratory in less densely populated areas; the evaluation of "an additional 'worst-case' scenario" involving the release of a contagious pathogen from the laboratory; the identification of any material differences in public health impacts from a "worst-case" release scenario between the proposed site and the alternative sites; responses to all comments submitted on the FEIR that fall within the Scope of the SFEIR; draft Section 61 findings; and identification of mitigation measures associated with the project. The mitigation measures include detailed discussions of the transportation safety measures and emergency response plans in place for the NEIDL. Boston University Medical Center's Community Relations plans as well as the extensive public outreach undertaken through community relations venues and an extensive NEIDL website are also described.

1.2.2 CITY OF BOSTON PROJECT REVIEW

The Boston Redevelopment Authority (BRA) reviewed the Project through the Article 80 Large Project Review process. A Project Notification Form was submitted in August 1999. The Draft Project Impact Report was submitted September 2003, and was followed by the Final Project Impact Report, submitted in July 2004. In December 2004, the BRA Board voted to approve the Project. In October 2005, the BRA issued an Adequacy Determination, finding that the Final Project Impact Report adequately described the potential impacts resulting from the project.

1.2.3 FEDERAL ENVIRONMENTAL REVIEW

Federal environmental review of the NEIDL portion of the Project was undertaken by the NIH as a requirement of the federal funding provided for the NEIDL. The process began in December 2003 with a Notice of Intent by NIH to prepare an Environmental Impact Statement (EIS). In January 2004 a public scoping period occurred, which was followed by the filing of a Draft

Environmental Impact Statement (DEIS) in October 2004. This was followed by a Supplemental Draft EIS (SDEIS) in March 2005 and a Final EIS (FEIS) in December 2005. A Record of Decision was issued on the FEIS in February 2006. Following the issuance of the Record of Decision, litigation was commenced in United States District Court involving the National Institutes of Health, the proponent and other parties.[1] Among other issues, the plaintiffs challenged the adequacy of the information about the risk of contagious pathogen release included in the FEIS. In response to these and subsequent Court proceedings, the National Institutes of Health initiated the preparation of a Draft and Final Supplementary Risk Assessment.

1.2.4 THE EVOLUTION OF THE RISK ASSESSMENT

In March 2008, the NIH announced additional steps in a comprehensive plan to address public safety concerns regarding the construction and operation of the national biocontainment laboratory at the Boston University Medical Campus (BUMC), stating that its "...number one concern is the safety of the people working in the laboratory and those living in the surrounding communities." To this end, the NIH established an internal Coordinating Committee to guide the agency's efforts to address safety concerns raised by community members, public officials, the National Research Council (NRC) of the National Academies, and other members of the public and scientific community. In addition, the NIH established an expert Blue Ribbon Panel (BRP) to provide scientific and technical advice to aid the agency. The NIH BRP was established to provide independent and scientifically based advice to the NIH Director on supplementary risk assessment studies. The BRP, which is described in more detail in Section 4.3.2, provided advice to the NIH on principles of engaging and sustaining communication with the community regarding the NEIDL, and independent technical expertise and guidance regarding the scope and content of the risk assessment as well as its conclusions. The BRP included 16 members with expertise in a broad range of fields, including infectious diseases and modeling of those diseases, public health and epidemiology, risk assessment, environmental justice, risk communication, bioethics, biodefense, and biosafety.

In addition to the BRP, the NRC convened the NRC Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL (the NRC

[1] Klare Allen, et al. v. National Institutes of Health, et al. U.S. District Ct. No. 06-10877-PBS

Committee). The NRC Committee provided comments to the NIH and EOEEA on the Draft Supplementary Risk Assessment and Site Suitability Analysis (DSRASSA) in July 2007, and was engaged at the request of EOEEA, and reconvened in 2008 to assist the NIH and the BRP in the preparation of a new risk assessment. This assistance involved input into the development of a supplementary risk assessment, which was undertaken by NIH with guidance and input from the NRC Committee and the BRP. The first formal noticed meeting of the two advisory groups occurred by teleconference on April 9, 2009.

The initial result of this collaborative process was the delivery by the NRC committee of its report in April, 2010, which found the proposed approaches to conducting the risk assessment suitable and well planned. Additionally, the NRC committee determined that the 13 pathogen agents selected for analysis were appropriate and comprehensive, and the expertise available on and to the assessment team seemed strong. The committee encouraged NIH and its contractor (Tetra Tech) to develop qualitative analyses (an explanation of the safety and risk profile) of all 13 pathogens in a manner that is clear and accessible to the public. The committee also suggested that the qualitative analyses in the body of the assessment be supplemented with results of quantitative modeling planned for five pathogens, with details provided in appendices. Further, the committee encouraged NIH to rely on data available from existing case studies, public health surveillance of the surrounding communities, and release incidents, not only to support its models but also to provide a complete and understandable picture for the public. The NRC committee again emphasized that the final risk assessment serve as an effective risk communication tool.

During the course of the preparation of the supplementary risk assessment, the NRC committee (the "Committee) met with the NIH BRP on September 22, 2010 to hear about approaches the contractor was taking to conduct the risk assessment. The NRC committee expressed concerns regarding the approach to the risk assessment including illustrative analyses presented, and provided a number of constructive suggestions to address the NRC committee's recommendations to provide a thorough assessment of the public health concerns raised in previous reports. The committee also met with the BRP on November 2, 2011 and provided a subsequent report on November 5, 2011, with specific suggestions on how to, among other things, provide more responsive quantitative and qualitative analysis and to

include actual data in models when they are available. This continued review and input, though at times critical and unflattering, was invaluable in crafting a throrough and objective approach to the supplementary risk assessment. The Chair of the Committee stated that "The work they (the NIH) had done was sound scientific work, the scenarios they developed were credible and the analyses they presented were also sound and credible."

The findings of the NRC Committee are described in a December 15, 2011 report titled "*Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 3*" and the report is included as Appendix 11.

Based on this, and subsequent guidance, the supplementary risk assessment was revised and adjusted, with the Draft Supplementary Risk Assessment (DSRA) issued for public review and comment on April 1, 2012. A public hearing to solicit public comment on the document was held on April 19, 2012.

The supplementary risk assessment contains a detailed analysis of potential health and environmental risks associated with the NEIDL. Carefully designed to be realistic and to consider input from the Boston Community, the BRP and the NRC, the analysis examines a series of scenarios describing the likely fates of specific pathogens that might be in involved in plausible procedural failures, containment system failures, and malevolent actions. The report also compares the potential public health consequences of biocontainment failures at the NEIDL facility in Boston, Massachusetts with two additional sites in suburban and rural locations.

The Final Supplementary Risk Assessment (FSRA), which is summarized in this SFEIR and included in its entirety in this document as Appendix 11, was released to the public and noticed in the Federal Register on July 9, 2012. The FSRA includes a transcript from the April 19, 2012 public hearing on the DSRA, as well as responses to the comments raised during the hearing. The required 30-day waiting period was extended to 45 days. The waiting period ended on August 24, 2012. A Supplemental Record of Decision was issued by the NIH and noticed in the Federal Register on January 2, 2013. The Supplemental Record of Decision is included in this document as Appendix 9.

1.3 SCOPE OF THE SFEIR

The Remand Certificate issued on September 5, 2006, requires the Proponent to submit a Supplemental Final Environmental Impact Report (SFEIR), to be prepared in accordance with MEPA regulations.

The requests in the Remand Certificate pertain solely to the NEIDL portion of the BioSquare Phase II Project and include additional analysis of specific issues raised in the Court's Memorandum and Order of July 31, 2006. This Supplemental Final Environmental Impact Report responds exclusively to the following requests:

1.3.1 ALTERNATIVE SITES

The Remand Certificate states that the Proponent should identify alternative feasible locations for the NEIDL, including at least one site "in an area less densely populated than the proposed location."

Utilizing the criteria established by NAID for the siting and operation of a NEIDL, three separate potential sites, each with different population characteristics corresponding to urban (the current Boston site), suburban (Tyngsborough, MA), and rural (Peterborough, NH) settings were evaluated. For a discussion of the criteria for selection of the current NEIDL site and the evaluation of two alternative sites, see Chapter 3, Alternative Sites and Relative Risks.

1.3.2 EVALUATION OF IMPACTS AT ALTERNATIVE SITES

The Remand Certificate states that the Proponent should evaluate the potential public health impacts from "an additional 'worst case' scenario" contagious pathogen release and identify any material differences between the impacts predicted for the proposed site and the alternative locations.

The FSRA provides an exhaustive "Event Sequence Analysis,' which expands the concept of a "worst case scenario" to evaluate a number of possible but unlikely events that have the potential to expose workers or the public to pathogens. The Event Sequence Analysis was performed for the proposed site as well as the two potential alternative sites. See Chapter 3, Alternative Sites and Relative Risks.

1.3.3 RISK ASSESSMENT

The Remand Certificate states that the Proponent should evaluate "an additional 'worst case' scenario" that involves the risk of contagion arising from the accidental or malevolent release of a contagious pathogen. The analysis should incorporate the initial anthrax spore based risk analysis included in the FEIR for comparative purposes. Where possible, the analysis should quantify the magnitude of the impacts, "in terms of actual or probable damage to the environment."

The SFEIR includes a discussion that compares the impacts of a number of possible scenarios at the NEIDL site in Boston with the impacts at the alternative locations identified in the "Alternative Sites" section. The basis for this analysis is the risk assessment prepared by the NIH.

The Draft and Final Supplementary Risk Assessments were undertaken by the NIH and monitored by a Blue Ribbon Panel (BRP) of scientific experts. The BRP was established in March 2008. Over the past three years the BRP has provided the NIH with independent scientific advice on the supplementary risk assessment, including questions to be addressed, possible scenarios, specific infectious agents to consider as well as guidance on processes, methods and modeling techniques that would result in a comprehensive, sound and credible risk analysis.

In addition, the National Research Council provided continuing assistance to the NIH on preparation of additional risk assessments for the NEIDL. The NRC Committee met with the NIH Blue Ribbon Panel at key milestones in the development of the draft risk assessment. At its most recent meeting on November 2, 2011, the Committee found that "the '90 percent' or penultimate draft of the risk assessment is a substantial improvement over the past documents we have reviewed." The NRC Committee further provided extensive comments on the report which were evaluated and addressed in the Final Supplementary Risk Assessment. See Appendix 11 for additional information about the NRC Committee findings.

The history of the risk assessment process for the Boston University National Emerging Infectious Disease Laboratories is summarized in the Reader's Guide to the FSRA, which is included as Section 4.3 of the FSEIR.

The FSRA examined a variety of possible scenarios, including those that posed the maximum realistic operational risks that might result in laboratory workers or the general public having primary or secondary infections

resulting from release of pathogens being studied in the NEIDL. While there can be no such thing as "no risk", the results of the analysis demonstrate that the risk of infections resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. The FSRA is included as Appendix 11.

The Final Supplementary Risk Assessment (FSRA) contains a detailed analysis of potential health and environmental risks associated with the NEIDL. Carefully designed to be realistic and to consider input from the Boston community, the BRP, and the NRC, the FSRA examines a series of scenarios describing the likely fates of thirteen specific pathogens, including anthrax that might be involved in plausible procedural failures, containment system failures, and malevolent actions. These pathogens are considered likely research areas of interest at Biosafety Level (BSL) 3 and BSL-4. See Chapter 2, Project Description. The original FEIR Risk Assessment for Anthrax is included herein for comparison as Appendix 6.

The FSRA compares the frequency and public health consequences associated with the potential loss of pathogen biocontainment in a range of population density areas that represent urban, suburban and rural environments at the proposed location (the NEIDL) with the alternative locations identified in the FEIR.

1.3.4 MITIGATION AND DRAFT SECTION 61 FINDINGS

The Remand Certificate states that the SFEIR should include a discussion of mitigation measures committed to by the Proponent. Revised Draft Section 61 findings should also be included in the SFEIR.

The SFEIR identifies measures that will be implemented to avoid or minimize potential impacts, including the impacts from a worst case scenario contagious pathogen release, as described in the "Risk Assessment" discussion above. Revised Draft Section 61 findings for MassDOT and MWRA are included in the SFEIR as Appendix 3.

Mitigation measures can be described as a myriad of actions, protocols, design features, public outreach, and compliance with Federal, State and Local regulations.

Mitigation measures that fall within the Scope of the SFEIR include numerous and extensive efforts made by the proponent to minimize the risk

to both laboratory workers and the public which could be associated with the operation of the NEIDL at all levels of research as well as the transportation and handling of pathogens. To that end, the emergency response planning and transportation safety planning measures designed by the proponent are described in detail in Appendix 7, NEIDL Comprehensive Emergency Management Plan. They are also addressed in detail in the FSRA, Appendix 11. A description of the proponent's community relations activities, which provide avenues to maintain vital and meaningful communication with the community, is also included in Chapter 5, Mitigation. A summary of all mitigation measures committed to and implemented by the proponent has also been included in the FSRA, and is included in Chapter 5.

1.3.5 RESPONSE TO COMMENTS ON THE FEIR AND NOTICE OF PROJECT CHANGE/PHASE ONE WAIVER REQUEST

The Remand Certificate states that the SFEIR should include responses to all comments issued on the FEIR to the extent that they fall within the Scope of the SFEIR, as outlined above. Copies of all comment letters and a single example copy of any form letters received should be included in the SFEIR.

The SFEIR addresses the comments received on the FEIR. These comments are summarized in Section 1.4, Summary of Comments Received on the FEIR. A detailed account of each of these comments and the related responses can be found in Appendix 4, Response to Comments on the FEIR. Copies of the letters can also be found in Appendix 4.

Subsequent to the issuance of the Remand Certificate, the Proponent submitted a NPC and Phase One Waiver request. The NPC and EOEEA Final Record of Decision (FROD) Certificates states that the Proponent should address the Metropolitan Area Planning Council's concern regarding the transport of hazardous materials to and from the project site.

The FSRA includes a detailed Transportation Analysis. Safety measures are incorporated into all aspects of handling and transportation of infectious pathogen samples. Those infectious pathogen shipments could involve both truck and air modes of transportation. The risks associated with both the truck and air shipment of infectious pathogens were thoroughly evaluated. See Chapter 5, Mitigation Measures and Appendix 11, Final Supplementary Risk Assessment.

In addition the SFEIR addresses the comments received on the NPC/Phase One Waiver Request which are germane to the Scope of the SFEIR. Responses to comments on the NPC/Phase One Waiver Request, and copes of individual comment letters can be found in Appendix 5.

1.3.6 DISTRIBUTION

The Remand Certificate states that the Proponent must distribute the SFEIR or provide notice to all parties that have submitted individual written comments on the FEIR, as well as any state agency from which the proponent will be seeking permits. A full list of these parties can be found in Appendix 2.

1.4 SUMMARY OF COMMENTS RECEIVED ON THE FEIR

In total, over seven hundred comment letters were received on the FEIR. The vast majority of these letters (659) supported the project, some were in opposition (40), and the remainder expressed neutral comments. Over ninety percent of the comments letters received were form letters. Of the sixty individual, non-form letters received, twenty-five included comments that fell within the Scope of the SFEIR. Sections 1.4.1 through 1.4.4 summarize the comments received on each of the topics included within the scope. See also Appendix 4, Responses to Comments on the FEIR.

1.4.1 ALTERNATIVE SITES

Thirteen letters were submitted on the FEIR that requested an analysis of alternative locations. Four of those letters used the language of the form opposition letter, which was comprised of a summary version of the language used in the Alternatives for Community and Environment (ACE) letter.

In general the comments requested:

- specific information on how the Albany Street site was selected (a list of criteria);
- an analysis of how the Albany Street location and other BU-owned properties fit that criteria; and
- examination of how the public health risks would differ at alternatives sites.

Three separate comment letters from the Conservation Law Foundation (CLF) requested the following: a complete list of BU-owned/controlled properties, specific analysis of Tyngsborough and Peterborough sites, examination of population density, environmental justice, demographics, and public health/safety as they relate to the alternative locations.

The ACE letter requests the following: an explanation of why (if proximity to BU and the Regional Center of Excellence is a criterion) other less densely populated sites within an hour's drive of Boston were not considered; explanation of how the siting decision took into account public health, safety, and environmental risks if the decision was made before the RWDI study was completed.

1.4.2 RISK ASSESSMENT

Eighteen letters requested additional analysis of "worst case" scenarios. Five of those letters used the language of the form opposition letter, which is comprised of a summary version of the language used in the ACE letter.

In general, the comments suggested the following:

- The initial anthrax spore risk analysis does not accurately represent the actual "worst case" because it underestimates the risk, is not site-specific, and doesn't consider non-human environmental impacts.
- An additional risk scenario that models contagious pathogens should be completed.
- An additional risk scenario that models an in-transit accident should be completed.
- An additional risk scenario that models a terrorist attack should be completed.

Newton Department of Planning and Development suggested examining the following scenarios: water contamination, hijacking, transportation, waste-disposal vehicles, animal carcass disposition, and failure of laboratory containment system. Other letters suggested an animal escape scenario.

Shirley Kressel, Marc Pelletier and others provided specific critiques of the anthrax modeling used in the FEIR. Ms. Kressel suggested that the model did not represent the way anthrax is typically disseminated. Mr. Pelletier suggested that a 3-D dispersion model would be more appropriate, taking into account localized wind patterns, etc.

ACE Letter included a critique of the worst case scenario by Dr. Jean Guillemin. Dr. Guillemin disagreed with the selection of anthrax as the worst case scenario. Given the anthrax analysis, the report should have included a workplace contamination scenario and a soil contamination scenario. She also disagreed with the estimated number of spores that could be released, the human dose response to anthrax, and the dispersion model for spores in the urban environment.

1.4.3 EMERGENCY RESPONSE

Seven letters requested additional information about emergency response plans.

The Boston Public Health Commission (Environmental Hazards Program) requested more information on training for public health and safety emergency responders. The BPHC also wanted to know how the public would be protected from an explosion or laboratory fire at the NEIDL. The Newton Dept of Planning and Development asked for a discussion of regional policies and plans and requested additional description of evacuation procedures, both within the building and within the community. Helaine Simmonds and Cinda Stoner requested additional information on community notification in an emergency situation, and how treatment/quarantine would be organized. David Mundel wanted more clarification on the coordination between city and institutional emergency response actions. Elliot Mishler and the Old Dover Neighborhood Association requested more concrete plans for the community in case of an emergency. The Metropolitan Area Planning Council listed a number of specific concerns including: potential shut-down of roads and air space near the facility during an emergency or period of heightened security, specifics of security fence, evacuation procedures, adequacy of secured area, and mitigation through emergency preparedness training.

1.4.4 TRANSPORTATION SAFETY

Thirteen letters requested additional information about transportation security. The majority of these letters used the language of the form letter, which is comprised of a summary version of the language used in the ACE letter.

The majority of the letters suggested the following:

- The SFEIR should include a worst case scenario for when a select agent is in transit to the laboratory.
- The SFEIR should "provide other essential information about the transport of hazardous biological and toxic agents to the laboratory".

The ACE letter suggests that a transportation-related accident needs to be analyzed as part of the worst-case scenario and cites two recent transportation related incidents. The letter also mentions the prohibition on hazardous cargo in local tunnels and asks the proponent to describe the planned transportation routes in recognition of this prohibition.

The Metropolitan Area Planning Council submitted a letter containing many transportation-related comments. MAPC requested that "some discussion of containment practices during these trips, and hazardous transport issues in general, should be included in the FEIR." In recognition of the hazardous cargo ban, it requested that the SFEIR "demonstrate that the anticipated hazardous materials can be safely transported in Boston."

1.5 ENVIRONMENTAL ISSUES AND MITIGATION MEASURES

The requests in the Remand Certificate pertain solely to the NEIDL portion of the BioSquare Phase II Project and include additional analysis of a few specific issues, including potential alternative sites and risks associated with the Project ("worst case scenarios"). The Proponent has also been requested to identify mitigation measures that fall within the SFEIR Scope. The FSRA was undertaken in response to the additional analysis requested in the SFEIR scope, and provides a thorough and exhaustive treatment of the concern regarding infections or mortalities resulting from loss of containment, either from accidental occurrences or from malevolent acts.

Mitigation has been described in the Reader's Guide to the Final Supplementary Risk Assessment as "a variety of precautions and steps [that] can be taken to reduce the possible risks....Mitigation may be accomplished through the use of specialized building design features, personnel protective equipment, personnel training, and administrative features." Mitigation measures are described in Section 5.0, Mitigation, and Appendix 11, Final Supplementary Risk Assessment.

