Executive Summary:

The Institutional Biosafety Committee (“IBC”) enjoyed a productive year providing oversight of the Biosafety Program for Boston University and Boston Medical Center (“BMC”). The monthly meetings were well attended and the Committee continued its close collaboration with the Research Occupational Health Program (“ROHP”) and the Environmental Health and Safety (“EHS”) program. The Academic Year (“AY”) 2015 goals of the Committee included:

- Perform annual review and approval of the Biosafety Manual.
- Conduct annual IBC self-assessment; complete annual review of List of Biological Agents with Potential to Cause Laboratory Acquired Infection (“LAI”); and update the Principal Investigator Recombinant DNA (“rDNA”) and IBC Policy Training.
- Provide IBC Training Sessions to Committee members on relevant topics.
- Identify ways to further improve communication between the IBC and: EHS; ROHP; Office of Sponsored Program (“OSP”); Institutional Animal Care and Use Committee (“IACUC”); Institutional Review Board (“IRB”); Laboratory Safety Committee (“LSC”); and Radiation Safety Committee (“RSC”).
- Evaluate the IBC application, review and approval process in the Research Information Management System (“RIMS”) to make recommendations for improvements.
- Assess the protocol submission management procedures and office processes to improve the time to completion metrics for IBC applications, amendments and annual renewals.
- Improve time to completion for annual IBC Protocol Renewals, ROHP Personnel Clearance and Laboratory Safety Training.
- Promote a culture of safety through education and training.
- Revise process for reviewing biological toxins.
- Review the IBC’s policy on “Dual Use Research of Concern” to ensure it is consistent with the finalized “US Government United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.”
2015 AY Accomplishments:

- **Biosafety Manual**: The Biosafety Manual was updated after a thorough review of each section was performed by relevant experts or institutional officials, as appropriate. This updated Manual has been available on-line to the public since August 2014.

- **Annual Public IBC Meeting**: The annual IBC public meeting was held on September 17th 2014. As required by the Boston Public Health Commission (“BPHC”) “Biological Laboratory Regulation”, advance notice of the public meeting was announced on the IBC and BU Office of Research Compliance websites and in the local newspaper the “Boston Herald”. The Safety Committees Manager presented the IBC Office 2014 Annual Report, which included an overview of all protocols submitted for review based on their biohazard category and recombinant DNA research status, including that of the Biosafety Level 3 (“BSL3”) and proposed Biosafety Level 4 (“BSL4”) protocol, and a review of changes to IBC policy, committee membership and the BPHC permits issued over the past year.

  The Biosafety Officer provided the committee with an annual update of the research safety program at BU. This included a categorized inspection report and analysis of quarterly and yearly changes in the compliance status, which showed a positive trend in their continuing efforts to increase the culture of safety at the university.

- **National Biosafety Stewardship Month and Health and Safety Requirements for NIH Grantees (September 2014)**: NIH instituted a National Biosafety Stewardship Month to encourage NIH grantee institutions to examine and strengthen biosafety oversight and practice. The IBC sent a broadcast email to remind all Principle Investigator (“PIs”) with IBC protocols to examine current laboratory policies and protocols, conduct inventories of infectious agents and toxins, and to reinforce proper biosafety practices.

- **Annual Review of Biological Agents with Potential to Cause Laboratory Acquired Infection (“LAI”) list**: The LAI subcommittee reviewed potential agents to determine if they should be added to the LAI List. The subcommittee recommended removing three viruses that are no longer used at BU and adding the following five agents: Brazilian Vaccinia Virus; Cowpox Brighton Virus; Newcastle Disease Virus; Pseudomonas Fluorescens (bacterial); and Acanthamoeba Castellani (parasite). The updated LAI list is available online at http://www.bu.edu/orc/files/2015/08/List-of-biological-agents-with-potential-to-cause-LAI-Revised-08.03.2015.pdf

- **BU Dual Use Research of Concern (“DURC”) Policy**: The BU DURC Policy was revised to ensure it conformed to the final US Government policy released on September 24th 2014. The updated policy was circulated to the IBC members by email for vote and was approval unanimously.
IBC Blast Email for Summer Students: The IBC sent a broadcast email notice to all PIs to remind them of the Laboratory Safety Training and ROHP Clearance requirements for summer student researchers.

BU IBC in USA Today: The IBC responded to a request from a USA Today reporter to provide IBC minutes and incident reports. In the resulting report “Inside America’s Secretive Biolabs” published in USA Today, the University was lauded for being among only a few labs that follow the NIH guidance recommending that institutions post IBC minutes online.

