Boston University
Institutional Biosafety Committee (IBC)
Annual Public Meeting Minutes
September 16, 2025
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 1:10 PM

Members Present:	R. Ingalls, R. Davey, P. Liu (joined 12:24 pm), N. Dey, C. Thurman, M. Mazur, J. Keeney, R. Timmerman (joined 12:12 pm), V. Britton (joined 12:10 pm), S. Ghosh, T. Winters, V. Gouon-Evans, E. Loechler (joined 12:36 pm), R. Morales
Guests Present:	A. Lerner, A. Ahmad, C. Fernald, J. Wood, P. Richmond, M. Fitzgerald, B. McKinney, T. Killeen, J. Farland, D. Galarza Vergara, K. Tuohey, K. Mellouk, F. Fortin, A. Ellis, X. Zhu, G. Wei
Staff Present:	C. McGoff, L. Campbell

I. Introduction to the Public Meeting

The Chair informed IBC members and guests that the IBC Annual Public Meeting is a requirement set forth by the Boston Public Health Commission's Biological Laboratory Regulations Implementation and Enforcement Guidelines section 7.5. The Chair also stated that IBC is a NIH-mandated institutional regulatory body and provided a brief synopsis of the role of the IBC and how it oversees the compliance requirement set by federal, state, city and local authorities.

II. Review of August 19, 2025 IBC Meeting Minutes

No concerns were voiced.
Motion: Approved
For: 10; Against: 0; Abstain: 0; Absent: 4

III. Chair's Report:

The Chair thanked all IBC members for their valuable time throughout the year in reviewing protocols, and the IBC office staff for their hard work. EHS and Research Occupational Health Program (ROHP) staff was thanked for their support for the Biosafety Program. The Chair informed members that I. Afasizheva, an IBC member since 2017 and a former Chair, has stepped down from the committee.

IV. New Business:

A. Presentation: BSL3 and BSL4 Research in the NEIDL, Boston University
Dr. Robert Davey, NEIDL Director, gave a detailed presentation on ongoing and future BSL3 and BSL4 research in Boston University, which are carried out exclusively in the NEIDL building. The IBC office will forward any questions on this work to Dr. Davey.

B. EHS Annual Biosafety Report:
Dr. N. Dey, EHS Program Manager and Biosafety Officer, provided the EHS annual report for July 1, 2024 to June 30, 2025.

C. IBC Office Updates:
Members were informed that this meeting information was made available to the public by way of advertisement in the Boston Herald, posting on the IBC website, the CRC and BUMC calendars.

D. Research Occupational Health Program (ROHP) Report and Environmental Health and Safety (EHS) Report: One incident from August 2025 and the corrective action taken was reported and presented to members for review.

V. Protocol Review

1. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus

2700	Andrew Wilson	BTX-302-001: Beam Therapeutics Inc.: A phase 1/2 dose-exploration and dose-expansion study to evaluate the safety and efficacy of beam-302 in adult patients with alpha-1 antitrypsin deficiency (aatd)-associated lung disease and/or liver disease	2	N/A	BUMC
Primary Reviewer: Adam Lerner			Secondary Reviewer: Robin Ingalls		
Applicable NIH Guidelines: Sections III-C-1 and Section IV-B-6.					

Meeting Comments: This protocol proposes to introduce recombinantly modified nucleic acid molecules into human participants to rectify a gene mutation that causes Alpha-1 antitrypsin deficiency (AATD). It was noted that this protocol has been reviewed by the Human Gene Therapy (HGT) subcommittee. The current protocol involves infusion of lipid nanoparticle that contain guide RNA for the AAT gene and a chimeric mRNA that code for the CRISPR protein that is conjugated to deaminase enzyme. The HGT subcommittee reviewed the IND brochure and informed consent form to assess the scientific background of the proposal and biosafety issues for the researcher and pharmacists. Progress and success of the trial will be assessed through a combination of measurements such as safety and tolerability of the study drug; rates of adverse events; and levels of normal AAT protein. Unused drug will be returned to sponsor or destroyed on site, according to BMC investigational pharmacy policies. Used vials will be discarded in the appropriate bin (hazardous, non-hazardous, sharps, etc.). Standard precautions will be taken to ensure that BMC personnel are not exposed to the study drug. These include use of PPE which includes gown, gloves, and mask when mixing the drug. No significant safety issues were noted for study personnel. The following will be communicated to the PI:

- Please add [redacted] in the personnel list as the [redacted].
- Complete the 'Where and When experience' for [redacted], [redacted] and [redacted] and 'Experience related to this application' for [redacted] and [redacted].
- Complete the table for BMC lab building/room/Shared PI information.
- Please also include the laboratory/procedure location for sample collection and infusion, Pulmonology procedures and Biopsy processing in the main laboratory procedure description section.
- Clarify what is the actual procedure for destruction and disposition of any unused drug in the IPS that are not picked up by the sponsor.
- It is noted that Biosafety Cabinets will be used in the IPS facility. Please check this box and provide their certification information.
- Provide the IRB approval expiration date.

BUA Site Assessment: The specific locations where the work would be performed needs to be mentioned in the protocol. All wastes are managed by IPS and BMC clinical enterprise staff as per BMC policies. All blood, serum and BAL samples are stored in the designated storage area and are usually shipped to different locations the same day. Shipping supplies are available.