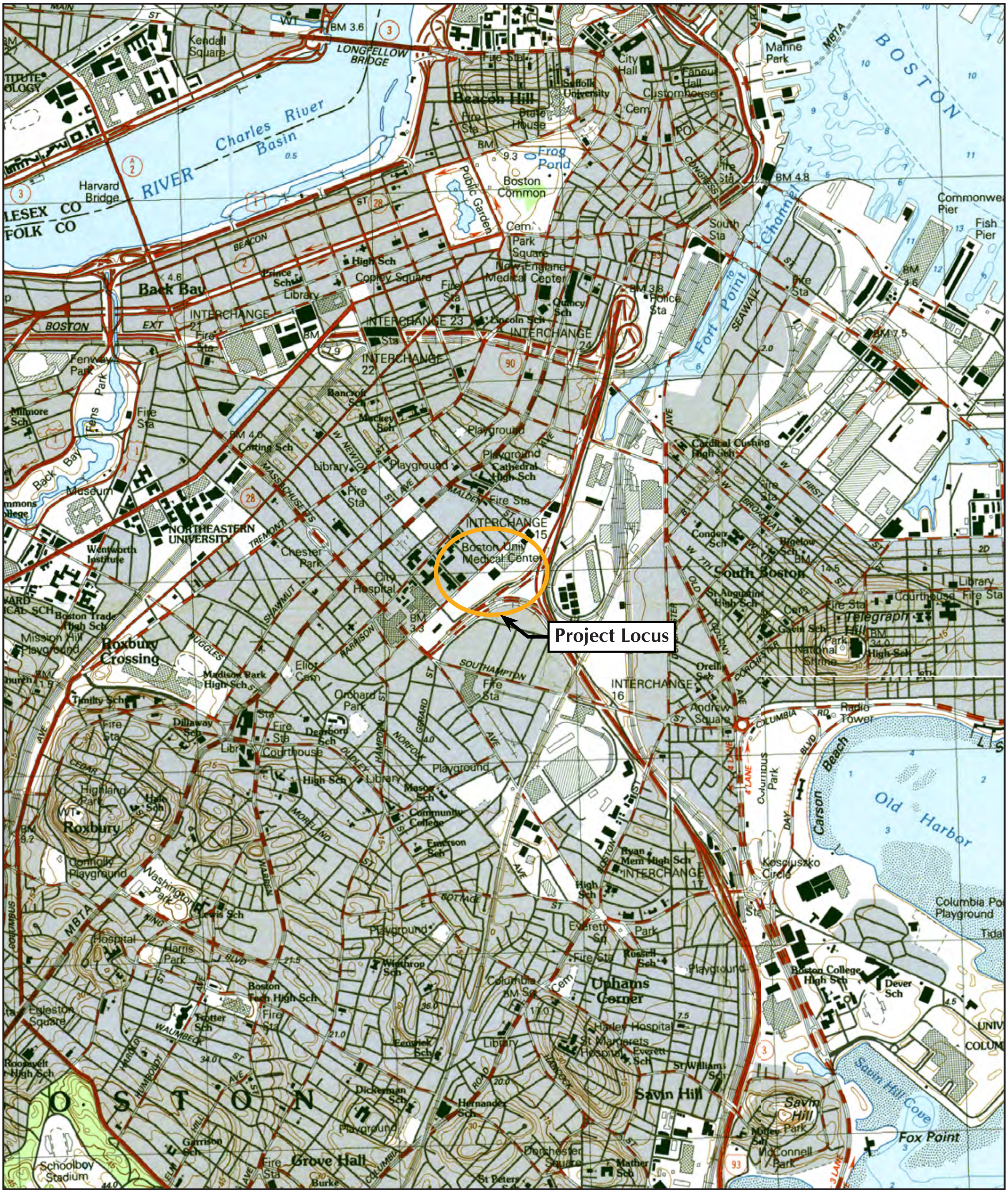
1.6 REGULATORY CONTROLS AND PERMITS

Many permit applications have been filed and approvals received for NEIDL. The Project is required to secure additional local, state and federal permits and approvals prior to operation of the NEIDL at BSL-3 and BSL-4. The following additional permits are outstanding: Industrial Discharge Permit from the Massachusetts Water Resources Authority for BSL-3 and BSL-4 research, Boston Public Health Commission approvals, and permits from the National Centers for Disease Control.

Boston Public Health Commission's (BPHC) approval process for all BSL-3 and BSL-4 facilities is an additional requirement unique to the City of Boston.

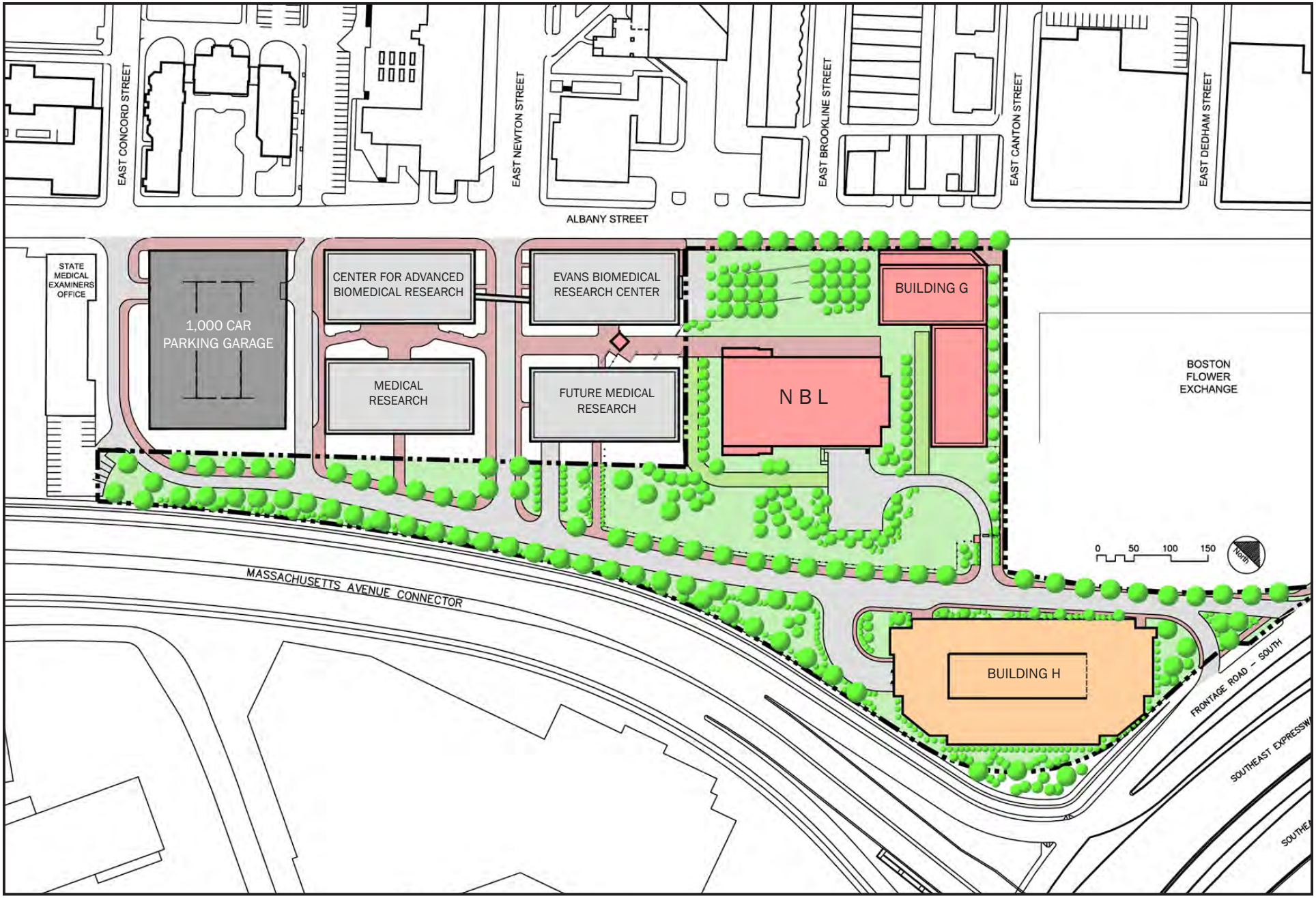
1.7 PROJECT TEAM

Project Proponent/Property Owner:	**Trustees of Boston University/ BioSquare Realty Trust** 715 Albany Street Boston, MA 02118 (617) 353-6500 Contact: Gary W. Nicksa
Permits/Approvals:	**Fort Point Associates, Inc.** 33 Union Street 3rd Floor Boston, MA 02108 (617) 357-7044 Contact: Jamie Fay
Legal Counsel:	**Foley Hoag, LLP** 155 Seaport Boulevard Boston, MA 02210 (617) 832-1203 Contact: Seth Jaffe



BioSquare Phase II
SFEIR

Figure 1-1
Locus Map
Source: MassGIS



BioSquare Phase II
SFEIR

Figure 1-2
BioSquare Research Park

Chapter 2

PROJECT DESCRIPTION

2.0 PROJECT DESCRIPTION

2.1 PROJECT DESCRIPTION/UPDATE

The 192,000 sf NEIDL facility contains state-of-the-art Biosafety Level (BSL) -2, -3 and -4 laboratories, as well as associated research and administrative support space. The BSL laboratories have been designed and built using the strictest federal standards, incorporating special engineering and design features to prevent microorganisms, including pathogens, from being released into the environment. The NEIDL incorporates extensive biocontainment features. Biocontainment features, as described in the FSRA, include Administrative Controls, Safety Equipment and Facility Design and Construction features. Biocontainment features support the biosafety requirements for BSL 1 through 4. Biocontainment features are described in detail in Appendix 11, Final Supplementary Risk Assessment.

The seven-story building is approximately 126 feet in height with four stories of occupied biomedical research space and three stories of mechanical and building support space. The building program includes BSL-2, BSL-3 and high-level containment BSL-4 modules. The BSL-4 modules will support work with live agents for tissue culture, antigen production, and in-vivo studies. The three BSL modules each include procedure space such as centrifuge and isolation areas; support spaces such as suit rooms and decontamination showers; and animal holding space. A discussion of the building program follows and is summarized in Table 2-1, NIEDL Building Program.

Table 2-1: NEIDL Building Program

Use	Program SF
BSL-4 Laboratories	30,720
BSL-3 Laboratories	24,960
BSL-2 Laboratories	38,400
Administrative	15,360
Building Support	82,560
Total	192,000

2.1.1 BIOSAFETY LEVELS

The following is a description of laboratory Biosafety Levels which is taken from the National Emerging Infectious Diseases Laboratories Final Environmental Impact Statement prepared by the National Institutes of Health in December of 2008.

BSL-1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or related science.

BSL-2

Biosafety Level 2 builds upon Biosafety Level 1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in Biosafety Cabinets (BSCs) or other physical containment equipment.

BSL-3

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research or production facilities where work is done with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious

materials must be conducted within BSCs or other physical containment devices. A BSL-3 laboratory has special engineering and design features.

BSL-4

Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission. Agents with a close or identical antigenic relationship to agents requiring BSL-4 containment must be handled at this level until sufficient data are obtained either to confirm continued work at this level, or re-designate the level. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design features. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment. In accordance with institutional policies, the laboratory director strictly controls access to the laboratory.

Further information about Biosafety Levels and related agents, practices, safety equipment, and facilities can be found in Section 5.3.1.

2.1.2 LABORATORIES

BSL-4 core laboratory space incorporates the most technologically advanced scientific equipment for infectious disease research in a high containment environment. The BSL-4 modules will support research on agents with no known prevention or treatment and those found in animals that may cause human infection. All of these agents are found on the Centers for Disease Control and Prevention (CDC) select agent list.

BSL-3 laboratories will be provided to accommodate research work on many of the NIH and Centers for Disease Control and Prevention (CDC) "A" and "B" list agents, which can be safely handled for routine use in a BSL-3 environment. Additionally, BSL-3 laboratories are used for agents that are regulated by the Boston Public Health Commission that are not included in the CDC "A" and "B" lists, such as Mycobacterium tuberculosis, the agent that causes the Tuberculosis (TB) disease.

Basic biochemistry and molecular biology laboratories at BSL-2 are provided to support the work on BSL-3 and BSL-4 infectious disease agents that are at the lower biosafety levels. The adjacency of the BSL-2 and BSL-3 laboratories at the NEIDL facility with similar, nearby BioSquare Research Park facilities will increase productivity for researchers and lab workers. Animal holding rooms and their associated support space will also be provided in connection with the BSL-3 and BSL-4 laboratories. All research protocols involving animals would be reviewed and approved by the Institutional Animal Care and Use Committee, in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (U.S. DHHS 2002e). In addition, all potential research projects are reviewed with and approved by the Institutional Biosafety Committee (IBC), which includes public representation. For more information about the IBC and other BUMC Research Committees, see Appendix 6.

2.1.3 OFFICE AND SUPPORT SPACE

Offices and support space are provided to house administrative staff, safety staff, resident principal investigators (PIs), visiting PIs and facility support staff employed to operate the facility. Building support spaces form the infrastructure backbone of the facility, including spaces for glassware cleaning, materials handling, waste handling, security, radiation safety and housekeeping.

2.2 PROJECT STATUS

2.2.1 CONSTRUCTION AND OPERATION OF THE NEIDL

Boston University commenced construction of the NEIDL building on March 6, 2006. By fall 2008, major construction was substantially complete and the building was ready for commissioning. The NEIDL facility was completed, with all systems made ready for partial occupancy, in the first quarter of 2011. Administrative activities that did not include research in BSL-2, BSL-3 and BSL-4 laboratories were carried out in the NEIDL. Following the completion of the MEPA review process on the NPC and the Phase One Waiver request in December 2011, which is discussed in Section 1.2, the Proponent initiated BSL-2 research in April 2012. Current research at BSL-2 levels is focused primarily on Tuberculosis, which kills two to three million people worldwide each year.

Operations at the NEIDL are governed by numerous federal, state and local laws, regulations and guidance. Agencies involved in regulatory oversight include, but are not limited to: Centers for Disease Control and Prevention, US Department of Transportation, Occupational and Safety Hazard Agencies, US Environmental Protection Agency, National Institutes of Health, National Research Council, US Department of Agriculture, MA Department of Public Health, MA Department of Environmental Protection, MA Water Resources Authority, Boston Public Health Commission, Boston Fire Department, Boston Water and Sewer Commission and Boston Inspectional Services Department.

In addition to compliance with these regulations, BU has developed and implemented policies that inculcate a "culture of safety". This includes detailed, on-going training, prompt reporting of possible problems before there are adverse consequences, and shared responsibility for safety to ensure prompt and appropriate responses to any accidents that do occur.

2.2.2 STATUS OF MITIGATION MEASURES IDENTIFIED IN THE FEIR

The Certificate on the Final EIR for the BioSquare Phase II project included a number of mitigation measures required for the full development of the entire Project. The Proponent has implemented the majority of the measures it committed to. A detailed list of each of these measures and their current status can be found in Section 5.1.

Figure 2-1
Aerial View of Project Site
Source: Google, 2011

Chapter 3

ALTERNATIVE SITES AND RELATIVE RISKS

3.0 ALTERNATIVE SITES AND RELATIVE RISKS

In order to provide the reader with background information describing the extensive evaluation process that was undertaken prior to the initial selection of the preferred NEIDL site by the Proponent, the following sections describe the process Boston University Medical Center (BUMC) followed to evaluate potential sites and to select the BioSquare Research Park as the proposed facility location for the NEIDL. Specifically in response to the Remand Certificate, the process undertaken in the Final Supplementary Risk Assessment to evaluate alternative sites is summarized. A detailed discussion of the relative risks of the two alternative sites as compared to the proposed location is included Appendix 11, Final Supplementary Risk Assessment.

3.1 BACKGROUND

In the fall of 2002, the National Institute of Allergy and Infectious Diseases (NIAID) issued a Broad Agency Announcement (BAA) for the construction of national biocontainment laboratories. BUMC administrators proceeded to evaluate the BAA to determine if a nationally competitive and institutionally feasible response could be developed. BUMC conducted an intensive evaluation of the grant requirements and assessed how such a facility would further the medical, research and teaching missions of the institution. Concurrently with the development of the grant application, BUMC completed an extensive siting analysis to determine feasible locations for siting such a laboratory. In February 2003 a grant application was submitted to NIAID for the proposed South End location and in September 2003 the grant was awarded.

3.2 BUMC SELECTION OF POTENTIAL SITES

The BUMC committee charged with evaluating the BAA and preparing the grant application included representation from BUMC's financial, medical, research, facility planning, and safety and security departments. The first task of the committee was to identify all sites that could potentially serve as a location for the NEIDL. A requirement of the BAA was that the applicant own or control the project site. No funding was available for site acquisition.

All Boston University and Boston Medical Center landholdings were reviewed and evaluated based on their potential for development. Potential development parcels were identified in several locations: four parcels at the Boston University Medical

Center Campus, four at the BioSquare Research Park, 20 at the Charles River Campus, and one at each of two BU-owned sites in Tyngsborough, MA, and Peterborough, NH. Brief descriptions of the sites subsequently evaluated in the FSRA are provided below. See also Figure 3-1, Locations of Three NEIDL Sites for Suitability Analysis.

3.2.1 BIOSQUARE RESEARCH PARK

The BioSquare Research Park, located immediately adjacent to the BUMC on a 14-acre site with a capacity for 2.2 million square feet of medical research facilities, is the City of Boston's only research park devoted exclusively to the life sciences sector. The Research Park is owned by BioSquare Realty Trust, the beneficiaries of which are Boston Medical Center Corporation and Trustees of Boston University. In December of 1991, the Mayor approved a Planned Development Area Master Plan for the future NEIDL site. The Master Plan recommended development of the site for biotechnology uses and identified six development parcels for a Phase I build out that included a parking garage, four medical research building and a hotel. The Master Plan was amended in 2003 with the addition of the Phase II build out which included two medical research buildings and a parking garage, and removed the hotel.

At the time of the site analysis, the BioSquare Research Park had four parcels available for development: Parcels E, F, G and H. Parcel F was eventually selected for construction of the NEIDL. See Figure 3-2, Parcel F at BioSquare Research Park.

3.2.2 BOSTON UNIVERSITY CORPORATE EDUCATION CENTER TYNGSBOROUGH, MA

At the time of the BAA, the Boston University Corporate Education Center was located on the site of the former Wang Institute for Graduate Studies on Tyng Road in Tyngsborough, MA. The University no longer owns the site. The site consists of 210 acres, the majority of which are located in the Town of Tyngsborough, with 6.6 acres located in Chelmsford and 22 acres located in Westford. The town of Tyngsborough has a population of 11,785 and is located over 30 miles from Boston.

The site was home to a high-tech training facility providing over 20,000 square feet of conference space including a 280-seat auditorium and seven conference rooms, a caretaker's residence and a Quonset hut. The conference center complex was located along the northern portion of the site off of Tyng Street. The balance of the property contains heavily wooded

areas, wetlands, several open fields and the remnants of a rock quarry operation. See Figure 3-3, Boston University Corporate Education Center.

The Wang Institute transferred ownership of the property to Boston University in 1987. Prior to 1979, the site was the property of the Saint Joseph's Novitiate. Subsequent to acquiring the property, Wang Institute made several changes including installation of new domestic water and fire protection systems, a new subsurface sewage disposal system, renovation of existing buildings, landscaping improvements and construction of additional parking areas. The University sold the site to a private developer in 2008.

3.2.3 BOSTON UNIVERSITY SARGENT CENTER FOR OUTDOOR EDUCATION, PETERBOROUGH, NH

The Boston University Sargent Center for Outdoor Education is located along Sargent Camp Road in Peterborough, New Hampshire. The town of Peterborough has a population of 5,686 and is located over 70 miles from Boston. The facility has operated since 1912 as a training facility, summer youth camp, and year round outdoor education and conference center. The site was founded by Dr. Dudley Sargent (who also founded Boston University's Sargent College of Allied Health Professions) and was formerly known as the Sargent Camp. The focus of the facility, which services school children, college students and adults, is outdoor education.

The entire site consists of 850 acres with 505 acres in Hancock and 345 acres in Peterborough. Of the 850 acres, approximately 166 acres are non developable with an estimated 24 acres of protected wetlands, 82 acres of protected watershed and a 60 acre pond, Half Moon Pond. Of the 684 remaining acres, the main campus of Sargent Camp, located in the southern portion of the site, occupies a 16-acre parcel. This parcel is improved with a number of buildings including staff and guest housing as well as support lodges and offices containing approximately 59,000 sf.

