



October 30, 2016

Julien Farland  
Director of Biological Safety  
Community Initiatives Bureau  
Boston Public Health Commission  
1010 Massachusetts Avenue, 2nd Floor  
Boston, MA 02118

Dear Mr. Farland,

This letter is in response to the Boston Public Health Commission's (BPHC) approval of [REDACTED] proposed research work involving full-length cDNA of Risk Group 4 non-segmented negativesense RNA virus genomes.

- Recommendation:

BU should include in the training for those personnel working on the proposed BL2 project that currently Nipah and Hendra viruses are not approved for storage and use at the NEIDL, and that there are serious ramifications should the proposed safeguards fail or be ignored for the work to be conducted at BL2.

Response: The approved full-length cDNA work is classified as BSL-2 and will be performed independently of the planned BSL-4 work described in [REDACTED] IBC protocol [REDACTED]. The full-length cDNA work and the future BSL-4 work will be kept strictly separated. To clarify, any generation of BSL-4 pathogens, including filoviruses and henipaviruses, without the necessary permits would be illegal and considered a criminal act.

- Recommendations:

BU should consider upgrading the proposed background checks for FLCL personnel to include aspects required for Select Agent Personnel Suitability Assessments such as a thorough psychological assessment.

Response: All NEIDL personnel undergo initial psychological assessment at employment and annually through the ROHP. This includes the personnel working in the FL-CL.

BU should develop, implement and communicate a policy to those authorized to work in the FLCL, addressing the consequences of failing to adhere to the required FLCL policies.

Response: Personnel will be trained on FLCL-specific SOPs to assure compliance with the developed procedures.

BU should establish a visitors' entry log book at the entry points of the FL-CL to record entries of trainees and other approved visitors who do not have personal access.

Response: The FLCL will have a logbook at the entrance to the facility to document entry and exit of all visitors into the space.

- Recommendation:

BU should include the results of the annual inventory in a report to BPHC.

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Response: The FLCL will conduct an annual inventory of the master clones in storage and a copy of the report will be provided to BPHC.

- Recommendation:

BU should provide the biosafety manual and/or SOPs for work in the FLCL facility to BPHC for

Response: SOPs shall be developed and will be available on site for review as needed.

- Recommendation:

BU should provide BPHC with training completion files for all personnel working in the FLCL, including training content, for review.

Response: Records of trainings and training materials are kept and will be made available on site for review as needed.

- Recommendation:

BU should provide BPHC with more detailed protocols describing what to do in an event of emergency. BU should post emergency protocols in the FLCL laboratories so they are readily accessible.

Response: The procedures for emergency incidents in BSL-2 laboratories in the FLCL are consistent throughout all of Boston University. Laboratory Safety Training and Annual Refresher is required of all working in a laboratory and covers: Hazard Communication, Fire Response, Chemical Spills, Biological Spills, Laboratory Exposure, Incidents and Accidents, Emergency Equipment. Basic Radiation Safety training covers spills and clean up. In addition, the Emergency Response Flip Charts are posted in the laboratories and they include the written response procedures for each type of emergency, phone numbers and other emergency information relevant to incidents in BSL-2 laboratories

- Recommendation:

BU should submit copies of annual reports and research protocols involving RG4 cDNA to the BU IBC, the NIH OSP upon request, and also to the BPHC.

Response: The FLCL will submit to BPHC a copy of the annual report provided to NIH and the IBC.

Please let me know if you have any question.

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