



To: Huy Nguyen
From: Julien Farland
Date: March 5, 2015
RE: NEIDL Biosafety Level 4 Permit Application

As you know, Boston University's application for work in the NEIDL facility using Biosafety Level 4 pathogens was submitted to the Boston Public Health Commission for permitting under the Biological Laboratory Regulation more than one year ago. All 18 documents in the permit application were reviewed by the members of the Boston Biosafety Committee (BBC) during eleven meetings. At each meeting BPHC provided an overview of each section and the two reviewers from the BBC were designated as responsible for providing comments based on their review. Comments from the BBC were sent to Boston University and edited documents were reviewed until the committee felt the document was ready to be used.

At the March 2nd, 2015 meeting the BBC recommended the following pending items as conditions of approval:

- Boston University must receive Centers for Disease (CDC) Select Agent approval before Biosafety Level 4 agent work can begin.
- Facilities and plans for isolation of an exposed individual must be provided to the satisfaction of BPHC.
- Boston University must provide evidence of training of personnel on Standard Operating Procedures (SOP) and permit documents.
- A Class III biosafety cabinet specific SOP must be submitted to BPHC and approved before work with that piece of equipment can begin.
- Notification of new BSL-4 research projects shall be made to the Boston City Council and BPHC Executive Director at least thirty (30) days before initiating any BSL-4 research project.

In addition to the specific requirements, Boston University will be required to adhere to the following prohibitions in the Boston Public Health Commission regulations:

- a. The current BPHC Biological Laboratory Regulations prohibit: "Any research that has the potential to enable the use of a High Risk Agent to serve in any way as a principal component of a biological weapon, or significantly aid in the construction of a biological weapon or any research that has the potential to increase a High Risk

Agent's pathogenicity, reduce a High Risk Agent's resistance to treatments by antibiotic, anti-viral or other anti-microbial agent, alter the High Risk Agents' vector of transmission, that is conducted for no prophylactic, protective, treatment or other peaceful purposes, is forbidden in the City of Boston."

b. The BPHC Biological Laboratory Regulations also prohibit: "All research on High Risk Agents, designated by Presidential Executive Order 12958 or any other federal rule, regulation or law, as "Top Secret," "Secret," "Confidential," or any other classification or requirement including by contract, grant or funding requirement, that would prohibit the Boston Public Health Commission's complete knowledge of the research, shall be prohibited in the City of Boston."

c. The BPHC RDNA Use Regulations specifically prohibit: "RDNA use requiring containment defined by the Guidelines (NIH Guidelines) as "BL4" shall not be permitted in the City of Boston."

The BBC felt a consultant with additional BSL4 knowledge should be hired to add strength to the review process moving forward. BPHC will retain the services of a consultant with BSL4 research experience to review Boston University's training and procedures. In addition, the Biological Safety Office feels that Boston University is ready to be permitted to conduct Biosafety level 4 work as long as all bulleted pending items are submitted and meet Boston Public health approval.