A Master Plan for the site was developed in October of 2001, which defined the facility needs and programs necessary to serve its primary outdoor educational constituency as well as to achieve financial goals. The Master Plan suggested several improvements to the physical plant and creation and expansion of nature trails. The Master Plan did not recommend the development of other uses at the site. See Figure 3-4, Boston University Sargent Center for Outdoor Education.

3.2.4 TIER 1: SITE SCREENING CRITERIA

The BUMC committee charged with evaluating the BAA and preparing the grant application included representation from BUMC's financial, medical, research, facility planning, and safety and security departments. The committee evaluated BUMC's and NIAID's programmatic requirements including building design and siting criteria.

The Committee identified specific criteria that would need to be considered in the design and siting of the proposed facility. Based on the BAA restrictions, programming needs, and federal safety criteria, two minimum siting criteria were established to assist in the site selection. Any sites that did not meet these criteria were eliminated from further evaluation. The minimum siting criteria included the following:

- Site must be controlled (owned or currently leased) by Boston University.
- Lot size must be sufficient to accommodate a minimum building size of 190,000 sf and at the same time meet federal security setback requirements.

The BAA required applicants to identify a proposed site which was under the ownership or control of the applicant. The BAA did not allow any grant funds to be used for the acquisition of a site; thus potential sites not owned by the University were not feasible to consider. This significant constraint on funding limited Boston University to considering only sites which it owned or controlled.

3.2.5 TIER 2: PROGRAMMATIC AND INSTITUTIONAL LOCATIONAL CRITERIA

The committee then sought to develop a second tier of siting criteria that would address programmatic and locational objectives deemed necessary to make the proposal nationally competitive and institutionally feasible from a medical, research, and teaching perspective.

The committee first determined how such a national laboratory could be programmed to both complement and enhance the existing BUMC institutional programs and objectives and at the same time meet NIAIDs national research goals. The committee hoped to take advantage of BUMC's existing medical research facilities and to support the research of other institutions in the greater Boston area. The committee determined that the facility should incorporate components necessary to support cutting edge basic, translational and clinical research in emerging infectious diseases and

should implement comprehensive research, development and training programs for the development of diagnostic, preventive and therapeutic projects.

Creation of a partnership with the then-proposed Harvard University Medical School's NIH/NIAID-sponsored Regional Center of Excellence (RCE) was seen as a vital component of the medical research program for the facility. Such a relationship would also respond to the BAA requirement the Applicant be "associated with or have planned linkages to one or more institutions or consortia that are applying for NIH/NIAID Regional Centers of Excellence (RCE) Biodefense and Emerging Infectious Diseases research grant awards" (U.S. DHHS, 2002b). To pursue this relationship, BUMC medical researchers held several strategic meetings with colleagues at the proposed RCE to identify mutual goals and objectives for the research of infectious diseases and to determine how a proposed national biocontainment laboratory might best assist in meeting such mutual objectives. The proximity to and ability to utilize the facilities of the institutional laboratories to be associated with the RCE was also seen as a key factor in the committee's decision to pursue the NIH grant.

Based on these and other institutional considerations, a second tier of siting criteria was developed. The criteria include the following:

- Proximity to a proposed NIH/NIAID Regional Center of Excellence
- Ease of access to and use of existing medical research institutions/research facilities, opportunities for efficient medical research collaboration and ability to function as a training center
- Proximity to a trained workforce
- Proximity to state of the art emergency response programs and facilities including police, fire, public health and medical trauma
- Proximity to interstate highway systems and a regional airport
- Presence of adequate public infrastructure including water and sewer
- Facility use and building dimensions allowed under local zoning
- Siting achieves Smart Growth objectives

Based on all of the aforementioned information, the committee proceeded to evaluate a number of Boston University-owned sites as detailed below.

3.2.6 SELECTION OF PREFERRED SITE BY BUMC

All potential development parcels identified in the early stages of the site selection process were evaluated based on their compatibility with the Tier

1 and Tier 2 site screening criteria. Of the 30 parcels originally identified, 24 were under the control of Boston University. Ten of those parcels met the minimum lot size requirements, but only three met the federal safety zone setback requirements. After the application of the Tier 1 siting criteria, only Parcel F at BioSquare Research Park, the Tyngsborough site, and the Peterborough site remained viable options. These sites are more fully described in Section 3.2.1 through 3.2.3.

The three sites were then compared based on the Tier 2 screening criteria. The Peterborough site did not meet any of the screening criteria. The Tyngsborough site met or could potentially meet only three of the criteria. The BioSquare Research Park site met all eight of the screening criteria. Accordingly, the BioSquare Research Park site was recommended as the location for the proposed national biocontainment laboratory.

The conclusion of the BUMC's site screening analysis was that, of the thirty parcels located at five sites in two states; only three sites met the minimum screening criteria for the project. Of these three sites, one site, Parcel F in BioSquare Park, was clearly the superior site in terms of the Tier 2 site evaluation criteria. The sites in Tyngsborough, MA and Peterborough, NH were ranked significantly lower in every respect, with no offsetting benefits to be obtained. The rural and suburban sites were undeveloped locations which would have required rezoning at a Town Meeting in order to be feasible, which was a challenging prospect at best. Accordingly, the BUMC recommended Parcel F in BioSquare Research Park for the location of the proposed NEIDL facility.

3.3 FSRA COMPARISON OF RELATIVE RISKS AT THREE ALTERNATIVE LOCATIONS

The Remand Certificate includes a requirement to analyze the potential differences in impacts and environmental consequences between the preferred site and at least one alternative location for the NEIDL facility. Specifically, in the comparison of alternative locations, the SFEIR must "evaluate whether the potential public impacts due to the release of a contagious pathogen, including a "worst case" scenario, would be materially different if the biocontainment building were located in a feasible alternative location in a less densely populated area."

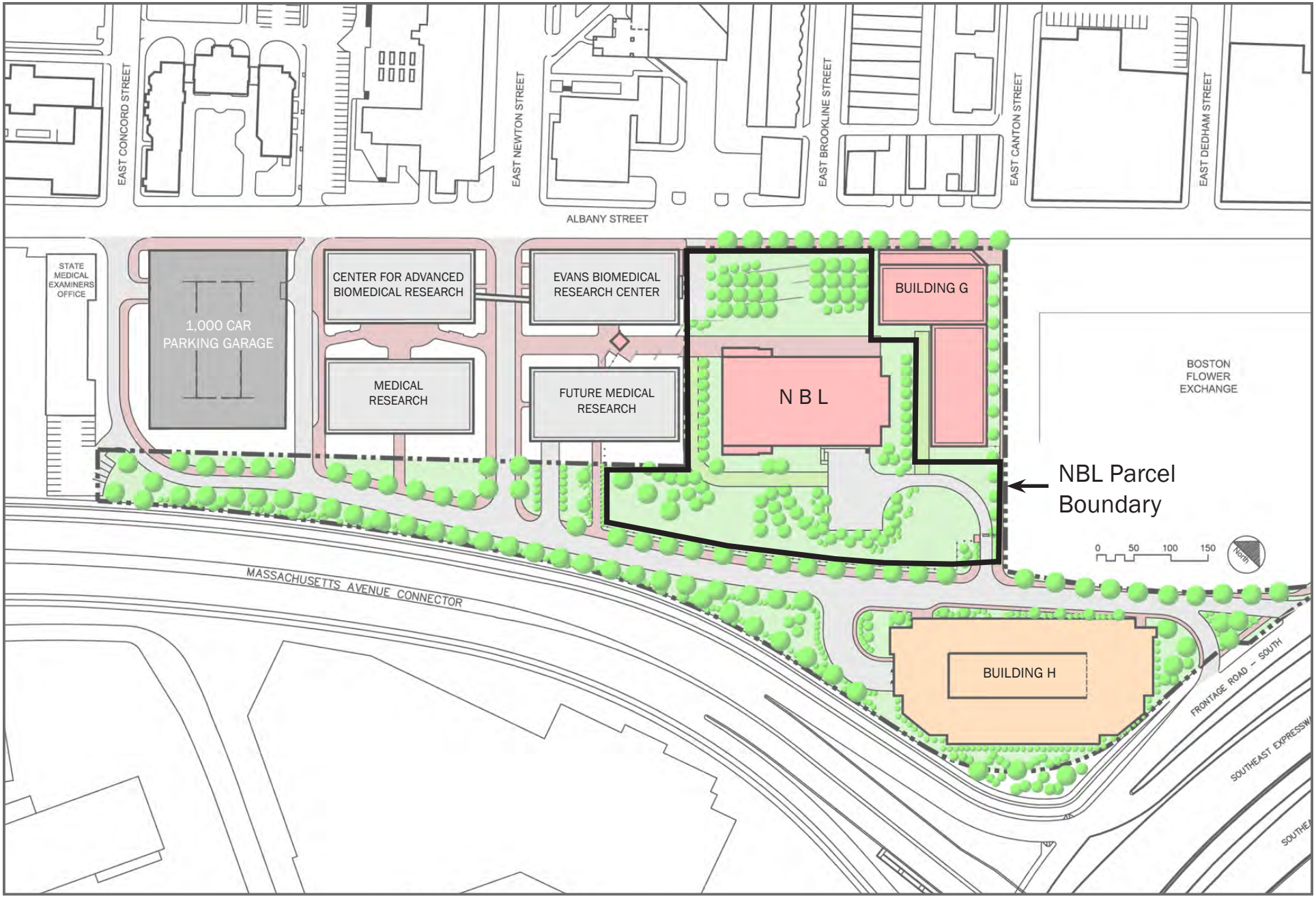
The FSRA evaluated the environment around the current NEIDL site as well as the two alternative locations described in Section 3.2.

The FSRA considered the impacts of the same potential events on urban, suburban and rural settings for the NEIDL facility. For the reasons described in Section 3.2 above, the FSRA compared and evaluated the Boston, Massachusetts; Tyngsborough, Massachusetts; and Peterborough, New Hampshire sites, which met the siting and other criteria outlined by the NIH for suitability as the location for a NEIDL facility.

The FSRA evaluated and compared the potential human health consequences of a potential accidental event or malevolent action resulting in the loss of a pathogen or biological containment at the BUMC NEIDL biological research facility in the three locations. This evaluation and comparison was based on the following site characteristics: Location, Livestock and Animals, Utilities, Transportation and Access, and Healthcare and Emergency Response.

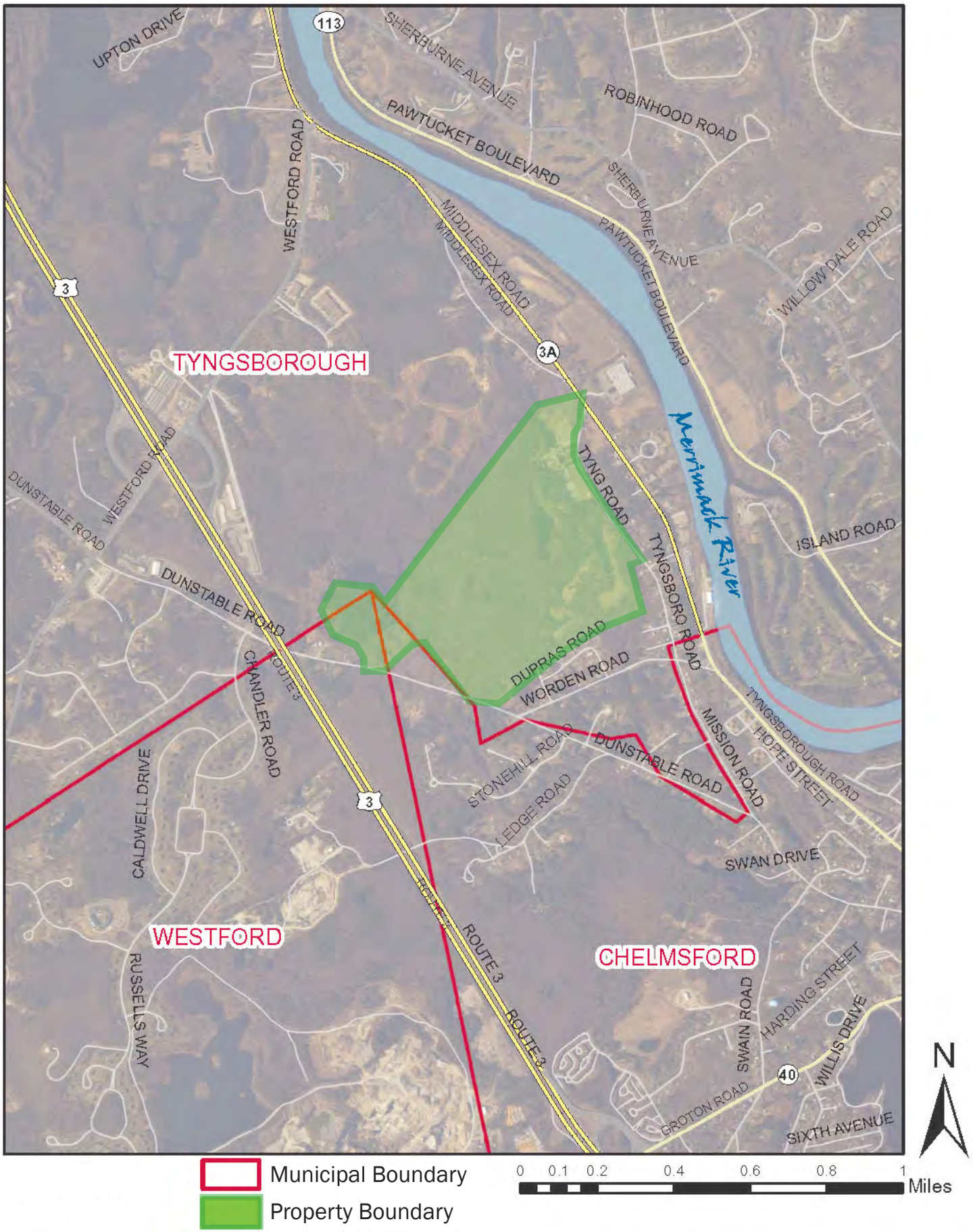
Although statistical differences in the potential outcomes of various occurrences evaluated at the three locations were identified, the exhaustive and thorough analysis contained in the 1,700 page report supports the conclusions of the FSRA that the risk of infections or deaths resulting from accidents or malevolent acts at the NEIDL at any of the sites are generally very low to only remotely possible. Also, while there are some limited differences in the risks for the three sites, they were small in comparison to the range of probabilities for each of the sites. Although medically vulnerable populations may be more susceptible to infections and perhaps suffer more severe consequences, the analysis did not show any significantly increased risk to these groups when analyzed as a group or individually. In addition, Environmental Justice Communities (located within closer proximity to the NEIDL facility in BioSquare Research Park) have been shown to not be affected disproportionately. See Appendix 11, Final Supplementary Risk Assessment.

Figure 3-1
Locations of Three NEIDL Sites for Suitability Analysis
Source: Final Supplementary Risk Assessment for the Boston University NEIDL, 2011



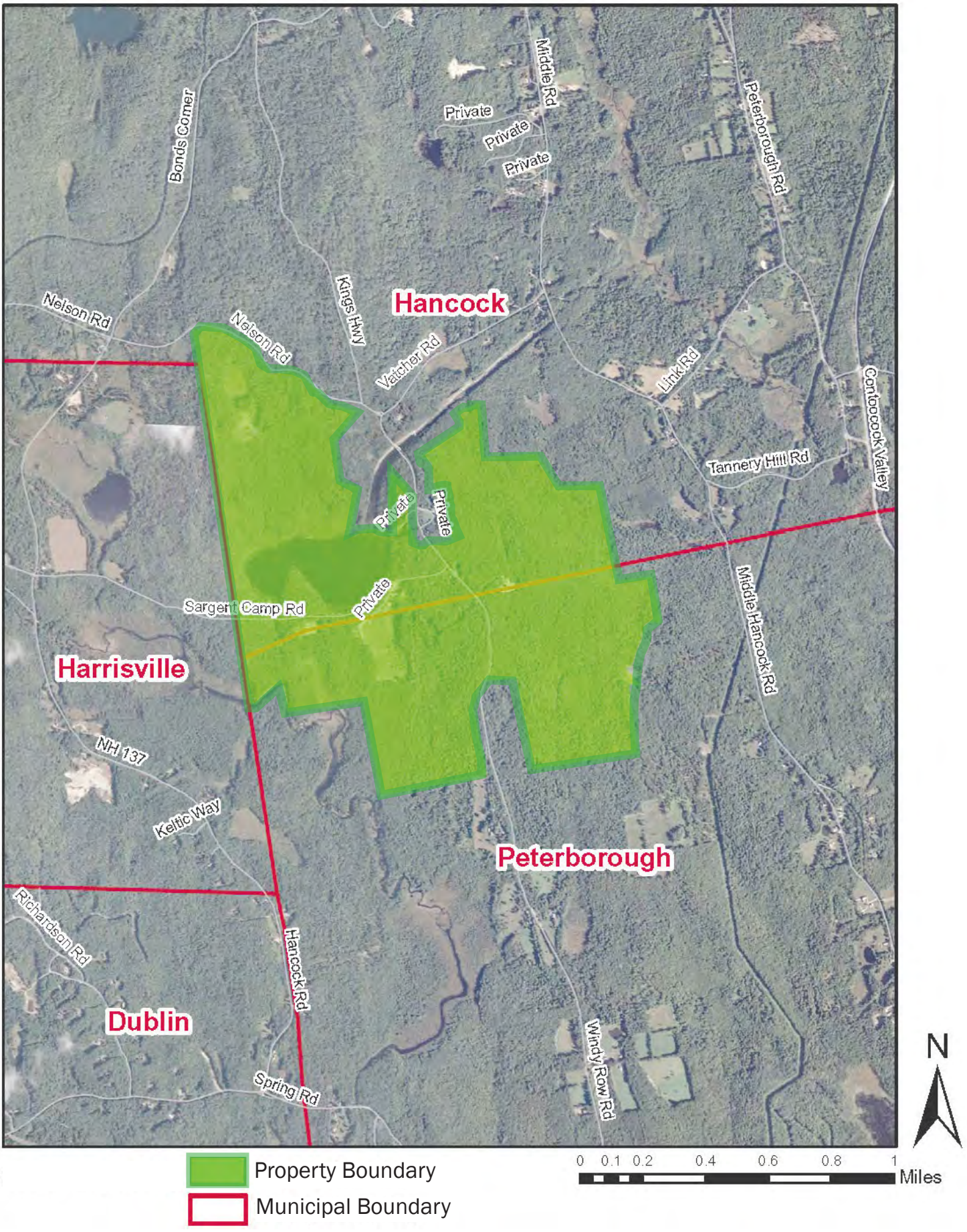
BioSquare Phase II
SFEIR

Figure 3-2
Parcel F at BioSquare Research Park



BioSquare Phase II
SFEIR

Figure 3-3
Boston University Corporate Education Center
Source: MassGIS



BioSquare Phase II
SFEIR

Figure 3-4
Boston University Sargent Center for Outdoor Education
Source: MassGIS

Chapter 4

ASSESSMENT OF IMPACTS/ FINAL SUPPLEMENTARY RISK ASSESSMENT

4.0 ASSESSMENT OF IMPACTS/FINAL SUPPLEMENTARY RISK ASSESSMENT

4.1 BACKGROUND

Through the initial state and federal environmental review processes and prior to the NIH Final Supplementary Risk Assessment, four risk assessments were conducted for the NEIDL portion of the BioSquare Phase II project. These risk assessments modeled a release of aerosolized anthrax as the "worst case" scenario. Each has found that even in the worst case scenario, the risk to public health posed by the NEIDL in all of the three potential locations would be negligible.

Anthrax was originally selected for the worst case scenario due to its ease of airborne dissemination and its resistance to environmental factors. Because anthrax is a spore, it is highly resistant to adverse environmental conditions including sunlight, temperature, and lack of humidity. Additionally, a single anthrax spore is of a size, shape and weight that can remain airborne for extended periods of time. The Centers for Disease Control and Prevention (CDC) classified anthrax as an agent that poses the greatest possible threat to public health. The CDC had determined that, second to smallpox (which is restricted in its possession and use by international agreements), anthrax poses the greatest real and perceived threat to public health if used as a weapon, or through accidental release. Other select agents potentially studied at the NEIDL are much more susceptible to environmental conditions and some require direct cutaneous contact for transmission. For example, Ebola virus requires a host in order to survive and cannot be transmitted by air.