IBC Member Training Sessions: The IBC continued to provide information and training on important biosafety issues, and on emerging biological research topics that require special attention, to its members. Short presentations, from experts or by committee members with appropriate expertise, followed by discussion occurred during the regular monthly meetings. Topics presented included: Biological Toxins in Research; Prions in Laboratory Research; DURC Policy Updates; Update on Biological Waste Disposal Policy; What We Need to Know About Ebola Virus; Risk-based Lab Inspection Program; Review of NIH Guidelines on Gene Therapy Protocols; Biosafety Practices in the Laboratory Animal Science Center; and Lentiviral Vectors in Biological Research and Safety Concerns.

Annual rDNA Report to BPHC: The IBC submitted its annual rDNA report for the period from Nov 2013 to October 31 2014 in accordance with the “Boston Public Health Commission Recombinant DNA Technology: Use Regulations” to the BPHC.

BSL-3 and BSL-4 Permit with National Emerging Infectious Diseases Laboratories (“NEIDL”): The IBC prepared the supporting materials as part of the BSL-4 permit application with BPHC. Responses to the BPHC comments for NEIDL BSL-4 permits were sent to BPHC, which included modification of the “Verification of the identity of attenuated BSL-3 and BSL-4 pathogens”.

With decommission of room W934, the BSL-3 permit (111B) for W-934 was closed with BPHC. All research work previously done at W934 was moved into the NEIDL’s 6th floor and is covered by BSL-3 Permit 160 for Non-Select Agent work with Mycobacterium Tuberculosis, and BSL-3 Permit 161 for Select Agent work with Francisella tularensis and Yersinia pestis. The IBC worked with the three research groups to remove W934 and include the NEIDL in their IBC protocols.

Human Gene Transfer Protocol Review: The IBC and the Human Gene Therapy Subcommittee reviewed and approved a human gene transfer protocol, which studies the safety and effectiveness of hepatocyte growth factor plasmids injected into the leg of subjects with critical limb ischemia.

Compliance with ROHP Clearance & Laboratory Safety Trainings: Use of the improved tracking mechanism for monitoring ROHP Clearance and Laboratory Safety Training helped improve compliance.
- **Biological Use Authorization Site Assessments and Incident Reporting**: No rDNA related incidents occurred during AY2015.

- **Campus-wide Communication**: A flowchart outlining the responsibilities and timeline for completion between the IBC, the LSC, the RSC, the IACUC, the EHS office and the ROHP helped to clarify roles and improve communication. The IBC Office also worked in collaboration with OSP and the IRB to review Material Transfer Agreements and IRB Protocols to identify materials that would require an IBC approval prior to use.

- **Communication and Outreach to Principal Investigators**: The IBC Office published quarterly IBC newsletter to update PIs about IBC policies.

- **Research Information Management System (RIMS)**: The IBC office participated in weekly meeting with the RIMS team to identify opportunities for improvements and enhancements in the RIMS usability and functionality.

- **New Members**: The IBC welcomed a new chair and appointed two new members during AY 2015.

- **Protocol Review and Approval Process**: There were 103 IBC applications, including 26 new applications and 77 three-year resubmissions that were reviewed and approved during AY 2015. There were 33 reviewable amendments, 114 expedited amendments, and 188 annual renewals reviewed and approved during AY 2015.

A summary of IBC data are provided in the Figures below.

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**Figure 1. BSL Level of active protocols (317 total)**

- BSL 1: 29
- BSL 2: 274
- BSL 2+: 8
- BSL 3: 6

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Figure 5. Protocols by School (Total 317)

- College of Arts and Sciences: 70%
- College of Engineering: 11%
- Sargent College of Health and Rehab Sci: 12%
- School of Dental Medicine: 4%
- School of Medicine: 1%
- School of Public Health: 2%

Figure 6. Number of Protocols per PI (Total PI 265)

Number of Protocols per PI:
- 1: 228
- 2: 27
- 3: 7
- 4:
- 5:

Total PI: 265
Figure 7. IBC Office Workload

Figure 8. Time to Completion
Institutional Biosafety Committee Goals AY 2016:

- Streamline the protocol submission management procedures and office processes to decrease the time-to-completion approval of all IBC applications, amendments and annual renewals.

- Perform annual review and approval of the Biosafety Manual.

- Conduct annual IBC self-assessment; complete annual review of List of Biological Agents with Potential to Cause LAI: and update the Principal Investigator rDNA and IBC Policy Training for PI.

- Implement the BU DURC Policy and update the BU DURC website and training materials as required by the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

- Provide IBC Training Sessions to Committee members on relevant topics.

- Conduct review of IBC policies; perform annual membership analysis; and identify areas for improvements.

- Identify ways to further improve communication between the IBC and: the EHS; the ROHP; the OSP; the IACUC; the IRB; the LSC; and the RSC.

- Evaluate the IBC application, review and approval process in the Research Information Management System (“RIMS”) to make recommendations for improvements.

- Improve time to completion for annual IBC Protocol Renewals, Personnel ROHP Clearance and Laboratory Safety Training.

- Promote a culture of safety through training and education.