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) 2016 goals of the Committee included:

- Perform annual review and approval of the Biosafety Manual.
- Conduct IBC self-assessment and update the Principal Investigator rDNA and IBC Training Policy.
- Provide IBC Training Sessions to Committee members on relevant topics.
- Identify ways to further improve communication between the IBC and the institutional research community.
- Assess the protocol submission management procedures and office processes to improve the time to completion metrics for IBC applications, amendments and annual renewals.
- Continue to promote a culture of safety through education and training.

2016 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. The full IBC committee reviewed and approved the revised version. The updated Manual has been available online since November 2015.

- **Annual Public Meeting of the IBC**: The annual Public Meeting of the IBC was held on September 22, 2015. As required by the Boston Public Health Commission (BPHC) “Biological Laboratory Regulation” the meeting was held in a facility that was handicap accessible and open to public, and advance notice for the meeting was posted in the local newspaper the “Boston Herald’, as well as on BU Research Compliance and IBC websites.

  The Safety Committees Program Manager presented the IBC Office 2015 Annual Report, which included an overview of: all protocols submitted for review based on Biosafety Levels and use of recombinant or synthetic nucleic acid molecules; changes in IBC policies; BPHC permit issued: and committee membership.

  Senior Research Safety Specialist presented the annual update on the research safety program at BU. This included an overview of inspection report results, which showed a positive trend in continuing efforts to increase the culture of safety at BU.

- **IBC Member Training Sessions**: The IBC continued to provide information and training to its members on important safety issues, and on emerging biological research topics that require
special attention. Short presentations from experts or from committee members with appropriate expertise, followed by discussion, continued to be an essential agenda item during monthly IBC meetings. Topics presented included: Update on the West African Ebola Epidemic; Herpes B Virus Exposure Management in Non-human Primate Research; Update on the BU Waste Management Policy; BSL-4 Training; CRISPR/Cas9 Technology in Biological Research; BioSafety Considerations for Fieldwork on Wild Orangutans; Emergency Preparedness in Clinical Settings for Viral Hemorrhagic Fever and Other High Risk Infections; Overview of the Zika Virus; and Dual Use Research of Concern (DURC).

- **IBC Self-Assessment**: The IBC completed the National Institutes of Health (NIH) Office of Science Policy (OSP) Institutional Self-assessment Tool to evaluate its program of oversight for research involving recombinant or synthetic nucleic acid molecules for compliance with the requirements articulated in the NIH “Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.” Evaluation of the 83 questions revealed that BU programs are in line with the expectations, standards and requirements of the NIH guidelines and identified areas that could be further improved.

- **Annual rDNA Activity Report to BPHC**: In accordance with the BPHC’s “Recombinant Technology: Use Regulations” the IBC submitted its annual report on research activities involving rDNA for the period from November 1, 2014 to October 31 2015.

- **IBC Blast Email for Summer Students**: To facilitate timely completion of training requirements and medical clearance for summer students, the IBC sent a broadcast email notice to all Principal Investigators to inform them of the Laboratory Safety training and ROHP clearance requirements.

- **Routine NIH OSP Site Visit**: The NIH OSP conducted a routine site visit at BU to evaluate the performance of the IBC. They commended BU on their biosafety program and provided comments on how to improve the performance of the program, which the IBC has addressed.

- **Routine Department of Homeland Security (DHS) Site Visit**: The Compliance Assurance Program Office of the DHS conducted a routine site visit to evaluate BU’s Biosafety Program. They commended BU’s biosafety program and provided comments on how to improve the performance of the program, which the IBC has addressed.

- **Policy and Guidance Updates**:

  **Incident Reporting Requirements for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**: The purpose of this new policy is to set forth the incident reporting requirements for research involving recombinant or synthetic nucleic acid molecules.

  **Training and Health Clearance Requirements**: The purpose of this revised policy is to set forth the training and health clearance requirements for individuals listed on active IBC protocols who will be constructing and handling recombinant or synthetic nucleic acid molecules.

  **Obtaining USDA and CDC Permits for Importing and Transferring Animal Pathogens and Related Biological Materials**: This new guidance provides BU researchers with information regarding the USDA and CDC regulatory requirements on importing or transporting animal pathogens and related biological materials used for research purposes.
• **Communication and Outreach to Principal Investigators:** To keep researchers updated on the IBC activities, policy changes and to provide helpful tips in maintaining regulatory compliance, IBC published the quarterly “Biosafety Bulletin” newsletter.

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

• **Incident Reports:** There was one incident involving recombinant DNA that was reported to the NIH OSP and the BPHC during this academic year. There was no violation of safety procedures for this incident and no further information was requested by NIH or BPHC.

• **Protocol Review and Approval Process:**
  There were 90 IBC applications, including 23 new applications and 67 three-year resubmissions that were reviewed and approved during AY 2016. There were 17 reviewable amendments, 118 expedited amendments, and 208 annual renewals reviewed and approved during AY 2016.

A summary of IBC data is provided in the Figures below.
Figure 1. BSL Level of Active Protocols
(340 total)

<table>
<thead>
<tr>
<th>Biosafety Level</th>
<th>Number of Protocols</th>
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</thead>
<tbody>
<tr>
<td>BSL 1</td>
<td>34</td>
</tr>
<tr>
<td>BSL 2</td>
<td>292</td>
</tr>
<tr>
<td>BSL 2+</td>
<td>9</td>
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<tr>
<td>BSL 3</td>
<td>4</td>
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<tr>
<td>BSL 4</td>
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Figure 2. ABSL Level of Active Protocols
(136 total)

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<thead>
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<th>Animal Biosafety Level</th>
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<tr>
<td>ABSL-1</td>
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<tr>
<td>ABSL-1+</td>
<td>3</td>
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<tr>
<td>ABSL-2</td>
<td>77</td>
</tr>
<tr>
<td>ABSL-3</td>
<td>2</td>
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</tbody>
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Figure 3. Nature of Protocols (Total 340)

Figure 4. Number of Protocols per PI (Total PI 282)
Figure 7. IBC Office Workload

Figure 8. Time to Completion
Institutional Biosafety Committee Goals AY 2017:

• *Continue to 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.*
• *Continue to provide IBC Training Sessions to Committee members on relevant topics.*
• *Update the IBC Website.*
• *Develop workshop on “How to Prepare an IBC Application”.*
• *Continue to conduct review of IBC policies; perform annual membership analysis; and identify areas for improvements.*
• *Continue to promote a culture of safety through training and education.*