However, the Remand Certificate requires the evaluation of an additional "worst case" scenario, one which involves "the risk of contagion arising from the accidental or malevolent release of a contagious pathogen." In response, the NIH commissioned a supplementary risk assessment, which was prepared by Tetra Tech. Infectious diseases and accident scenarios of particular concern to the community were modeled and analyzed for the NEIDL location and the two alternative locations (Tyngsborough, MA and Peterborough, NH), as discussed in Chapter 3.

The results of the new NIH risk assessment are summarized in Section 4.3. The full Final Supplementary Risk Assessment can be found in Appendix 11.

4.2 FEIR RISK ASSESSMENT

4.2.1 FEIR RISK ASSESSMENT (JULY 2004)

As part of the FEIR submitted to EOEA in July of 2004, a "worst-case scenario" risk assessment was completed by RWDI. A draft report was included in the FEIR. See Appendix 6, FEIR Risk Assessment - RWDI, July 2004.

Model & Assumptions

The "worst-case scenario" was defined as the accidental release of aerosolized anthrax spores and the simultaneous complete loss of containment systems in the BSL-4. The accidental release involves a laboratory worker dropping and breaking a 15cc vial containing 10 billion anthrax spores. This accident coincides with a catastrophic and total failure of the NEIDL's double HEPA filtration within the exhaust system. At the same time, the HVAC system continues to operate despite multiple monitoring, alarming, and automated safety sequences.

The study modeled three conceivable scenarios to provide an estimate of the maximum possible risk of exposure to spore concentrations along the path of the dispersing plume. The three scenarios include accidental release in laboratory with functioning HEPA filters, accidental release with single HEPA filter malfunction, and accidental release with neither HEPA filter functioning. Ventilation flow rates from exhaust stacks were assumed to correspond with 12 air changes per hour for the BSL-4 space (corresponding to an exhaust flow rate of 14,000 cubic feet per minute). Dispersion modeling of the spores was performed using SLAB, a U.S. EPA-approved dispersion model. The study analyzed the impact on nearby residents, workers, inmates, patients and pedestrians. The study did not include laboratory worker exposure.

Results

The calculated worst-case exposure for any single individual from the scenario was found to be 0.0024 spores. This exposure reflects the most dense dispersion location and the inhalation of anthrax for the duration of the event. The exposure of 0.0024 spores over the duration of the event is significantly less than one spore. Since the release and inhalation of a partial

spore is not feasible, this number may be practically considered as zero. The FEIR Risk Assessment concluded that the worst-case exposure does not approach an infectious dose of inhalation of anthrax; therefore the risk of public harm was so minute that it was considered to be negligible.

4.3 FINAL SUPPLEMENTARY RISK ASSESSMENT

4.3.1 INTRODUCTION

In response to the Secretary's Certificate Following Remand on the FEIR (the Remand Certificate), and to the lawsuits filed by local citizens and public interest groups, the NIH engaged in an unprecedented effort to perform a supplementary risk assessment to further analyze and determine what, if any, adverse human health effects would occur from an accidental or malevolent release of a pathogen from the NEIDL.

NIH convened a panel of experts, known as the Blue Ribbon Panel (BRP), to advise NIH during the development and preparation of the Draft and Final Supplementary Risk Assessments. In addition, NIH contracted with the independent National Research Council to provide further guidance and input into the risk assessment. For a more detailed description of the history of the risk assessment, see Section 1.2.4.

Information about the supplementary risk assessment and summaries of measures undertaken by the Proponent to protect the health and safety of the community, as well as the researchers and workers who participate in the daily activities at the NEIDL, can be found throughout this SFEIR. The Final Supplementary Risk Assessment, contained in two "books", consists of over 2,700 pages and took more than three years to produce. During the course of the preparation and distribution of the supplementary risk assessment, the NIH and Boston University maintained project-specific websites which were continually updated with relevant information. Members of the public were encouraged to subscribe via email to receive updates and communications from the NIH and Boston University. Both the Draft and Final Supplementary Risk Assessments were noticed in the Federal Register, and were widely distributed and made available to the public through numerous venues, including local libraries. The Proponent notified community members about the availability of the risk assessments through email, community outreach meetings, monthly Community Liaison Committee meetings, and through the April 11, 2012 and August 8, 2012 electronic editions of the MEPA Environmental Monitor. See Appendix 1,

MEPA Certificates, for additional information from the MEPA Environmental Monitor.

Both Boston University and NIH maintain project-specific websites which are consistently updated with relevant information and the option to subscribe via email for updates. Further information on the NEIDL website and other outreach efforts can be found in Section 5.5, Community Relations.

4.3.2 NIH BLUE RIBBON PANEL

Purpose

The Blue Ribbon Panel was established to provide independent and scientifically based advice to the National Institutes of Health (NIH) Director on supplementary risk assessment studies to be performed regarding the NEIDL, as the agency responded to the comments and concerns voiced by the courts, the local community, the National Research Council, and the general public regarding the construction and operation of a national biocontainment laboratory at Boston University Medical Center.

Membership and Structure

The Blue Ribbon Panel was established as a Working Group of the standing Advisory Committee to the Director (ACD), NIH. The Panel's recommendations have been conveyed to the NIH Director through the ACD. The Panel's 16 members have notable expertise in infectious diseases, public health and epidemiology, risk assessment, environmental justice, risk communications, biodefense, biosafety, and infectious disease modeling. The BRP met frequently during the course of the preparation of the supplementary risk assessment. Between March 13, 2008 and April 19, 2012, the BRP met on 15 occasions to review progress, provide significant and substantive input and coordinate constructive progress on the risk assessment. The BRP also participated in public meetings and community meetings during this period.

The Blue Ribbon Panel members are as follows:

Chair

Mahmoud, Adel, Ph.D., M.D.
Professor
Department of Molecular Biology and Woodrow Wilson School
Princeton University

Members

- **Burke, Donald, M.D.**
  Dean, Graduate School of Public Health
  Director, Center for Vaccine Research
  Associate Vice Chancellor for Global Health
  UPMC-Jonas Salk Chair in Global Health
  University of Pittsburgh

- **Eubank, Stephen, Ph.D.**
  Professor, Virginia Bioinformatics Institute
  Deputy Director of Network Dynamics and Simulation Science Laboratory
  Adjunct Professor, Department of Physics Professor
  Virginia Polytechnic Institute and State University

- **Freimuth, Vicki, Ph.D.**
  Professor, Department of Speech Communication and Grady College of Journalism and Mass Communication
  University of Georgia

- **Friedman-Jimenez, George, M.D.**
  Director, Bellevue Hospital Center
  New York University Occupational and Environmental Medicine Clinic
  New York School of Medicine

- **Hamburg, Peggy, M.D., M.P.H.** (resigned in March 2009 when she assumed the position of FDA Commissioner)
  Senior Scientist
  Nuclear Threat Initiative

- **Holbrook, Karen, Ph.D.**
  Vice President for Research and Innovation
  University of South Florida

- **Kasper, Dennis, M.D.**
  William Ellery Channing Professor of Medicine
  Professor of Microbiology and Molecular Genetics
  Harvard Medical School
  Director, Channing Laboratory
  Department of Medicine
  Brigham and Women's Hospital

- **Lewis, Johnnye, Ph.D., D.A.B.T.** (resigned in September 2010)
  Director, Community Environmental Health Program
  College of Pharmacy, Health Sciences Center
  Co-Director, Environmental Health Signature Program

Health Sciences Center
University of New Mexico

- **Lipkin, W. Ian, M.D.** (resigned in November 2010)
  Principal Investigator and Scientific Director
  Northeast Biodefense Center
  John Snow Professor of Epidemiology and Director
  Center for Infection and Immunity
  Mailman School of Public Health
  Professor of Neurology and Pathology
  College of Physicians and Surgeons
  Columbia University

- **Murray, Tom, Ph.D.**
  President
  The Hastings Center

- **Northridge, Mary, Ph.D., M.P.H.**
  Professor, Clinical Sociomedical Sciences
  Mailman School of Public Health
  Columbia University

- **Patterson, Jean, Ph.D.**
  Scientist and Chair, Department of Virology and Immunology
  Southwest Foundation for Biomedical Research

- **Robson, Mark Gregory, Ph.D., M.P.H.**
  Director of the New Jersey Agricultural Experiment Station
  Professor of Entomology
  School of Environmental and Biological Sciences
  Rutgers, The State University of New Jersey

- **Stanley, Samuel, M.D.**
  President
  Stony Brook University

- **Thomann, Wayne, Dr.P.H.**
  Assistant Professor
  Director of Environmental Safety
  Duke University Medical Center
  Duke University

4.3.3 NATIONAL RESEARCH COUNCIL (NRC)

Purpose

The National Research Council was organized in 1916 in response to the increased need for scientific and technical services caused by World War I.

Due to the success of Council-directed research in producing a sound-based method of detecting submarines, as well as other military innovations, the NRC was retained at the end of the war, though it was gradually decoupled from the military. The Research Council is currently administered jointly by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, and its work is overseen by a Governing Board and an Executive Committee.

The president of the National Academy of Sciences is the chair of both the Governing Board and Executive Committee; the president of the National Academy of Engineering is vice chair.

Its members are drawn from the councils of the National Academy of Sciences (NAS), the National Academy of Engineering (NAE), and the Institute of Medicine (IOM). The members of its committees are chosen for their special competencies and with regard for appropriate balance. Its reports are reviewed by a group other than the authors, according to procedures approved by a Report Review Committee, which also consists of members of the NAS, NAE, and IOM.

Membership and Structure of the NRC Committee

The NRC committee established to review the Boston University NEIDL (officially called the Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL) was comprised of individuals uniquely qualified to review this facility in particular. Chaired by John Ahearn of the Scientific Research Society in Research Park, NC, its members are affiliated with a diverse range of universities and private consulting practices from across the nation:

- John Ahearn (Chair), The Scientific Research Society, Research Triangle Park, NC
- Thomas Armstrong, TWA8HR Occupational Hygiene Consulting, LLC, Branchburg, NJ
- Gerardo Chowell, Arizona State University, Tempe, AZ
- Margaret Coleman, Consultant, Cicero, NY
- Gigi Kwik Gronvall, University of Pittsburg, Baltimore, MD
- Eric Harvill, Pennsylvania State University, University Park, PA
- Barbara Johnson, Barbara Johnson & Associates, LLC, Herndon, VA

- Paul Lock, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
- Warner North, NorthWorks, Inc., Belmont, CA
- Jonathan Richmond, Jonathan Richmond & Associates, Southport, NC
- Gary Smith, University of Pennsylvania School of Veterinary Medicine, Kenneth Square, PA

At the request of the NRC, the committee met with the Blue Ribbon Panel at key milestones in the development of the Draft Risk Assessment, culminating in an open session on November 2, 2011. The Committee subsequently issued a report summarizing the comments gathered at the open session. Findings and recommendations contained in the report were taken under advisement and addressed in the Draft and Final Supplementary Risk Assessments. The report, titled "*Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments for the Boston University NEIDL, Phase 3*," is included in this document as Appendix 11.

4.3.4 PURPOSE OF THE RISK ASSESSMENT (RA)

The purpose of the RA is to address and respond to the human health issues raised in the public and judicial review process and to respond to findings from the BRP and the NRC of the NAS. In a human health RA the analyses determine what, if any, adverse human health effects would occur from an accidental or malevolent release of a pathogen or infected insects/animals from biocontainment. It also determines whether there are differences in the effects of the facility if it were in an area with lower population density than the BioSquare Research Park location.

The supplementary risk assessment contains a detailed analysis of potential health and environmental risks associated with the NEIDL. Carefully designed to be realistic and to consider input from the Boston Community, the BRP and the NRC, the risk analysis examines a series of scenarios describing the likely fates of specific pathogens that might be in involved in plausible procedural failures, containment system failures, and malevolent actions. The report also compares the potential public health consequences of biocontainment failures at the NEIDL facility in Boston, Massachusetts with two additional sites in suburban and rural locations.

To adequately respond to human health issues raised by the public, the courts, and the BRP and NRC, the RA process identifies the characteristics of a known pathogen, the events that can result in an individual's exposure to a pathogen, the likelihood that such exposure will cause an infection, the potential for an infected person to transmit the pathogen to contacts, the probable health consequences in terms of infections, and mortalitiesattributable to the pathogen. A laboratory acquired infection (LAI) is a result of laboratory related activities with a pathogen. Generally an LAI results from contact with an infectious pathogen via inhalation, ingestion, direct contact or puncture wounds from a sharp object (e.g. needle or scalpel).

An infection can also occur as a result of contact with an infectious pathogen outside the laboratory setting, i.e., if they are being transported to or from the NEIDL. In addition, an infection could be acquired from contact with an infected and infectious individual. A chain of such secondary transmissions stemming from NEIDL-related events could occur, resulting in the spread of a pathogen through the community.

The FSRA contains detailed analyses for a total of thirteen pathogens, including B. anthracis or Anthrax. These thirteen pathogens were carefully selected by the NIH after thorough consideration and considerable input from the BRP and the NRC Committee. Because they differ in their transmissibility, their mode of transmission, their pathogenicity, and their case mortality rate, they are considered to be comprehensive and representative of current and reasonably anticipated potential future scenarios. Note that Agents 2 – 6 are designated for study using BSL-3 containment, and Agents 8 -13 are designated for study using BSL-4 containment.

These thirteen pathogens are identified in Table 4-1.

Table 4-1, Pathogens Selected for Analysis

	Pathogen	Abbreviation
BSL-3	1. Bacillus anthracis (either BSL-2 or BSL-3)	B. anthracis
	2. Francisella tularensis	F. tularensis
	3. Yersinia pestis	Y. pestis
	4. 1918 H1N1 influenza virus	1918 H1N1V
	5. SARS-associated coronavirus	SARS-CoV
	6. Rift Valley fever	RVFV
	7. Andes virus (either BSL-3 or BSL-4[a])	ANDV
BSL-4	8. Ebola virus	EBOV
	9. Marburg virus	MARV
	10. Lassa virus	LASV
	11. Junin virus	JUNV
	12. Tick-borne encephalitis virus, Far Eastern sub-type, formerly known as tick-borne encephalitis complex (Russian spring-summer encephalitis virus)	TBEV-FE
	13. Nipah virus	NIPV

[a] BSL-4 is required when infecting rodent species permissive for (susceptible to) chronic infection.

Section 4.3.4 includes the Reader's Guide to the Final Supplementary Risk Assessment (Reader's Guide) in its entirety as a useful summary of the contents of the complete FSRA, which is included as Appendix 11. The Reader's Guide is not intended to provide all of the information contained in the FSRA, nor is it intended to provide the reader with an adequate or full knowledge of the detailed information included in the FSRA. It is, however, a thoughtful summary of the information contained in the FSRA. For this reason it has been included in the body of the SFEIR.

The Reader's Guide contains a history and overview of the Risk Assessment process, a definition of terms used in the document, an overview of the organization of the document, and summarizes the results of the risk assessments. In addition, it summarizes the following major findings and overall conclusions of the FSRA:

- Due to the safeguards built into the facility, the small amounts of pathogens that will be present, and the culture of biosafety and training that will be integrated into everyday practice at the NEIDL, the risk of infections resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible.
- The greatest potential risk is to laboratory workers, yet 12 of the 13 pathogens analyzed are unlikely to cause infections even to laboratory workers in the estimated 50-year lifetime of the facility.

- The risk to the public of direct infection resulting from an earthquake is beyond that reasonably expected to occur for all pathogens except Rift Valley Fever virus. Even that risk was found to be highly unlikely.
- While there are some differences in the risks for the three sites, they were small in comparison to the range of probabilities for each of the sites. Although medically vulnerable populations may be more susceptible to infections and perhaps suffer more severe consequences, the analysis did not show any significantly increased risk to these groups when analyzed as a group or individually. Environmental justice communities have been shown to not be affected disproportionately.
- Environmental persistence is possible but the long-term impact cannot be evaluated due to lack of relevant data.
- Transportation accidents are extremely unlikely to result in infections or deaths.

With the inclusion of the complete FSRA (as Appendix 11), this SFEIR contains detailed and comprehensive information pertaining to potential adverse human health effects from the accidental or malevolent release of a pathogen, or infected insects or animals from biocontainment.

4.3.5 READERS GUIDE TO THE FINAL SUPPLEMENTARY RISK ASSESSMENT

See following page.

Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories (NEIDL)

Reader's Guide

National Emerging Infectious Diseases Laboratories

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JULY 2012

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Note to the Reader

This Reader's Guide was developed by NIH as an aid to the reader. Its purpose is to provide a synopsis of the Final Supplementary Risk Assessment for the National Emerging Infectious Diseases Laboratories at Boston University. It is written to be brief and more accessible than the full risk assessment, which is more than 2,700 pages long. It is not meant to replace the risk assessment as a source of analysis and information.

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Table of Contents

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History of the Risk Assessment Process for the Boston University National Emerging Infectious Diseases Laboratories

Responsibility for protecting the health of the American people lies primarily with the Department of Health and Human Services. Within the Department, the National Institutes of Health (NIH) is the key agency for conducting and supporting biomedical research. The National Institute of Allergy and Infectious Diseases (NIAID) is the lead organization within the NIH that conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 60 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world.

Following the terrorist attacks on the United States in the fall of 2001 and the mailing of letters containing anthrax, the federal government amplified focus on funding research related to developing vaccines, diagnostics, and therapeutics against naturally occurring or deliberately released biological agents. By February 2002, NIAID had convened an expert panel composed of distinguished infectious disease scientists to provide objective guidance on the Institute's future biodefense research agenda. The expert panel determined that the capacity of Biological Safety Level (BSL)-3 and -4 laboratory space was insufficient and that this deficiency was, in fact, a barrier to progress in protecting the United States from further bioterrorist attacks.

Additionally, concerns about naturally occurring emerging and reemerging infectious disease threats heightened in the fall of 2002 when a new viral illness called Severe Acute Respiratory Syndrome (SARS) emerged. Around the same time, it became apparent that a form of avian influenza, H5N1, had moved from birds to humans and was causing illness among some people who had close contact with infected poultry. The potential for H5N1 influenza to spark a human pandemic is still being monitored closely.

Responding to these ongoing threats from new and emerging pathogens, Congress and the Administration in 2002 mandated a major expansion of research on such biological agents with an emphasis on the development of vaccines, therapeutics, and diagnostics to address these public health threats. This expansion of federally sponsored research recognized that, regardless of whether the sources of unexpected infectious disease outbreaks were natural or deliberate, the nation must be better prepared to control epidemics and protect the American public against such health threats.

As part of its response to the Congressional mandate, on September 30, 2003, NIAID awarded grant funding to 11 US academic research institutions for the construction of biocontainment facilities to enhance the nation's capability to do research on biological agents. Specifically, awards were made for the construction of nine Regional Biocontainment Laboratories (RBLs) which provide BSL-2 and BSL-3 capacity and two National Biocontainment Laboratories (NBLs) containing BSL-2, BSL-3, and BSL-4 laboratories. These comprehensive, state-of-the-art biocontainment facilities were selected through a competitive peer review process on the basis of multiple factors but primarily on the scientific and technical merit of the applicants' applications. The NBLs and RBLs were to be constructed to support

development of improved diagnostics, therapeutics, and vaccines for protecting the public from emerging and reemerging infectious diseases.

Trustees of Boston University, the Boston University Medical Campus (BUMC), received one of two NBL construction grants. The Boston University NBL, later to be named the National Emerging Infectious Diseases Laboratories (NEIDL), was proposed to be located in BioSquare, a biomedical research and business park adjacent to BUMC in Boston, Massachusetts. The NEIDL stands today as a 192,000 square foot, seven-story building that includes BSL-2, BSL-3, and BSL-4 capacities. The containment area (the specially designed areas where work with pathogens can be conducted safely) includes specialized research facilities and support spaces. In addition, the facility houses a BSL-4 training simulator to provide hands-on training for research staff, faculty, and support personnel. The NEIDL's design employs state-of-the-art technologies to enable the conduct of research in safe and secure environments.

During the design phase of the NEIDL and prior to the start of construction, both NIH and Boston University performed environmental reviews that examined the potential impacts of the NEIDL on the environment and the public. As part of the Federal Environmental Impact Statement (EIS), prepared pursuant to the National Environmental Policy Act, a risk assessment was conducted involving the theoretical release of an infectious agent from the NEIDL into the community as a result of the complete failure of containment systems in the BSL-4 laboratory. The EIS concluded that the risk to the community arising from the potential release of an infectious agent from the NEIDL was negligible. Boston University also prepared an Environmental Impact Report (EIR) as required under Massachusetts state law. The EIR was approved by the appropriate state agency.