Motion: Conditional Approval (Admin Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

2. rDNA/Bhz-Three-Year Renewal

BUA	**(PI)**	**Title**	**BSL**	**ABSL**	**Campus**
2397	Florian Douam	Host and viral determinants regulating Flaviviridae and Coronaviridae pathogenesis and immunogenicity	2	2	BUMC
Primary Reviewer: Robin Ingalls		Secondary Reviewer: Colleen Thurman			
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-3-a, III-E-1; Appendix-B-II-D, Appendix G-II-B					

Meeting Comments: The goal of this protocol is to characterize both the viral and mammalian host response to infection that leads to pathogenicity and immunity using members of the Flavivirus and Coronavirus family, including Yellow Fever, Dengue, Zika, West Nile, and SARS-CoV2. The protocol involves both *in vitro* and *in vivo* work, involving mosquitoes which are the natural vector for some of these viruses as well as mouse infections to model various aspects of human disease. It describes safety issues of the ongoing research work in detail which include use of sharps, disposal of liquid and solid waste and animal carcasses, use of PPE, and protection of vulnerable personnel handling specific pathogens, for example, Zika virus and pregnant women. The only new aspect of this 3-year renewal is the addition of SARS-CoV-2 mouse work being moved from ABSL3 down to ABSL2 level. The committee has previously noted that NIH has reclassified SARS-CoV-2 as a risk group 2 agent. The following will be communicated to the PI:

- Please complete the 'Where and When experience' and 'Related experience' for all listed members those who are marked as "No" in the experience column (indicating what academic experience they have and what work will they do).
- BBP training update required for [redacted], [redacted], [redacted], and [redacted].
- rDNA/IBC policy training update needed for [redacted].
- Remove names of Dr. [redacted] and Dr. [redacted] from the room sharing information pages.
- Since there are now both ABSL2 and ABSL3 rooms in ASC [redacted] vivarium, please list the actual rooms (not [redacted]). EHS indicated [redacted] and [redacted] are being used for this protocol.
- Please clarify if back fastening gowns and safety glasses are indeed being used in BSL2 research labs.
- In Section A, is the "IACUC approval" part up-to-date? It says adenovirus and enterovirus D68 are pending. Are Hep C and Cedar virus also being added?

BUA Site Assessment: Room [redacted] and [redacted] are also being used in the protocol and thus need to be added to the IBC application. All biosafety cabinets are duly certified. O-rings/safety cups are available for centrifuges and vacuum lines have filter protection. Eye washes/fire extinguishers are certified. AED/First aid kit available. Biohazard stickers are present. Door sign are posted. Lab has emergency spill kits. In section 8.9 the PI explains his cell-sorting preparation process. He states "Face Protection" as a PPE and clarified that he means either safety glasses, goggles or a face-shield which is sufficient.

Motion: Conditional Approval (Admin Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

3. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2406	Hadi Nia	Probing physical tumor microenvironment	2	2	CRC

Primary Reviewer: Valerie Gouon-Evans | Secondary Reviewers: M Mazur

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1; Appendix-B-II-D, Appendix G-II-B

Meeting Comments: This project investigates mechanical and biological stresses in the tumor environment associated with the diseases of the lung and brain, and how these stresses affect the tumor biology in these diseases. The lab uses *in vitro* organoid systems, *ex vivo* systems involving cancer cells, mouse and human lung tissue thick sections, *in vivo* models of diseases in mice, large animals such as pig, and also in human and non-human primate (NHP) tissues (implantation of tumor cell-hydrogel construct). Biohazards used in the protocol include aerosolized bacteria (*S. pneumoniae* and *E. coli*) delivered *ex vivo* to lung slices or *in vivo* mouse lungs, LPS (lipopolysaccharide) to induce lung diseases, human cell lines, human lung tissues obtained from blood borne pathogen free organ donation service and NHP tissues obtained from BU collaborators. The protocol also uses chemotherapy agents, commercially purchased lentivirus vectors expressing reporter fluorescent proteins to transduce human and mouse cell lines, and chemical and carcinogenic agents that disrupt mechanical stress in *in vitro* organoids. Confocal and multiphoton microscopy are used to image changes of tumor cell and the hydrogel structure during their experiments. Protocol

provides detail description of safety concerns and mitigation plan for each of their experiments. Disinfection of hazardous liquid waste is done by treating with bleach at a final 10% concentration for 30 minutes and solid waste in red biohazard boxes, which are appropriate for the proposed work. IACUC protocol to use human cell line containing hydrogel construct will be submitted as an amendment after this IBC protocol is approved. IRB approval information from MGH for human lung specimen is provided. The following will be communicated to the PI:

- [redacted] needs ROHP clearance.
- Please include respirator N95 for human lung experiments and bacterial aerosolization experiments.
- Update certification date of the biological safety cabinet.

BUA Site Assessment: PI was not available for the site assessment as of the meeting date. Once completed, EHS comments or concerns will be included in the meeting comments sent to the PI.

Motion: Conditional Approval (Admin Review and completion of BUA Site Assessment)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

VI. List of Protocols reviewed by DMR (not discussed in the meeting)

A list of protocols that were reviewed by DMR was displayed in the meeting.
No opinions were voiced.