BIOSAFETY LEVEL DESIGNATION

BSL 2: for work involving agents that pose moderate hazards to personnel and the environment

BSL 3: for work involving indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route

BSL 4: for work involving dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease

Concern was expressed by local residents of the Roxbury neighborhood and other Boston residents, who opposed the location of the NEIDL. After the EIR was approved, lawsuits were filed by local citizens in 2005 at the state level and by local citizens and public interest groups in 2006 at the federal level claiming that the environmental reviews inadequately assessed the risks that the NEIDL posed to the community. The lawsuits also alleged that the reviews failed to consider reasonable alternative locations for the NEIDL. The lawsuits raised specific questions about the most stringent high-containment laboratory within the NEIDL, designated BSL-4, which is a small component of the overall facility. A Massachusetts state court held that the state agency's approval of the state EIR was arbitrary and capricious and vacated the approval. That decision was upheld by the Supreme Judicial Court of Massachusetts.

In response to the concerns brought to the federal court by the plaintiffs and at the request of the federal judge for additional risk analyses, the NIH embarked upon what has become an unprecedented effort to perform a supplementary risk assessment to further analyze and determine what, if any, adverse human health effects would occur from an accidental or malevolent release of a pathogen from

the NEIDL. This supplementary risk assessment is also intended to address the issues raised in the state lawsuits.

In March 2008, the NIH established an expert Blue Ribbon Panel (BRP) to provide scientific and technical advice to aid the agency as it responded to the comments and concerns voiced by state and federal courts, the local community, the National Research Council (NRC) of the National Academies, and the general public regarding the construction and operation of a national biocontainment laboratory at BUMC. The BRP included 16 members with expertise in a broad range of fields, including infectious diseases and modeling of those diseases, public health and epidemiology, risk assessment, environmental justice, risk communication, bioethics, biodefense, and biosafety. The BRP has provided the NIH with independent scientific advice on the supplementary risk assessment, including questions to be addressed, possible scenarios, specific infectious agents to consider as well as guidance on processes, methods, and modeling techniques that would result in a comprehensive, sound, and credible risk analysis.

Additionally, NIH requested the services of the National Academies to reconvene the independent NRC committee involved in the review of a prior risk assessment in order to provide technical input and make recommendations regarding the characteristics of the supplementary risk assessment. Throughout the process, the NRC committee performed multiple technical reviews at key milestones and provided valuable recommendations and advice in order to help the NIH prepare a comprehensive, sound, and scientifically credible analysis.

This supplementary risk assessment contains a detailed analysis of potential health and environmental risks associated with the NEIDL. Carefully designed to be realistic and to consider input from the Boston community, the BRP, and the NRC, this analysis examines a series of scenarios describing the likely fates of specific pathogens that might be involved in plausible procedural failures, containment system failures, and malevolent actions. The report also compares the potential public health consequences of biocontainment failures at three separate, proposed sites, each with different population characteristics corresponding to urban (the current Boston site), suburban (Tyngsborough, MA), and rural (Peterborough, NH) settings. Although some of this analysis is highly technical, the goal in preparing the report was to follow objective and well established methods and to make the basis for the risk assessment findings as thorough and transparent as possible.

This companion synopsis is intended to provide an overview of the 2,717 page risk assessment as well as to highlight the key points of the methods, approach, and conclusions contained in the risk assessment.

Definition of Risk Assessment Terms and Process Overview

Definitions and Technical Issues

In order to fully understand the risk assessment, it is necessary to appreciate some technical issues that have a substantial influence on both the way the risk assessment was conducted and the results obtained.

The principles of risk assessment include transparency, clarity, consistency, and reasonableness. Every effort has been made to follow these principles throughout the risk assessment process. Existing guidance for conducting risk assessments (from such agencies as the Environmental Protection Agency and the Department of Energy) was followed throughout the risk assessment process as well. When qualitative and quantitative analyses were performed, scientifically validated peer-reviewed methods were used.

Data sources and quality: Central to the risk assessment is the data used for the analyses. To the extent possible, real data from peer-reviewed sources and real-world experience were used. For example, the risk of a 1918 H1N1 influenza outbreak in the community that might occur in the event of a loss of containment at the NEIDL was estimated based on data available from actual outbreaks of this disease. For other diseases, no appropriate studies have been published, or the diseases are so rare that data does not exist. Where such information is unavailable, estimates, reasonable assumptions, and expert opinion were used. Throughout the report, the sources of data and any data limitations are clearly indicated.

In instances where no definitive information to estimate potential risk exists, the analysis used estimates at the higher end of values that are available, which generally results in an over-estimation of risk. This is known as conservatism. However, the use of broad data estimates leads to uncertainty and impacts the precision of results. In the risk assessment, such results are generally expressed as ranges of values to account for this uncertainty. Range of values may also account for variability, where, because of random chance, the same event may yield different outcomes should that event occur a number of times. Considerable effort, therefore, was devoted in the risk assessment to understand the impact of uncertainty and variability associated with the results of the analysis.

Qualitative and quantitative analysis: The analysis of data in a risk assessment may be *quantitative*, where measurements or other numerical data are analyzed using mathematical approaches, or *qualitative*, where characteristics that are not numerical or directly countable are assessed with non-mathematical methods. For 4 of the 13 pathogens, sufficient numerical data was available, and the analyses were performed quantitatively. Qualitative analysis was also performed on these 4 pathogens as well as the other 9 pathogens for which numerical data was insufficient.

Measures of likelihood, ranges of values: An event may be possible, but knowing how likely (or probable) it is to occur is of more value when calculating or estimating risk. If an event is very unlikely, the overall risk is less. Generally, likelihood (probability) is expressed in the risk assessment in one of two ways: first, as a frequency (the number of times a specified periodic phenomenon occurs within a specified interval; for example, 0.01 per year, which is equivalent to once in 100 years), or second, in this case 100 years is known as the return period, which is an estimate of the interval of time between the occurrence of events like an earthquake or flood of a certain intensity or size. Therefore, on average the event would occur once every 100 years but could happen more or less often (next year or 99 years from now). Likelihoods are expressed this way throughout the report, or as a probability of occurring during the facility lifetime (estimated to be 50 years). Since the values are not precise, ranges are usually presented when performing risk assessments.

Exposure and risk categories: Because of the uncertainty associated with the results of the risk assessment, results are sometimes presented as categories of exposure, infection, or risk. In this risk assessment, we have identified Category A events as having a frequency range of once a year to once in a 100 years. Category B events have a frequency range of once in 100–10,000 years. Additional categories are similarly measured in increasingly longer durations. According to federal guidance, analyzing events that occur once in 10 million years or greater is considered sufficient and was applied throughout this study.

Biosafety levels: When working with infectious pathogens, specialized facilities, procedures, precautions, and practices are used that are appropriate for the potential danger associated with the particular pathogen. In the guidance *Biosafety in Microbiological and Biomedical Laboratories*, the Centers for Disease Control and Prevention and the NIH have defined the four biosafety levels and recommend facilities, procedures, precautions, and practices for each of the four levels of increasing risk. Agents with a greater potential to cause serious disease and death are studied under BSL-3 or BSL-4 conditions. The pathogens analyzed in this risk assessment are all BSL-3 and BSL-4 agents.

Dose-response curves: Dose-response is the relationship between the amount of a pathogen (the dose) received (e.g., inhaled, ingested) by an individual and how likely it is that an infection would result from the exposure (response). This relationship is typically represented by a graph curve. Ideally, risk analysis would use real-world, quantitative information from well-documented human infections to develop dose-response curves. However, for many of the pathogens included in the NEIDL risk assessment, such data does not exist because the required studies cannot ethically be performed on humans. As a substitute, data from animal studies, data from other human infectious diseases and real world events, or estimates from experts have to be used. This leads to some uncertainty, which has also been analyzed. Two sets of dose-response relationships are used in the risk assessment, the first based on information drawn from the scientific literature and the second based on advice from subject-matter experts who followed a widely used consensus approach to provide estimates. The expert opinions were used only when appropriate estimates were not available from the scientific literature, as is the case for some of these rare pathogens.

Modeling and Delphi Method: Modeling is the process of using mathematical approaches or formulas to predict the range of possible outcomes from an event. This method was used to analyze secondary infections and to estimate whether outbreaks are likely and what size they might be. In some cases, there is no human data or any way to accurately quantify probabilities using available information in the scientific literature. In those instances, a technique called the Delphi Method is used to develop estimates based on opinions from subject matter experts.

Mitigation: Many of the possible events or circumstances that might lead to release of pathogens and subsequent problems are known or predictable. Thus, a variety of precautions and steps can be taken to reduce the possible risks. This is known as mitigation. Mitigation may be accomplished through the use of specialized building design features, personnel protective equipment, personnel training, and administrative procedures. Generally, system failures or personnel failures cause events that lead to loss of containment. However, at the NEIDL filtration systems prevent release of pathogens from the

laboratories. Workers wear masks or negative-pressure suits to avoid inhaling pathogens (respiratory protection). In addition, a "culture of safety" that involves detailed, on-going training, prompt reporting of possible problems before there are adverse consequences, and shared responsibility for safety has been developed and implemented at Boston University to reduce the risk of accidents and to ensure prompt and appropriate responses to any accidents that do occur.

Risk Assessment Process

To guide the supplemental risk assessment process, the following questions were posed:

1) What could go wrong? What is the likelihood of each kind of potential incident or accident? What would the consequences be should something go wrong?
2) What are the risks to the workers at the NEIDL and to the public?
3) Would the risks be different if the NEIDL were to be located at a suburban or rural site?

A major objective of the analysis was to estimate how many primary and secondary infections and possible fatalities might occur in lab workers or in the public were any of the studied pathogens accidentally released. Primary infections result from direct exposure to a pathogen that is released during an event; secondary infections occur when a person with a primary infection transmits the disease to others. A further objective of the assessment was to evaluate the possibility that pathogens released from the NEIDL could persist in the environment. The risk assessment process is explained in further detail below.

In general, a risk assessment involves

- Identifying possible hazards;
- Analyzing their likelihood;
- Evaluating the resulting consequences should a hazard occur.

In the case of the NEIDL, where the concern is infections or fatalities resulting from loss of containment, the risk assessment process involved the following steps:

- Identify pathogens;
- Identify and analyze events;
- Estimate Initial infections;
- Assess and model secondary infections;
- Characterize risk.

Each of these steps is outlined in further detail below.

Identify pathogens: The pathogens chosen for study in the risk assessment were based on agents that are

- Expected to be studied at NEIDL;
- Of concern to the public and the courts;

- A representative sample of the range of pathogens requiring BSL-3 and BSL-4 containment.

From this step of the process, a total of 13 bacteria and viruses were selected for inclusion in the risk assessment study. They were characterized based on how likely they are to make people ill; how likely they are to be fatal; and how easily and by what means they are transmitted.

Of these 13 pathogens, 7 require BSL-3 containment (the name of the disease each causes is shown in parentheses):

- *Bacillus anthracis* (anthrax)
- *Francisella tularensis* (tularemia)
- *Yersinia pestis* (plague)
- 1918 H1N1 influenza virus (influenza)
- SARS-associated coronavirus (severe acute respiratory syndrome)
- Rift Valley fever virus (Rift Valley fever)
- Andes virus (hantavirus cardiopulmonary syndrome)

The remaining 6 pathogens require BSL-4 containment:

- Ebola virus (Ebola hemorrhagic fever)
- Marburg virus (Marburg hemorrhagic fever)
- Lassa virus (Lassa fever)
- Junin virus (Argentine hemorrhagic fever)
- Tick-borne encephalitis virus (tick-borne encephalitis)
- Nipah virus (viral encephalitis)

It is important to note that only small quantities of each pathogen will be used in studies at the NEIDL. This is a key point in determining risk because the overall risk of an infection is a function of both the characteristics of the pathogen and how much of that pathogen is present in the lab.

Identify and analyze events: Next, the risk assessment process involves identifying, selecting, and analyzing events that might cause the release of a pathogen and result in the exposure of laboratory workers or members of the public. Several hundred possible events were considered, evaluated, and grouped into categories. Events were chosen based on several factors including real world operating experience in existing BSL-3 and BSL-4 labs, knowledge of NEIDL operations, and predictions based on the nature of the work that will be conducted. From this comprehensive list of events, four event categories representing the overall range of what might possibly happen were selected for detailed analysis. The events included

- a needlestick accident in which a lab worker breaks his or her skin with a hypodermic needle or other contaminated sharp object so that a pathogen enters the body;
- a centrifuge aerosol release in which a centrifuge tube breaks and a pathogen is released into the air when the centrifuge is opened (centrifuges are commonly used in microbiology laboratories to separate materials based on their density);

- an earthquake; and
- a transportation mishap.

It is important to note that events not chosen for detailed analysis were either similar to the events listed above or were considered less likely to pose more risk relative to those chosen for further analysis. For example, a hurricane event was considered but not included in the risk assessment because it is similar to an earthquake in the structural damage it could cause to the building; furthermore, analysis shows that a severe earthquake is more likely to have greater consequences than a hurricane.

Analysis was then performed to estimate how often the chosen events would occur. These events were analyzed in situations involving both BSL-3 and BSL-4 operations. Finally, exposure could be approximated using these estimates as well as taking into account the quantities of pathogens on hand, the number of people exposed, and the amount of pathogen units (a unit is one bacterial cell or virus particle or a small clump of them).

Estimate initial infections: Not all exposures to a pathogen lead to infection and disease. Estimating the number of initial infections involves considering the type of event that led to the exposure, then estimating the amount of the pathogen a person would be exposed to following the event. Whether an infection occurs depends on several factors, including the amount of the pathogen the person was exposed to, the dose-response relationship for that pathogen, and mitigating features. Higher exposure doses are more likely to cause infection, but this relationship varies by pathogen and the circumstances of the exposure. The number of people exposed as a result of an accident can range from zero to many. However, most laboratory incidents have the potential to expose only one or a few laboratory workers. In contrast, events such as a major earthquake might result directly in initial infections in members of the public.

Assess and model secondary infections: An infected person (either a laboratory worker or member of the public) may in some cases transmit the infection to other people, leading to a secondary infection. This aspect of the risk assessment involves, first, determining whether each of the 13 pathogens can be transmitted from person-to-person, and, second—for those that are transmissible—assessing the size and scope of outbreaks that might result. In some cases, there is sufficient existing information to allow detailed quantitative mathematical modeling of transmission. In other cases, only qualitative (or descriptive) assessment is possible.

Characterize risk: This last phase of risk assessment provides a summary of the number of possible exposures, infections, and fatalities that could potentially result from each event. It also synthesizes the key findings and interprets them.

In addition, the following issues were of interest and concern to the Boston community and were considered and analyzed.

Site differences and population differences: A major concern of some members of the public is whether potential risks resulting from the operation of the NEIDL would differ significantly if the NEIDL were located in a suburban or rural area instead of in the South End of Boston. This portion of the risk

assessment considered these issues from the standpoint of population density and other population characteristics. In addition, the issue of environmental justice was analyzed. Environmental justice is defined as the fair treatment and meaningful involvement of all people regardless of race, color, sex, national origin, or income with respect to the development, implementation and enforcement of environmental laws, regulations, and policies.

Threat assessment: The risk of infections or fatalities as a result of malevolent actions is the focus of a threat assessment. Because of the sensitive nature of the analysis and its results, only the general methodology is reported in a summary contained in the risk assessment released for public comment. The results of the threat assessment were vital as a means to implement important mitigation strategies and contributed to the data for the risk assessment.

Transportation analysis: As agents are transferred to and from the NEIDL, there is the possibility of infections or fatalities resulting from transportation accidents. This part of the RA analyzed the risks associated with such transportation-related events.

Environmental persistence: This aspect of the risk assessment deals with the possible retention in the environment (in the bodies of animals or insects or in the soil, or water) of a pathogen that had escaped containment. The analysis was based on known pathogen characteristics and the features of the three sites.

Organization of the Risk Assessment

Following an introductory overview in **Chapter 1**, the RA is divided into a series of chapters that present background information and then describe in-depth the specific stages of the analysis outlined briefly above. Many chapters also have appendices that provide additional details about methods, relevant secondary information, references, and explanations about assumptions made in the analysis. This section is intended to provide the reader a "map" of the full risk assessment, so that parts of interest may be found more easily.

Chapter 2, "Facility Design, Operations, and Site Description," describes the design of the NEIDL facility, how it will be operated, and the kinds of research activities that are expected to be conducted there. This chapter includes an overview of each of the three sites, including the downtown area that surrounds the NEIDL at its urban site, as well as the alternate suburban and rural sites.

Chapter 3, "Pathogen Characteristics," discusses each of the 13 pathogens that were analyzed and provides an overview about why they were chosen for this analysis, details about their biology, and the kinds of infections that each causes. It also describes the limits of the availability of information for each of them. The material in this chapter was summarized from information published in scientific journals.

Chapter 4, "Event Sequence Analysis," explains the overall process of identifying, selecting, and analyzing risk-related events that might occur at the NEIDL. The results of the analysis are the potential consequences of various events, expressed in terms of how many lab workers or members of the public

might be exposed to one of the pathogens following an accident or the failure of equipment; also predicted is the amount of exposure in terms of units of pathogen.

Chapter 5, "Transportation Analysis," deals in detail with risks associated with shipments of pathogens to and from the NEIDL facility. A traffic accident involving these shipments, in which packages containing pathogens might be damaged, may pose a risk to the surrounding community due to the risk of exposing members of the public to infectious materials. The results describe the probability and consequences of such events.

Chapter 6, "Threat Assessment Summary," is concerned with threats to the public that originate within the NEIDL, particularly those that might stem from deliberate efforts to expose personnel at the NEIDL or members of the public to the pathogens being studied there. The chapter describes the process used to develop the threat analysis. Because of the sensitive nature of the threat assessment, only an overview of the findings is available for public review and comment. The results of the threat assessment were used in the analyses included in the risk assessment.

Chapter 7, "Potential for Released Pathogens to Become Established in the Environment," considers whether, as a result of loss of biocontainment, a pathogen could find its way into the environment and become established in the environment (in animals, insects, soil, or water). This chapter considers all 13 pathogens to evaluate whether any have potential to become established in the environments near the sites under evaluation.

Chapter 8, "Health Effects, Initial Infection," and **Chapter 9**, "Health Effects, Secondary Transmission," together examine what might happen if any of the 13 pathogens escaped biocontainment. The first of the two chapters looks at the probability of an infection or fatality occurring as a result of direct exposure from an accident in the research facility. It focuses on personnel at the laboratory who routinely work with pathogens and are, thus, at greatest risk in an accidental exposure. Also considered are accidents that could potentially lead to direct exposures of the public to the pathogens. This chapter also describes the analytic approaches taken for estimating how likely it is that a particular exposure to a pathogen, or dose, is likely to result in an infection.

Chapter 9, considers the likelihood of an initial infection (either in a laboratory worker or member of the public) subsequently being transmitted to others. This chapter also describes mathematical approaches for quantitatively assessing the likelihood of infections being transmitted from one person to others and the likely size of such outbreaks, an approach known as modeling. Mathematical modeling was applied to four pathogens for which adequate information from the published scientific literature is available. These are pathogens that can generally be spread directly from one person to another through close contact.

Chapter 10, "Environmental Justice," is concerned with the requirement for fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income in significant actions taken by the federal government. The final supplementary risk assessment must evaluate whether events associated with the NEIDL might have a disproportionate negative effect on minority or low-income populations residing near the NEIDL. In addition to minority and low-income populations,

Massachusetts also requires consideration of foreign-born populations and populations with limited English skills. The report examines in detail the populations in the vicinity of the three sites and looks at whether the inadvertent release of pathogens from the NEIDL facility would affect members of such communities in a different way than other neighboring communities.

Chapter 11, "Risk Characterization," presents key findings of the overall report. Those findings are highlighted in the next section.

Results of the Final Supplementary Risk Assessment

Chapter 11, "Risk Characterization," summarizes the results of the supplementary risk assessment and answers these questions:

1) What could go wrong? What is the likelihood of each kind of potential incident or accident? What would the consequences be should something go wrong?
2) What are the risks to the workers at the NEIDL and to the public?
3) Would the risks be different if the NEIDL were to be located at a suburban or rural site?

The majority of the results provide likelihoods for primary and secondary infections and fatalities that could occur in lab workers or the public if various events occurred.

Identify and analyze events: Approximately 300 events that could lead to loss of containment were identified, examined, and grouped initially into 30 categories of related events. Based on their likely risk, a small number was 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. The included events encompass the anticipated range of possible severe events. Selected for further analysis were a needlestick accident, a centrifuge aerosol release, an earthquake, transportation accidents, and malevolent acts. The results are estimates of the number of people who would be exposed as a result of an event and the level of exposure in terms of units of pathogen.

A variety of building design features, standard operating procedures, and training are in place at the NEIDL and other BSL-3 and BSL-4 laboratories to prevent possible system failures from occurring or to reduce their impact. This is known as mitigation. When all mitigation strategies are in place and working properly, release event frequencies are often extremely low, and/or procedures are in place to prevent exposures and consequences if they do occur. For example, reporting accidents and confining an exposed worker greatly reduces the possibility of secondary transmission. Working in a biological safety cabinet and having standard operating procedures for conducting centrifuge work substantially reduce the possibility of initial exposures due to the escape of aerosols. To examine the consequences of the most negative possible outcomes, assumptions were made that increase 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. In reality, lab personnel are trained to recognize and report needlesticks, thus mitigating the consequences should such a lab accident occur.

Similarly, the risk assessment considered what would happen if a centrifuge release went undetected and unreported.

First examined are common lab accidents that might expose lab workers. Needlestick accidents or accidents that almost result in a needlestick are common in both BSL-3 and BSL-4 laboratories, typically occurring once or more per year. However, these incidents only involve a single lab worker; the public cannot be exposed directly to pathogens this way. In addition, needlesticks are likely to be detected and reported, thus preventing secondary infections. An undetected and unreported needlestick is estimated to occur and expose the lab worker to infection about once in 100–10,000 years. An undetected or unreported needlestick has the possibility of leading to a secondary transmission of infection. Whether this worker would become infected (i.e., have enough of an exposure to get the disease) or might subsequently infect others is discussed below.

Similarly, the results of the centrifuge accident analysis show that an undetected and unreported event is likely to occur about once in 1–100 years. No scenarios were found that would result in exposure of workers in a BSL-4 lab from a centrifuge release because of the positive pressure suits they wear. BSL-3 lab workers wear respiratory protective equipment (masks or hoods that filter entering air) that greatly reduces exposure if there is a release. The results of the centrifuge accident analysis indicate that one to four laboratory workers would be exposed with exposures in the range of 0–9 units of pathogen depending on the pathogen (a unit of pathogen is one bacterial cell or virus particle, or in some cases a clump of cells or viruses), with Rift Valley fever virus giving the greatest exposures. If a worker's respiratory protection is not functioning properly, the exposure would be greater, but such a potential greater exposure would be predicted to occur less frequently, since a centrifuge accident and respiratory equipment failure would have to occur at the same time. The analyses estimate a frequency of once per 100–10,000 years for a centrifuge accident concurrently with respiratory protection failure with worker exposures in the range of 0–900 pathogen units, with again RVFV being the greatest.

At the other extreme, a very rare event, like a severe earthquake, has the potential for substantial impact. In addition, an event of this sort could expose the public directly to pathogens. Based on known seismic data for the region, an earthquake of sufficient magnitude to destroy the NEIDL building and release all of the pathogens in the BSL-3 and BSL-4 labs might occur once in 10,000–1 million years. Because a fence surrounds the building site, the closest members of the public are about 100 feet away. Depending on the pathogen, one would predict that members of the public would be exposed to no more than one unit of Rift Valley Fever virus and far less than one on average for the other pathogens. People further away would receive even less exposure. Lab workers are not likely to survive the building collapse, but any who might are assumed to be exposed to levels similar to the public. Whether any of these people would be infected or might subsequently infect others is discussed below.

Estimate initial infections: To determine whether the exposures estimated above in the event analysis would actually result in infections or fatalities, dose-response curves were developed for the 13 pathogens. These curves allow one to estimate the likelihood of infection or fatality from a given dose of pathogen. Since available data from human cases was limited, data from animal experiments and expert opinions were used; the latter was generated by a Delphi expert panel process. The Delphi process

results are presented in the risk assessment. The results from the two methods were fairly similar, considering the overall uncertainty. Lab workers who are exposed via needlestick are assumed to get infected. This is not always the case, but data to estimate the likely dose received is not readily available. Making this conservative assumption, the results show that infections would occur on average about once per 100–10,000 years for an undetected and unreported event; fatalities to laboratory workers from the 13 agents due to the same event would occur once in 200–1 million years. The large range of frequencies for fatalities are due to differences in case fatality rates for the pathogens, with Ebola and Marburg being the greatest for BSL-4 agents; *B. anthracis*, *Y. pestis*, and Andes virus being greatest for BSL-3.

Using the exposure levels and event probabilities from the event sequence analysis, the dose-response curves were used to estimate infections and fatalities in lab workers as a result of a centrifuge accident. Since no plausible BSL-4 scenario could be identified that produced an exposure from a centrifuge accident, only BSL-3 pathogens were studied. In general, predicted exposures were in the lower range of the dose-response curves where the uncertainty is greatest. As a consequnce, the results include a wide range of values. The results for the seven BSL-3 pathogens show that the probability of one worker being infected ranges from once in 100–10,000 years for an event that is undetected and unreported. The large variation is due to differences in the amounts of the various pathogens expected to be on hand as well as differences in the amount of pathogen units that is needed to cause an infection. Rift Valley Fever Virus and *F. tularensis* had the greatest infection and fatality rates due to their low infectious doses. The range for fatalities was once per 5,000–2 million years. Some agents with high fatality rates were not as likely to cause fatalities because of the large infectious dose needed and thus produce a low number of estimated infections.

These results are consistent with real-world experience about laboratory-associated infections that show few infections or fatalities. Infections or fatalities resulting from an earthquake were not analyzed separately for lab workers. They are discussed in the results section relating to risk to the public.

The only event included in this risk assessment that can directly expose the public to infection is an earthquake. The probability of an infection for 12 of the 13 pathogens as a result of a severe earthquake was less than once in 10 million years or more. For Rift Valley Fever virus, the probability is in the range of once per 10,000–1 million years, which is due to the very low probability of such an event occurring and the very low exposures even for those members of the public closest to the building. Since the likelihood of initial infections is so low, the risk of secondary transmission is even lower, which is beyond what might reasonably be expected to occur. Of particular note is that this analysis only evaluated the likelihood of direct exposure and infection due to an earthquake and did not consider the potential injuries, trauma, and fatalities from the earthquake itself, which are likely to be more substantial.

Assess and model secondary infections: If an infected lab worker or infected member of the public interacts with other people, there is the possibility of secondary infections, and a number of additional infections or fatalities may occur. Most important in determining what could happen is whether the pathogen is transmissible from person-to-person. If it is, the probability and the number of secondary infections is dependent on several factors, including the number of additional people that an initially

infected person typically infects, how many contacts an infected person makes with other people, and the effect of instituting mitigating procedures like vaccines, drugs, and isolation. Information from the scientific literature about previous human infections and other relevant information were used to assess this outcome. Four pathogens had enough scientifically vetted, detailed information to model quantitatively. Secondary transmission was not analyzed separately for laboratory workers and others. For analyzing secondary infections, laboratory workers were considered members of the public.

All 13 pathogens were analyzed in a qualitative manner. Of the 13 pathogens, *B. anthracis, F. tularensis*, Rift Valley fever virus, and tick-borne encephalitis are not transmissible, so no further analysis was done. Andes, Lassa, Nipah and Junin viruses are probably transmissible, but available information suggests a low probability of transmission and, therefore, a low probability of secondary infections or fatalities. Modeling was not performed since existing data for these pathogens is very limited. Marburg virus is very similar to Ebola, so it was not analyzed separately. *Y. pestis*, SARS, 1918 H1N1 influenza, and Ebola were modeled quantitatively. Quantitative modeling consists of taking known information about the pathogen and its characteristics related to its transmission, and applying mathematical formulas to the data that can estimate the nature of transmission and possible outbreaks. The results of the analysis allow determination of several kinds of estimates, including 1) the probability of one or more subsequent infections resulting from an initial infection, and 2) the probability of outbreaks of various sizes, for example 10, 100, or 1,000 secondary infections. In addition, modeling results provide estimates of the uncertainty. For example, the probability of one or more secondary infections might be on average 1 in 500 years, but the range (resulting from uncertainty) might be 1 in 150–2,000 years.

The results for a *Y. pestis* exposure via a needlestick event show that the probability of one or more infections is in the range of once in 100–10,000 years; the probability of a fatality falls in the same range. The results for larger outbreaks, such as 10 cases, are between 1 in 10,000–1 million years. Larger outbreaks with of plague caused by *Y. pestis* are even less likely. Similar analyses were done for SARS, 1918 H1N1 influenza, and Ebola.

The results for SARS and Ebola are similar to plague and indicate that one to a few cases might possibly occur, but not likely over the anticipated lifetime of the facility (50 years). Larger outbreaks are unlikely even over 1 million years.

The results for 1918 H1N1 influenza are different and show higher probabilities for more infections, due to the fact that an infected person is more likely to infect many others. For influenza, the estimate for one or more infections is between 1 in 100–10,000 years. An outbreak of more than 1,000 cases might happen once in 10,000–1 million years. The risk to the public from centrifuge accidents is similar to that of needlesticks, so this event was not analyzed separately. The risk from an earthquake is beyond what might be expected even in 1 million years.

Transportation analysis: Shipments of pathogens into and out of the NEIDL are handled according to detailed Department of Transportation regulations with additional precautions specified by Boston University. Shipments arrive at the lab by truck from the sender's location or by truck after air shipment to Logan International Airport. The pathogens are encased in multiple layers of containers and

packaging to prevent release under virtually all conditions. The results of the analysis show that a truck accident that is sufficient to breach the packaging and release pathogens into the vicinity of the accident would occur rarely, certainly no more often than an accident that would cause fatalities to the occupants of the truck. A transportation related accident resulting in the breach of containment is estimated to occur less than once in 1 million years based on known transportation accident data. A similar analysis involving airplane crashes yielded similar results. The analysis determined that crash-related injuries and fatalities are more likely than public exposure to infectious pathogens. Finally, the risk from transportation accidents is less than that from an earthquake.

Environmental persistence: The possibility that pathogens might be released into the environment and remain there in an infectious form was examined. Based on known characteristics of the 13 pathogens, the analysis suggests that it is reasonable to conclude that five of the pathogens could possibly become established in animals, insects, or soil in the vicinity of the lab. These are *F. tularensis, Y. pestis*, 1918 H1N1 influenza, Rift Valley Fever virus, and tick-borne encephalitis virus. One, *F. tularensis,* occurs in the United States and may already be present in some areas near the proposed sites since cases of tularemia have been known occur in Massachusetts over the years. Whether the persistence of these pathogens in the environment would ever result in infections or other consequences cannot be determined due to lack of appropriate data.

Site differences: There are no differences in the risks of infections or fatalities to lab workers at the three different sites because the lab and its operations would be the same at all three sites and similar potential accidents are possible. 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, in most cases analyzed, there are slightly smaller risks at the suburban and rural sites (Peterborough and Tyngsborough) compared to the urban site (Boston). However, these differences are considered minimal, and the ranges of values in the estimates for the three sites overlap considerably.

Medically Vulnerable Populations and Environmental Justice: The risk assessment analyzed the potential impacts of the NEIDL's operation on environmental justice communities and medically vulnerable populations at each of the three sites.

The urban site (Boston), where the NEIDL is located, contains an environmental justice community in its vicinity. This community is defined as an environmental justice area due to the fact that it contains more than a 25% minority population. The suburban and rural sites do not contain any environmental justice communities. Nonetheless, the environmental justice community surrounding the NEIDL will not experience any disproportionate impacts from the operation of the NEIDL because the impacts on the three sites are very similar.

For the purposes of this risk assessment, medically vulnerable populations were defined as those individuals who are

- very young

- elderly
- asthmatic
- HIV positive or have AIDS
- diabetic

Full consideration was given to the possibility that medically vulnerable populations may be more susceptible to infections and could suffer more severe consequences, but the analysis did not show any significantly increased risk to these groups when analyzed as a group or individually.

Final Supplementary Risk Assessment: Major Findings and Overall Conclusions

Major findings

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 harm from disease-causing microbes that will be studied in the NEIDL. While there is no such thing as "no risk," the results of this analysis show that the risk of infections or deaths resulting from accidents or malevolent acts at the NEIDL are generally very low to only remotely possible. While evaluation of the NEIDL and proposed activities in it make up the bulk of the assessment, analyses were also conducted examining different geographic locations as well the impact to site-specific populations.

The greatest potential risk identified in the analysis is to the people conducting research in the laboratories. Laboratory workers have a risk of infection and potential fatalities, particularly with pathogens that can cause infection with a small number of pathogen units. Infections caused by 12 of the 13 pathogens are unlikely to occur in the lifetime of the facility (estimated to be 50 years), only Rift Valley Fever Virus infection has a reasonable chance of causing infection in a lab worker.

The risk to the public of direct infection resulting from an earthquake is beyond that reasonably expected to occur for all pathogens except Rift Valley Fever virus. Even that risk was found to be highly unlikely. The risk to the public is from secondary infections with a few agents. The probability of small outbreaks of one to a few infections or fatalities is unlikely in the facility lifetime, and large outbreaks (more than 100 infections) are beyond reasonably expected (unlikely in 1 million years) except for 1918 H1N1 influenza. Even for influenza, the probability of a large outbreak is only once in 100–10,000 years.

While there are some differences in the risks for the three different sites, they were small in comparison to the range of probabilities for each of the sites. Although medically vulnerable populations may be more susceptible to infections and perhaps suffer more severe consequences, the analysis did not show any significantly increased risk to these groups when analyzed as a group or individually. Environmental justice communities have been shown to not be affected disproportionately.

Environmental persistence is possible but the long-term impact cannot be evaluated due to lack of relevant data.

Transportation accidents are extremely unlikely to result in infections or deaths.

Overall Conclusions of the Final Supplementary Risk Assessment

This 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 being 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. The greatest risk is to individuals conducting research in the building. The risk to the general public is extremely low, or beyond reasonably foreseeable, with the exception of secondary infections involving 1918 H1N1 influenza and SARS. Infections from a release of 1918 H1N1 influenza or SARS might occur over 500–5,000 years of operation, far beyond the facility lifetime of 50 years.

Chapter 5

MITIGATION MEASURES

5.0 MITIGATION MEASURES

The MEPA Certificate on the Final EIR for the BioSquare Phase II project included a number of mitigation measures required for the full development of the Project. This chapter contains a report on the status of these measures and an introduction to the biosafety and biocontainment measures that are incorporated in the NEIDL facility and serve as mitigation. As described in Section 5.2 and 5.3, biosafety at the NEIDL is addressed through both innovative facility design and rigorous standards for operating procedures. This chapter also describes the extensive community outreach efforts undertaken by the Proponent.

5.1 MITIGATION MEASURES IDENTIFIED IN THE FINAL ENVIRONMENTAL IMPACT REPORT

The MEPA Certificate on the Final EIR for the BioSquare Phase II project included the following mitigation measures associated with the full development of the Project. Below is a summary of the current status of the mitigation measures in place following the completion of the NEIDL and Parking Garage elements of the Biosquare Phase II development program. Note that Building G, a 235,000 sf medical research building, and the highway access point onto Frontage Road have not yet been constructed.

- **Provide 4:1 Infiltration and Inflow (I/I) removal program (approximately $480,000);**
  Boston University has elected to perform I/I removal at various locations throughout its campuses. The original discharges flows projected for the NEIDL have been revised based on more detailed analysis as part of the MWRA permit application process. The laboratory flows are now estimated at 25,000 gpd at full occupancy. At a 4:1 rate, 100,000 gallons of I/I removal is required to offset the NEIDL discharge. To date 120,000 gallons of I/I removal has been completed and another 50,000 gallons is underway. The excess I/I removal above that required for the NEIDL will be applied to future construction projects undertaken by Boston University.

- **Create a pocket park along Albany Street (approximately $246,000);**
  This park was completed as part of the NEIDL construction.

- **Modify the East Newton Street/Albany Street intersection as a four-way intersection (approximately $100,000 to $200, 000);**
  This intersection improvement has been completed.

- **Provide traffic and parking management plan for Albany Street between East Newton Street and Union Park Street;**
  This work will be completed in cooperation with BTD as part of the MDOT highway access permit which has not yet been approved.

- **Rebuild Albany Street sidewalks and provide pavement markings along Albany Street including lane striping and crosswalks (approximately $35,000 to $60,000);**
  This work was completed as part of the NEIDL construction.

- **Install fiber optic cables along Albany Street (approximately $20,000-25,000),**
  Conduit has been installed from East Canton Street to East Concord Street for BTD's use.

- **Provide the City of Boston with up to two variable message boards for real time traffic information (approximately $52,000);**
  This work will be completed as part of the MDOT highway access approval, which has not yet been issued.

- **Install directional signage at site (approximately $25,000);**
  This work was completed as part of the NIEDL construction.

- **Institute a Transportation Demand Management (TDM) Program that includes membership in Transportation Solutions for Commuters (TMA)**
  The University has adopted a Transportation Management Program and is an active participant in the TMA.

- **Provide a transit pass subsidy program (25 percent) for Boston Medical Center employees;**
  BMC employees currently receive the transit pass subsidy.

- **Provide a ridesharing program, preferential parking, a guaranteed ride home, direct-deposit payrolls, shuttle bus service to Orange and Red Lines, Zipcar, and flextime and telecommuting as part of its TDM program**
  The above measures are included in the BU TDM plan.

- **Provide safe and secure bicycle storage areas (up to 140 bicycles in the parking garage and around the site) (approximately $20,000) and shower facilities for employees;**

  There are secure parking spaces for approximately 24 bicycles in the BioSquare Research Park parking garage (610 Albany Street). There are an additional 132 spaces across the street at the Dental School and an additional 38 spaces at the 710 Albany Street garage, a block away. In total the BU campus has 382 bicycle parking spaces. The NEIDL building provides shower facilities for employees. Due to security concerns, bicycle parking is not provided within the building. Additional bicycle parking will be developed as demand increases.

5.2 NEIDL MITIGATION MEASURES IDENTIFIED IN THE FINAL SUPPLEMENTARY RISK ASSESSMENT (FSRA)

5.2.1 PRINCIPLES OF BIOSAFETY

As described in the FSRA, the most fundamental safety barrier for the public at the NEIDL is the high biocontainment laboratory itself. The fundamental objective of any biosafety program is the biocontainment (i.e. safe handling and containment) of hazardous biological material. Biocontainment are microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment and the public from exposure to infectious microorganisms that are handled and stored in the laboratory. One way to eliminate and/or mitigate hazards is through the development of effective controls; at the NEIDL these controls include, but are not limited to these basic principles of biosafety:

- Developing training to enhance the understanding and awareness of the hazards
- Providing clear Standard Operating Procedures (SOP)s for operational safety
- Providing suitable and appropriate alarms and warnings
- Restoring the system to the safe condition in an off-normal event
- Establishing safety barriers to defeat the hazards; and
- Containing the hazards if the barriers fail.

These principles of biosafety are described in Sections 5.2.2 through 5.3.5.

5.2.2 FACILITY AND SITE DESIGN

The NEIDL facility has been designed and is and will be operated in full compliance with the guidelines established in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition (CDC and NIH 2007). As described in the BMBL 5th Edition, "....BMBL has become the code of practice for biosafety. These principles are [bio] containment and Risk Assessment (RA). The fundamentals of [bio] containment include the microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms that are handled and stored in the laboratory."

The NEIDL facility is a steel-reinforced concrete building designed to provide an extra level of safety and redundancy. The design and construction of the facility contributes to the laboratory workers' protection, provides a barrier to protect persons outside the laboratory, and protects persons or animals in the community from infectious agents that may be accidentally released from the laboratory. To this end, the NEIDL is designed in accordance with the Level 5 NIH Security Guidelines, the most stringent and protective measures defined in the BMBL guidelines. Laboratory directors are responsible for providing facilities commensurate with the laboratory's function and the recommended biosafety level for the agents being manipulated. The NEIDL facility has been designed to meet or exceed the Massachusetts State Building code.

The most fundamental safety barrier for the public at the NEIDL is the high biocontainment laboratory. The BSL-4 core laboratory space incorporates technologically advanced scientific equipment for the infectious disease research in a high biocontainment environment. The BSL-4 laboratory barrier is based on the "box within a box" concept. Biosafety is also ensured through the facility layout, whereby the highest BSL research is contained in interior spaces to protect against and lower the likelihood of an aircraft crash or another external event from penetrating the containment areas. Research at each containment level is confined to its own floor, allowing for laboratory spaces and air flow systems to be segregated as necessary to avoid cross contamination.

All critical building systems within the NEIDL are redundant to ensure safety and uninterrupted operations at all containment levels. This is commonly

referred to as N+1, indicating that each critical system has at least one redundant system as a back-up.

The Final Supplementary Risk Assessment (Appendix 11) includes an exhaustive description of the design features of the NEIDL facility that serve to reduce the potential impacts from natural hazards and accidental or malevolent human acts.

5.2.3 LABORATORY DESIGN

The engineering controls and safety equipment within each laboratory constitute the primary barriers designed to remove or minimize exposures to hazardous biological materials. This section provides an overview of those design features.

The laboratory spaces are designed with redundant building controls, support systems and building control systems. The BSL-4 laboratory spaces are located within the interior areas of the building to provide added protection against outside events, such as an aircraft crash or malevolent act breaching the laboratory containment system.

HVAC Systems

Each laboratory floor has separate heating, ventilation and air conditioning systems with multiple air handling systems to avoid any cross contamination. The BSL-3 and BSL-4 laboratories' air handling units are equipped with High Efficiency Particulate Air (HEPA) filters which remove at least 99.97 percent of particles. At the BSL4 level, incoming laboratory air supply is routed through a HEPA filter and laboratory exhaust is routed through two redundant HEPA filters to ensure complete removal of airborne respirable particles.

Negative Air Pressure

BSL-4 laboratories are isolated from the rest of the building spaces through a series of interlocked air lock doors that allow only one door to be opened at a time to ensure a proper seal. The laboratory spaces have a lower air pressure than surrounding rooms so that when air lock doors are opened, air flow only into the laboratory and is exhausted out through the double HEPA filters.

Biosafety Cabinets

The biological safety cabinet (BSC) is the primary device used to contain infectious droplets or aerosols generated by many microbiological procedures. Open-fronted Class I and Class II BSCs are primary barriers that offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The Class II biological safety cabinet also provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet. The gas-tight Class III biological safety cabinet provides the highest attainable level of protection to personnel and the environment. Table 5-1 contains information about the relationship between BSLs and BSCs.

Safety Centrifuge Cup

An example of another primary barrier is the safety centrifuge cup, an enclosed container designed to prevent aerosols from being released during centrifugation. To minimize aerosol hazards, containment controls such as BSCs or centrifuge cups must be used when handling infectious agents.

Redundant Infrastructure Systems

The NEIDL building is served by redundant infrastructure support systems to minimize the risk of outages affecting laboratory operations from outside sources. The building is supplied by a looped water service that will allow water service into the building from two directions. There is a dual feed electrical supply, with emergency backup generators capable of supplying all critical building functions in the event of a loss of power, including the Building automation system.

Personal Protective Equipment

Safety equipment also may include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Personal protective equipment is often used in combination with BSCs and other devices that contain the agents, animals, or materials being handled. In some situations in which it is impractical to work in BSCs, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility. In

BSL4 laboratories, positive pressure suits are mandatory so that should there be a puncture, clean air flows out into the laboratory rather than into the protective suit.

5.2.4 SECURITY FEATURES

Security features which have been incorporated into the NEIDL facility include, but are not limited to, the following:

- Video Cameras
- Perimeter Fencing and Vehicle Barriers
- Retina Scanners
- Alarm Systems
- Building Control Systems

5.2.5 CULTURE OF SAFETY

In addition to the features described above, BU has developed and implemented policies that inculcate a "culture of safety". This includes detailed, on-going training, prompt reporting of possible problems before there are adverse consequences, and shared responsibility for safety to ensure prompt and appropriate responses to any accidents that do occur.

In March 2010, the Associate Vice President for Research Compliance (AVPRC) appointed a Task Force on Biosafety to review the safety programs at Boston University and to make recommendations for improving the culture of safety at Boston University. The Task Force made additional recommendations in a NEIDL–Specific Addendum, establishing more stringent criteria at the NEIDL with enhanced monitoring and safety requirements. While the details included in the 39-page report are too extensive to summarize in this document, key recommendations were targeted toward enhancements in programmatic areas that include:

- Active adoption of a *culture of safety* as a core value at every level
- Inclusion of a commitment to safety as a condition of employment for all those engaged in research as a key factor in annual Performance Appraisals

- Written confirmation by all individuals engaged in research that they have been adequately trained and that they will follow the safety requirements

- New procedures for the temporary or permanent removal of the laboratory and research privileges of individuals who violate health and safety requirements

- Clear indication that, while safety is a shared responsibility of each individual working in a laboratory, ultimately, Principal Investigators bear full responsibility for safety in their laboratories

- Appointment of a Laboratory Safety Coordinator who is specifically responsible for implementing day to day safety requirements in the laboratory

- Enhancements in the operation of the Institutional Biosafety Committee (IBC) operations and its membership to ensure expertise and support for all applications for work that could be reviewed

- Appointment of a Chief Safety Officer at the NEIDL with full oversight responsibility on all safety aspects of the NEIDL and with the authority to halt any operations that are judged to present a health and safety hazard, or are in violation of regulatory or policy requirements

- Appointment of a NEIDL Safety Committee with a specific charge for the review of all aspects of safety at the NEIDL

- Recruitment of a communication specialist to assist in developing campus wide and NEIDL-specific culture of safety communication plans

5.3 OPERATIONAL AND RESEARCH SAFETY AT THE NEIDL

In addition to the physical design features of the site, facility, and laboratories, rigorous observance of a number of standard operating procedures for safety, security and operations is in place to minimize risks and protect NEIDL researchers and the community from contact with infectious pathogens. As with the physical design features, these procedures have been established according to the standards in BMBL, with critical oversight provided by the Boston Public Health Commission and the Centers for Disease Control and Prevention.

5.3.1 OPERATING PROTOCOLS

BU Biosafety Manual

The BU Biosafety Manual (BUMC 2008 revised May 2012) defines and communicates the biological safety policies and procedures pertaining to BU and Boston Medical Center. BU principal investigators and laboratory workers must adhere to the biological safety policies and procedures as they conduct their research and manage laboratories. The complete BU Biosafety Manual can be found on the NEIDL Website: www.bu.edu/neidl.

A fundamental objective of any biosafety program is the containment of potentially harmful biological agents. The term "containment" is used in describing safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The use of vaccines may provide an increased level of personal protection. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements.

Biosafety Levels (BSLs)

The four BSLs, described in Chapter 2, consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. For a description of the four BSLs, see Table 5-1, Summary Table of Biosafety Laboratory Levels.

The BSLs described in this SFEIR should be differentiated from Risk Groups, as described in the NIH Guidelines and the World Health Organization Laboratory Biosafety Manual. Risk groups are the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans. The risk group of an agent should be one factor considered in association with mode of transmission, procedural protocols, experience of staff, and other factors in determining the BSL in which the work will be conducted. Risk groups are described in detail in the FSRA, which is included as Appendix 11.

Table 5-1: Summary Table of Biosafety Laboratory Levels

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
BSL-1	Agents not known to consistently cause disease in immunocompetent adult humans	Good microbiological practice; hand washing; and no eating, drinking or gum chewing in the laboratory	Pipeting devices-–mouth pipeting is prohibited	Open bench-top sink for hand washing is required
BSL-2	Agents that pose moderate hazards to personnel and the environment	BSL-1 practice plus specific training and supervision; limited access; most work may be performed on a bench top; biohazard warning signs; Sharp precautions; and biosafety manual defining any needed waste decontamination or medical surveillance policies	Class I or II Biological Safety Cabinets (BSC) or other physical containment devices and lab coats, gloves and face protection, as needed	Open bench-top sink for hand washing is required and autoclave or another approved decontamination procedure is available
BSL-3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus controlled access; decontamination of all wastes; and decontamination of lab clothing before laundering	Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices; protective lab clothing, gloves and respiratory protection as needed	BSL-2 plus physical separation from access corridors; self-closing, double-door access; no recirculation of exhaust air; negative airflow into laboratory and design includes backup/redundant systems
BSL-4	Dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that frequently results in mortalities, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission	BSL-3 practices plus clothing change before entering; shower on exit; and all material decontaminated on exit from facility	All procedures conducted in Class Ill BSCs or Class I or II BSCs in combination with full-body air-supplied positive-pressure personnel suit	BSL-3 plus separate building or isolated zone; dedicated supply and exhaust, vacuum, and decontamination systems; design includes back-up/redundant systems

Source: U.S. Department of Health and Human Services, 2004.

5.3.2 LABORATORY PRACTICES AND TECHNIQUES

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging the appropriate training of personnel.

Each laboratory will develop or adopt a biosafety or operations manual that identifies the hazards that will or may be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards. Personnel should be advised of special hazards and should be required to read and follow the required practices and procedures. A scientist, trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents must be responsible for the conduct of work with any infectious agents or materials. This individual should consult with biosafety or other health and safety professionals with regard to risk assessment.

When standard laboratory practices are not sufficient to control the hazards associated with a particular agent or laboratory procedure, additional measures may be needed. The laboratory director is responsible for selecting additional safety practices, which must be in keeping with the hazards associated with the agent or procedure.

Appropriate facility design and engineering features, safety equipment, and management practices must supplement laboratory personnel, safety practices, and techniques.

5.3.3 PERSONNEL TRAINING

Workers are the first line of defense for protecting themselves, coworkers, and the public from exposure to hazardous pathogens. Protection depends on an awareness of the hazard and a well-established protocol to operate safely. Humans are fallible, and mistakes have the potential to compromise any of the safeguards of the laboratory. For those reasons, it is critical that technical proficiency in using good microbiological practices, safety equipment, and emergency response are continuously trained, tested, emphasized, and enforced. In addition, a program of continuous improvement strengthens the biosafety program by constantly evaluating risk

and Standard Operating Procedures (SOPs) and work practices for areas requiring improvement.

5.3.4 RESEARCH APPROVAL PROCESS: INSTITUTIONAL BIOSAFETY COMMITTEE

Background

The Institutional Biosafety Committee (IBC) at Boston University (BU) is mandated through regulations, standards and policies to have oversight responsibilities and review of research work involving biological materials. These materials include:

- Recombinant DNA
- Infectious agents including, Biological Select Agents and Toxins (BSAT)
- Human materials including blood, bodily fluids, unfixed organs, tissues, cells and cell lines
- Materials of non-human primate origin including, bodily fluids, unfixed organs, tissues, cells and cell lines
- Creation or use of certain transgenic animals and plants
- Human gene transfer clinical trials
- Animal studies and use in research which may have the potential for zoonotics such as sheep and tissues derived from them due to potential for infections to *Coxiella burnetii,* which is the causative agent of Q-fever
- Studies of wild animals and certain vectors in the field that are known, or may carry zoonotic diseases (e.g., bats, raccoons, etc.)

IBC includes two voting public members that are not affiliated with Boston University. Minutes of the BU-IBC, which include the deliberation of the Committee, are posted publicly on the IBC website: http://www.bu.edu/orccommittees/ibc/

IBC Coordinated Review

Research and laboratory work at BU may involve materials and processes that also require oversight, review and approval by other technical committees. The IBC coordinates its review of biological and other materials in its purview together with the other technical committees. For a

visualization of this process, see Figure 5-1, NEIDL Research Project Approval Process.

Institutional Animal Care and Use Committee (IACUC)

According to federal regulations, the IACUC is responsible and has oversight for the use of laboratory animals in research. The BU IACUC has established policies and standards to regulate the use of laboratory animals for research or instructional purposes and to ensure that the use and treatment of the animals conform to the regulations and that they are given the proper care and handling required.

When biological materials such as infectious agents or recombinant DNA are used in conjunction with animals, the BU IBC and IACUC coordinate their review and approval of the research proposal. This process ensures that all the necessary measures are taken and in place, including but not limited to: the appropriate level for animal containment housing; required practices and procedures; appropriate personal protective equipment; required safety equipment; appropriate training; personnel medical clearance and participation in medical surveillance program, etc.

Note: BU Animal Care and use program is fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), an independent international accrediting body.

Institutional Review Board (IRB)

In accordance to federal regulations and requirements, the BU IRB is designated and has oversight over the human subject protection. The IRB is responsible for the review, approval and monitoring of biomedical and behavioral research involving humans.

The BU IBC and IRB coordinate their review and approval of research proposals involving materials from human patients such as blood, tissue, etc. This process ensures that all the necessary steps and permissions required are taken and in put in place before starting the study.

Laboratory Safety Committee (LSC)

The LSC at BU has oversight of chemical safety practices, review and approval of the Chemical Hygiene Plan (CHP) and development and review of policies involving highly hazardous chemicals. The IBC works with LSC and Environmental Health and Safety (EHS) in reviewing biological research proposals with intended use of highly hazardous chemicals.

Who Needs Approval

Principal Investigators (PIs) at BU proposing to carry out research using recombinant DNA and/or biologically hazardous materials that pose a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment submits a registration application entitled "Biological Use Authorization" (BUA) to the IBC for review and approval.

Note: The Boston Public Health Commission (BPHC) requires that all work with recombinant DNA, including those that are considered exempt by the NIH Guidelines for Research Involving Recombinant DNA Molecules, must be registered with the commission. BU requires the registration and review by IBC of all work with recombinant DNA including those that are considered exempt under NIH guidelines.

Researchers using any of the above identified biological materials that fall under the IBC oversight must submit an application for Biological Use Authorization" for review and approval.

Types of Application

New Applications

A new "Biological Use Authorization" must be submitted and reviewed by the IBC for any research using rDNA and/or biologically hazardous materials. PIs seeking IBC approval for the first time submits a copy of their curriculum vitae (CV) with their application. An application for both rDNA and biohazardous work may be submitted via the Research Information Management System (RIMS). This online system may be accessed from the IBC website at http://www.bu.edu/orccommittees/ibc/approval-process/.

IBC approval of recombinant DNA and biohazardous research projects is effective for three years. PI must complete a renewal form annually to continue work for up to three years after the initial approval. After three years, the application must be resubmitted and reviewed by the committee.

Annual Updates

A request for update notice is sent to the PI listed on the original approval every year for three years to ensure that all information regarding the approved protocol is up-to-date after the initial approval of a protocol. The PI is asked to list all proposed minor deviations from the protocol as initially approved (or since the last renewal notice).

If there are significant deviations from the protocol, the IBC may ask the PI to seek an additional approval to cover the additional experiments. This could be done through an amendment.

Renewals

A renewal notice serves as a mechanism for the PI to provide an annual update and this form is sent to the PI listed on the original approval the first and second year after initial approval of a protocol. The PI is asked to list all proposed deviations from the protocol as initially approved (or since the last renewal notice); changes in laboratory location; changes in laboratory staff working on the project; and any project titles to be added.

Amendments

If there are significant deviations from the protocol, especially deviations that affect the containment level (i.e., new study organisms, a new host-vector-donor system, or any other modifications that may affect the containment level), the IBC may ask the PI to seek an additional approval to cover the additional experiments.

When a project is renewed as part of the annual update process, all new lab staff must submit either an Initial Health Questionnaire or an Annual Health Questionnaire (Initial, if no prior baseline medical history on record) to Research Occupational Health Program (ROHP) and complete lab safety training. For changes in PIs, the new PI must attach his or her CV (two-page NIH format) to the renewal form.

Amendments must be submitted in electronic or hard copy form for changes within an approved project. All changes should be detailed in the "Protocol Amendment" form, which the IBC must review and approve.

Expedited review approval may be applied to several different amendment requests, including:

- Title change, but all research grant titles must be registered with the IBC. If the grant title changes, IBC may review the request as an expedited review.
- Lab space additions approval applies only to work performed in registered lab space.
- For non-PI personnel changes, individuals must be trained in lab techniques and have complied with necessary trainings or approval procedures, such as medical surveillance and lab safety training.

If technical changes (full committee review) are extensive, the IBC may require the PI to submit a completely new application. A change in PI also requires full committee review. The new PI must attach his or her CV (two-page NIH format) to the amendment.

Review Process

Once submitted to the IBC all applications are reviewed by administrative staff for completeness to ensure that all relevant sections of the applications have been completed and necessary documentation has been provided.

After the administrative review the application is assigned for two tier review:

- Two members of the IBC, who are referred to as the primary and secondary reviewers are assigned for an-depth review of the protocol. The reviewers are selected based on the nature of the proposed research and expertise of the members. While members of the IBC review and discuss the protocols at the monthly convened meeting of the IBC; the primary and secondary reviewers conduct an in-depth review of the research (e.g. scientific relevance and its appropriateness, techniques used, adequacy of experimental procedures, etc.) and present a summary of the proposed research and their commentary at the meeting.
- Environmental Health and Safety (EHS) is assigned the protocol for a safety risk assessment. This assessment is conducted by an EHS staff member familiar with the operations of the laboratory and includes a thorough review of the laboratory, existence of detailed operating procedures, safety record, adherence to protective measures, use of proper personal protective equipment (PPE) completion of training, decontamination methods, waste management, safety equipment and engineering controls, quality assurance program, emergency response procedures, enrollment in the medical surveillance program, etc. The findings of the review are submitted in writing to the IBC for their review during the convened meeting.

Description of IBC Protocol Review Outcomes

After the IBC discussion of the protocol the committee votes on the outcome of the discussions which may be one of the following:

<u>Approved</u>

A protocol that receives full approval requires no (additional) changes or clarifications to comply with Committee policies. Work may commence immediately upon full approval of a protocol. Approval is valid for the study as described in the protocol form for a period of three years from the approval date. PI's must complete a renewal form annually after the first and second year after initial approval.

The Boston Public Health Commission (BPHC) requires notification and submission upon IBC approval, of any new BSL-3 project. The project is reviewed and approved by BPHC at least thirty (30) days upon submittal pursuant to section 2.04.b of the *"Boston Public Health Commission Regulation Biological Laboratory Regulations"*. The research cannot start before the BPHC approval is granted.

Approved Pending

The granting of 'approval pending' is used when a protocol requires some relatively minor changes (e.g. additional training mandated by the IBC, additional equipment, etc.) to bring the protocol into compliance with Committee policies but does not need to be re-reviewed by the full committee. The PI must respond in writing to the particular issues and these may be administratively modified or reviewed by the designated reviewers or the Chair before final approval is granted.

Conditionally Approved

The Committee votes for a 'conditional approval'; when minor changes or clarifications are required to bring the protocol into compliance with Committee policies. The investigator must respond in writing to the Committee's notice of conditional approval. The response will be reviewed by the primary reviewer of the protocol. If no response is received within 60 days from the date of the conditional approval letter, the protocol is closed.

Tabled

The Committee votes to 'table' a protocol when numerous and/or major changes or clarifications are required to bring the protocol into compliance with Committee policies. A 'tabled' protocol will need to be entirely re-written by the Principal Investigator. The modified protocol will be reviewed at the next regular Committee meeting.

Rejected

A protocol may be rejected by the Committee if it contains serious violations of Committee policy and/or if repeated attempts to bring the protocol in compliance with Committee policy have failed.

Deferred
A protocol may be deferred when there is insufficient time at the IBC meeting to conduct review of the item.

Additional Approvals

Depending on the nature of the proposed research, in addition to the IBC approval, additional CDC and BPHC approvals are required.

Select Agent Approval/Registration
If the research involves a Biological Select Agents or Toxins (BSAT), as defined by the CDC for certain BSL-3 agents and all BSL-4 agents, the PI must obtain approval from the University Responsible Official (RO) for Select Agent Programs, in addition to the IBC approval, before any work can proceed. The additional approval requirement by the Boston University Responsible Official is to ensure that the researcher has appropriate space allocation for the proposed research and has met all training, occupational health and other regulatory requirements. If the BSAT, or individuals who plan to work with it, are not registered, then an additional application is submitted to the CDC for the approval of the agent and the individual. This approval requires submittal of detailed information regarding the agent used, safety measures, training program, etc., in addition all individuals involved must undergo a background check administered by the US Department of Justice. Once the CDC approval is granted, a similar application is submitted to BPHC for their review and approval. Any research may only start after all the appropriate approvals from the CDC and BPHC is granted can a research protocol be started.

High Risk Agents

The IBC will determine whether the work involved the use of what it determines as "high-risk agents" (e.g. Neisseria meningitidis; the bacteria that causes meningitis). If it includes the use of high-risk agents, in addition to IBC approval, the Office of Environmental Health and Safety registers the laboratory with the Boston Public Health Commission. The PI must also work with the Occupational Health Officer (OHO) to prepare a plan acceptable to the Occupational Health Officer for disease surveillance.

NEIDL Projects
An additional step in NEIDL is that before an investigator submits a proposal to a funding agency they must complete a "NEIDL Research Proposal Pre-Evaluation Form". The researcher is required to provide a brief description of the proposed research which is forwarded to the scientific advisory

committee which includes external scientists for review. The reviewers are asked to evaluate the proposal and answer two questions:

- Is the scope of the proposed research consistent with the NEIDL missions?
- Does the proposed research pose any ethical concerns?

If the scientific reviewers are affirmative in their answer, then the researcher may proceed with a full application for funding.

If the reviewers raise concerns the researcher must address them to the commenter's satisfaction, or the proposal will not go forward.

Attenuated Pathogens

The IBC will determine whether the research involves the use an attenuated pathogen(s). If it does, then, in addition to obtaining IBC approval for the project, the PI must verify the identity of the attenuated pathogen using an IBC approved method under Boston University's verification policy.

5.3.5 SECURITY AND ACCESS PROCEDURES

Extensive security and limited access procedures have been developed for the NEIDL facility. These include 24/7 armed security presence, visitor and personnel background checks, and a sophisticated alarm system.

5.4 TRANSPORT OF HAZARDOUS MATERIALS

The NEIDL operations will include incoming and outgoing shipments of infectious pathogen samples during the life of the facility. Those infectious pathogen shipments could involve both truck and air modes of transportation. The FSRA contains a thorough analysis of the potential risks (i.e. frequency and consequences) to members of the public because of a loss of an infections pathogen release resulting from a transportation accident.

All NEIDL shipments must comply with numerous federal, state and local regulations. The FSRA assumed that an average 15 infectious pathogens will be shipped per year. Of these, 13 will likely be truck shipments and two will involve a combination of truck and air. The FSRA determined that, in the case of a truck or air accident, handling and packing measures would contain the pathogens to the degree that exposure is extremely unlikely. The FSRA includes a detailed analysis of the potential risks to members of the public because of a loss of an infectious

pathogen release resulting from a transportation accident. Packaging requirements are governed by DOT Hazardous Materials Regulations (49 CFR Parts 171-180). The BSL-3 and BSL-4 pathogens being evaluated for NEIDL are classified as Category A infectious substances. The SFRA (Appendix 11) includes a detailed description of packaging requirements for Category A infectious substances.

5.5 COMMUNITY RELATIONS

The National Emerging Infectious Diseases Laboratories' (NEIDL) Charter states that community engagement in the NEIDL is important to the success of its missions. Boston University Medical Campus (BU) is committed to full community involvement through education, outreach, and the provision of relevant and timely information to the community regarding the safety, security, operations, and research activities at the NEIDL. Since the NEIDL's inception, BU has pledged to keep the community informed throughout the research process, from the selection of diseases to be studied to the completion of research and the publication of results. As lower–level research begins, and in anticipation of more advanced biosafety level research, Boston University remains committed to maintaining effective community outreach measures to ensure the transparency of NEIDL operations.

As such, BU has defined a comprehensive approach to community relations that includes establishing a dedicated Community Relations office on the BU Medical Campus; appointing community representation on NEIDL working committees such as the Community Liaison Committee, the Institutional Biosafety Committee, and the NEIDL Safety Committee; providing regular and updated information to stakeholders through e-mail, a NEIDL website, and traditional communication outlets; and educating community members about NEIDL operations through community meetings and informational guided tours of the NEIDL facility. Additionally, the NEIDL's lead researchers and operations directors work closely with the Community Relations office to identify and address issues of importance to the community.

5.5.1 COMMUNITY RELATIONS OFFICE – BOSTON UNIVERSITY MEDICAL CAMPUS

The office of Community Relations is a division of the Office of Government & Community Affairs. The Community Relations office on the Boston University Medical Campus is tasked with planning, implementing, and overseeing community relations activities between BU and the residents, business owners, and neighborhood associations near the BU Medical

Campus, on which the NEIDL is located. In addition to serving as the primary point of contact for any inquiries lodged by community stakeholders, the Community Relations team strives to maintain a strong presence within the community through regular attendance and participation at local business and community meetings and events.

Since 2003, Community Relations staff has participated in well over 500 community meetings and events at local organizations such as the Blackstone/Franklin Square Neighborhood Association, Newmarket Business Association, the South End Business Association, Washington Gateway Main Street, and Worcester Square Area Neighborhood Association.

5.5.2 NEIDL INSTITUTE COMMUNITY LIAISON COMMITTEE (CLC)

In direct response to the input received during community outreach meetings and discussions, BU has worked to expand access to information about the NEIDL, as well as facilitate open dialogue and a meaningful exchange with the community through the creation of the NEIDL's Community Liaison Committee (CLC). Its members represent community stakeholders in the development of the NEIDL. The CLC serves as a means by which BU and the community can exchange and share information, ensuring two-way communication between the NEIDL and neighboring communities. CLC members serve in an advisory capacity to the NEIDL leadership and staff, and play a central role in ensuring transparency and openness in the operations and activities of the NEIDL.

Membership

Since the committee's creation, the CLC had consisted of six members headed by a committee-elected chairperson. With the commencement of BSL-2 research at the facility in April 2012, BU decided to expand community representation on the CLC. In addition to the remaining prior participants, six new community or neighborhood representatives with specialized skills or interests in the NEIDL activities were added in December 2012. The CLC is now comprised of eleven members.

CLC community and neighborhood representatives are selected in accordance with the NEIDL Institute Charter and represent a broad array of neighborhood, resident, and community interests. These eleven community members were solicited through an open self-nomination process, which included advertisements in community newspapers, postings on the NEIDL website, presentations to community members and businesses, and direct mail and e-mail. Community representatives were selected on the basis of a

number of considerations including, but not limited to: local residence, meeting availability, and participation and/or leadership in other community groups or associations.

The additional six members possess specialized skills needed to facilitate the flow of information to the community. These additional members possess skills within fields of science, medicine, and communication, or possess the ability to speak one or more foreign languages. These members were selected by the acting Director of the NEIDL and in consultation with the Executive Director of Community Relations on the Medical Campus.

It is important to note that the CLC selection process is not contingent upon the nominee's support of or opposition to the facility.

Responsibilities

The CLC is tasked with the following specific responsibilities within the committee's overarching responsibility to develop and maintain communication between the community and the NEIDL:

- Share and distribute information to the community about the projects and activities at the NEIDL.
- Assist the NEIDL leadership with development and planning of activities to promote collaboration, cooperation, and information exchange between the NEIDL and the community.
- Assist the NEIDL leadership to effectively communicate and collaborate on programs and activities involving the NEIDL and the community.
- Advise the NEIDL leadership on potential issues of concern involving the NEIDL and the community.

The CLC's elected chairperson presides at CLC meetings. Attendees include other CLC members, an Associate Director of the NEIDL, the Executive Director of Community Relations on the BU Medical Campus, and the Executive Director of Research Compliance. CLC meetings are held every month, except for August. Agendas include a standing item for community concerns and the status of programs designed to address those concerns. The content, schedule, and success of efforts to address community concerns through education and outreach is discussed at every CLC meeting to ensure that the efforts being made are successfully addressing identified community needs.

BU-NEIDL Support

A committed team of BU officials representing the areas of science and research, public relations, community outreach, emergency planning, and public safety, work closely with the CLC in order to ensure that appropriate BU resources are available to CLC members seeking information to provide prompt and accurate responses to questions or concerns emanating from the community, and to support the Community Liaison Committee in its efforts to engage the community in information sharing activities.

These BU officials regularly attend CLC meetings and provide support for all educational programming, managing logistics for educational sessions (for CLC or community members), and providing space, notification of meetings, and agendas as necessary.

This group also utilizes the expertise and experience of the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases (NIAID), and other BU colleagues within the scientific research community to supplement their own expertise and to garner additional ideas for community outreach and educational activities.

This team of BU officials, led by Dr. John R. Murphy, NEIDL Interim Director, includes:

Science / Research Representative

Dr. Ronald Corley, NEIDL Associate Director

Community Relations and Outreach Representative

Valeda Britton, Executive Director of Community Relations/Medical Campus

Health and Safety Emergency Response and Regulations Representative

Kevin Tuohey, Executive Director, Research Compliance

5.5.3 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

To ensure that the community is both aware of all proposed research at the NEIDL and has the opportunity to participate in the formal review process of all proposed research, a CLC representative sits ex-officio on the Institutional Biosafety Committee (IBC), which provides oversight for the Biosafety Program at Boston University and Boston Medical Center. The IBC is the entity through which all requests to establish protocols and conduct

biological research are vetted and to which all accidents and incidents involving biological materials must be reported. The committee sets containment levels in accordance with the National Institutes of Health (NIH) Guidelines and the Center for Disease Control and Prevention (CDC).

Via the CLC member's place on the IBC, the community has a formal role in vetting research proposals, giving the CLC notice and an opportunity to comment before the approval of any research. The minutes from all IBC meetings are posted on the NEIDL website, further ensuring that the community has access to any information related to the discussion and/or approval of proposed NEIDL research. Recent IBC meeting minutes are included in Appendix 8.

5.5.4 NEIDL SAFETY COMMITTEE

A CLC representative holds an ex-officio seat on the NEIDL Safety Committee, which has full oversight of safety at the NEIDL, evaluating, monitoring, and analyzing safety plans and issues to reduce the risk of laboratory incidents, injury and property damage. Community members have direct access to important information relevant to the community's safety via this CLC representation on the NEIDL Safety Committee.

5.5.5 COMMUNITY OUTREACH AND EDUCATION

Community Relations is actively involved in educating community members about NEIDL activities and operations. Community residents, business leaders, and elected officials receive regular updates on federal, state, and local community meetings and decisions impacting the NEIDL through a variety of communication methods including e-mail, website postings, neighborhood canvassing, telephone calls, newspapers and traditional mail notices. Community Relations notifies interested parties about updates on issues such as the status of the Risk Assessment, by means of a community e-mail distribution list compiled over many years through continuous outreach efforts to surrounding neighborhoods.

The office routinely canvasses the community with flyers to inform residents about important meetings and events including the opportunity to tour the NEIDL facility. Community Relations also meets one-on-one with individual community leaders, residents and local housing safety task force committees to discuss NEIDL issues. This face-to-face outreach method has proven effective in the solicitation of new CLC members. Community Relations also

ran ads in five local newspapers for four consecutive weeks to solicit new CLC members.

Additionally, Community Relations actively engages in opportunities to share information on the NEIDL with the community via broadcast and print interviews; Community Relations has participated several newspaper interviews and appeared on multicultural local access television programs to educate the public of the NEIDL and solicit new CLC members.

NEIDL Tours

BU recently provided a series of guided tours of the NEIDL facility, one of the most significant community outreach initiatives to date. The presentation and walking tour was given by the NEIDL's lead researchers and covered all aspects of the facility's operations. They afforded the community a unique opportunity to view first-hand the state-of-the-art research facility to learn about the important safety features and the significant economic impact of all bio-safety level research to be conducted at the NEIDL, and to speak directly with senior researchers.

Between January and October 2012, Community Relations staff invited over 690 people to attend NEIDL tours. In close coordination with the senior NEIDL staff and researchers, approximately 34 tours were conducted for more than 446 business leaders, elected officials, city and state agency officials, community residents, members of the Boston University and Boston Medical Center communities, and members of other public and private educational institutions.

It is important to note that these tours were not limited to groups in support of the NEIDL. Extensive community outreach efforts were undertaken to include as many interested participants as possible.

Public Hearings and Meetings

In taking every opportunity to better inform community residents about the NEIDL, BU has voluntarily participated in approximately twenty public hearings and meetings since 2003. Descriptions of two such meetings, a meeting hosted by the NAACP and a Boston City Council hearing, are included below:

In June 2012, City Councilor Charles C. Yancey invited BU to testify at a Boston City Council hearing on safety and security issues related to the NEIDL. The hearing was held in the Community Room of the Cathedral

Housing Development Complex in the South End. Dr. Ara Tahmassian, Vice President of Research Compliance at Boston University, testified on behalf of BU. Opponents of the NEIDL also attended and were afforded the opportunity to testify. Members of the Boston Public Health Commission, the Boston Fire Department, Boston City Council and the public also participated.

In August 2012, BU joined with the NAACP to take part in a community meeting on the NEIDL. Available NAACP officials toured the NEIDL prior to the meeting. Dr. Ronald B. Corley, NEIDL Associate Director, participated in the panel discussion along with a representative from the Boston Public Health Commission and four other panelists affiliated with the group Roxbury Safety Net, which is opposed to the NEIDL. This discussion took place at Twelfth Baptist Church in Roxbury, and was moderated by the NAACP. Dr. Ronald B. Corley, Associate Director of the NEIDL, spoke about the NEIDL's design, safety features, suitability of location, and the importance of (and urgent need for) the type of infectious disease research that will be conducted in the facility. Residents and community leaders were able to speak directly with Dr. Corley and voice their individual concerns and comments.

BU welcomes the opportunity to engage with the community at these public meetings, and will continue to participate in public hearings and meetings in the future. It is important to note that in addition to panel speaker appearances, Community Relations and BU representatives also attend public NEIDL hearings and meetings in which they do not have a formal speaker role, such as the NIH public hearing on the Draft Supplementary Risk Assessment in April 2012, in order to make themselves available to answer questions and provide information to interested community members.

Public Information Repositories

NEIDL materials have been and continue to be placed in four branches of the Boston Public Library (Main, Dudley, Grove Hall, and South End) and are updated regularly with general information about infectious diseases and the importance of the research that will take place in the NEIDL. Additional information, such as new Boston Public Health Commission regulations, transportation policy, and emergency response plans, is also provided and kept up to date.

5.5.6 NEIDL WEBSITE

The NEIDL website is designed to provide accurate information on the NEIDL and any research conducted at the facility. It is an important information source for the community and has been updated several times to reflect recent developments at the NEIDL, including the commencement of BSL-2 research, NEIDL tour notifications, NIH announcements, and prospective research. When available, materials and documents related to the NEIDL will be posted on the website.

Information on the website (www.bu.edu/NEIDL) includes:

- A section on science and research.
- A section on the NEIDL's "culture of safety" which includes extensive information on the safeguards and oversight procedures in place to protect researchers and the community. This section also includes a NEIDL specific incident report which is updated quarterly.
- A community engagement section, including updated information on CLC activities and minutes of CLC meetings.
- IBC meeting minutes and a BU Agent Incident Report Summary. This report discloses all laboratory incidents and includes the following: date of the incident, a description of the incident, transmittability, reportable event and corrective action.
- A community event calendar.

The NEIDL website also provides a translator function for access to information in over sixty languages.

5.5.7 COMMUNITY PARTNERSHIPS

One of Boston University and the Boston University Medical Campus' top priorities is to maintain an active role in local organizations devoted to strengthening the physical, social, and economic conditions of neighboring communities. Community Relations on the BU Medical Campus maintains a community presence through participation in community events in addition to membership and annual contributions to various local community groups and organizations in the South End and neighboring Roxbury, Dorchester, and South Boston. Community Relations at BU strives to ensure that the University is fully aware of and responsive to the needs of its neighbors.

In addition to supporting existing community groups and organizations, the Boston University Medical Campus offers a wide array of community

programs, resources, and services through the Boston University School of Medicine, the School of Public Health, and the Henry M. Goldman School of Dental Medicine.

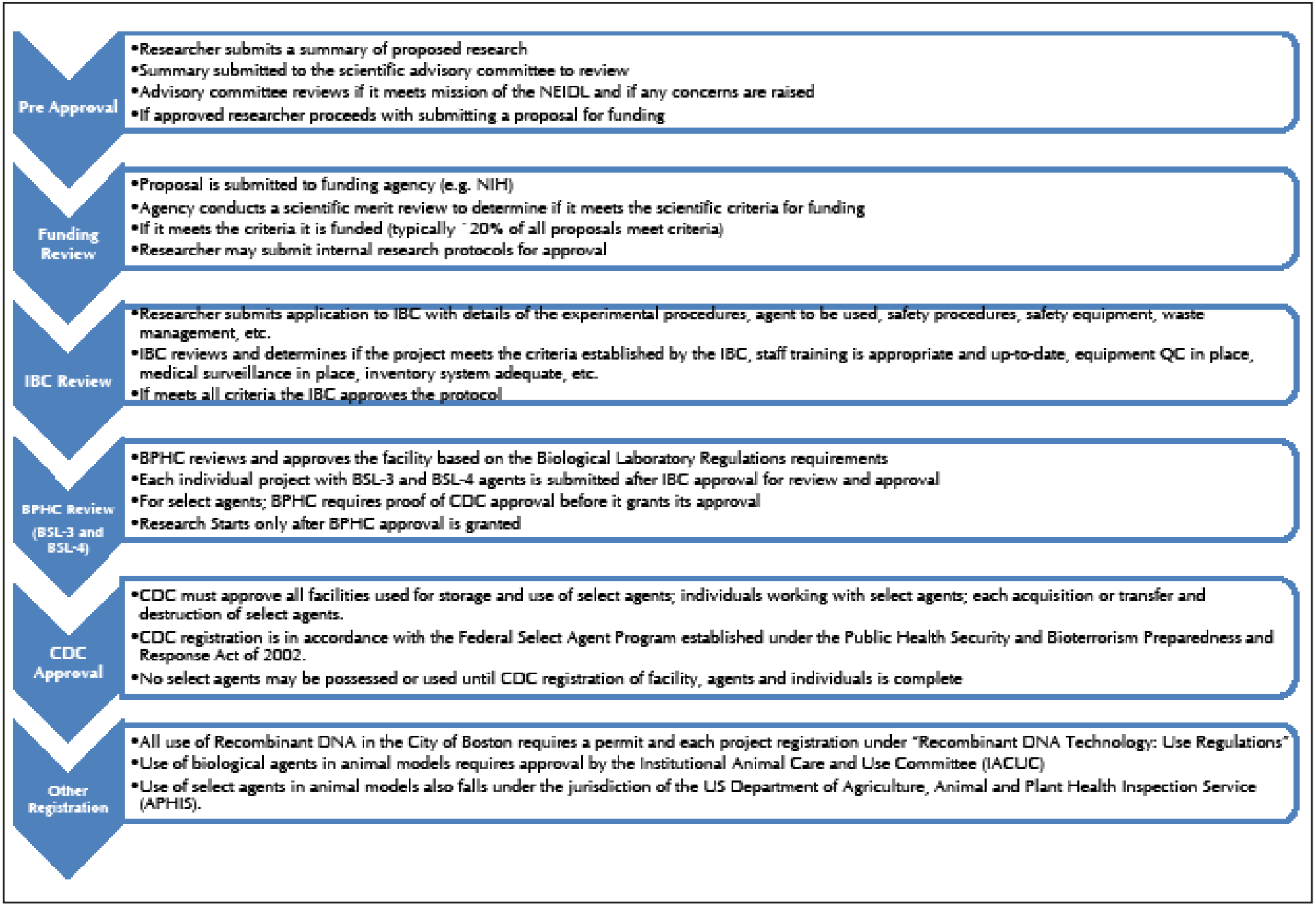
Boston University Community Grants Program

In late 2011, in response to drastic budget cuts undertaken by community organizations across the city, Boston University's Government & Community Affairs office, of which Community Relations on the BU Medical Campus is a satellite branch, implemented a community grants program. The $2,500 community grants are awarded to programs and services that benefit residents of Boston University's host community, with special consideration for programs and services that benefit local youth. Funding is intended to supplement the existing budgets of established organizations and agencies.

South End/Roxbury

The Boys & Girls Clubs of Boston Yawkey Club of Roxbury received $2,500 in support of their Young Leaders summer program, a seven-week program offering 13- and 14- year-olds a realistic work environment experience in a summer camp setting, the opportunity to be role model of young children, and the chance to acquire new skills and develop leadership abilities. The Young Leaders program encourages students to experience personal growth and develop meaningful relationships with peers and caring adults through travel and exploring the New England region.

Given the success of the Community Grants Program piloted in 2012, Boston University's Government & Community Affairs office will award two $2,500 grants in support of community programs or services in the South End or Roxbury in 2013.



BioSquare Phase II
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Figure 5-1
NEIDL Research Project Approval Process