Boston University
Institutional Biosafety Committee (IBC)
March 18, 2025 Meeting Agenda
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 1:35 PM

Members Present:	R. Ingalls, R. Davey, E. Muhlberger, V. Gouon-Evans, T. Winters, J. Celenza (left 12:31 PM), R. Morales (joined 12:29 pm), N. Dey, M. Mazur (joined 12:26 pm), J. Keeney, R. Timmerman (joined 12:18 pm), V. Britton (joined 12:10 pm), S. Ghosh
Guests Present:	P. Richmond, A. Ahmad, J. Wood, A. Ellis, A. Broos-Caldwell
Staff Present:	C. McGoff, L. Campbell

I. Review of February 11, 2025 IBC Meeting Minutes (R. Ingalls)
No concerns were voiced
Motion: Approved
For: 8; Against: 0; Abstain: 1; Absent: 4

II. Chair's Report: Nothing to report.

III. New Business:

A. IBC Office Updates: Members were informed that two new protocols on the agenda were being reviewed. Members were also informed of two changes that were made in a section of the IBC application. Members requested additional changes.

B. Review of Research Occupational Health Program (ROHP) Report and Environmental Health and Safety (EHS) Report: Nothing to report.

IV. Protocol Review

1. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2683	Tara Moore	Forensic Anthropology Body donation & teaching laboratory	2	N/A	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Tom Winters
Applicable NIH Guidelines: N/A	

Meeting Comments: This protocol supports educational resource development and soft tissue research by establishing a permanent collection of modern human skeletal remains. This collection serves as a critical resource for the BU forensic anthropology program for master degree students and the broader scientific community. In addition to human remains, the collection will also include animal bones for comparative research. Processing of all human remains obtained from the Office of Chief Medical Examiner and coordinated by licensed funeral director, occurs at the BU Medical School, while animal bones obtained from Tufts University, local butchers, or MA Fish and Wildlife, are processed at an off-site facility. This program has been exempted by the Institutional Review Board (IRB), and all materials have been reviewed and approved by the General Counsel. Transportation of human remains to the Medical School adheres strict biosafety and transportation protocols, which are outlined in detail in the protocol. They do not accept individual bodies with a medical history of communicable diseases. Elaborate description of methods of bone extraction from the cadaver, cleaning, and their preservation are available in the application. Universal protection is provided as they work with un-fixed human material. The personal protective equipment described in the protocol is appropriate. Sharps are disposed of in sharps containers. Disinfection of instruments is performed with fresh 10% bleach and 30-minute immersion. The following will be communicated to the PI:

- It is stated in the protocol that personnel listed in the IBS (should be IBC) protocol engage in the tissue removal process. Please provide detail of experience of [redacted] ([redacted]/[redacted]) for each of the three categories (Overall experience, Where and when and Experience related to this IBC

application). [redacted] is the only listed personnel other than the PI. Please check 'yes' for [redacted] experience and provide the details.

- Is any other personnel associated in any of the listed activities in the protocol? If so, please list them all and provide their experiences.
- Protocol only lists [redacted] in the laboratory facility information. But activities in Room [redacted] and [redacted] have been mentioned multiple times in the application. Include all these lab locations in the list (including the cold room where tissue remains are stored before being dispatched for cremation or incineration).
- List [redacted] as an Off-Site location for preparation of animal bones.
- Where exactly the tissue removal process from the cadaver takes place (which specific room? Down-draft table? etc.). How the liquid waste generated during disarticulation and organ removal (like blood, body fluid, etc.) is collected, disinfected and disposed of? The Liquid waste disposal section only talks about disinfection of surgical instruments.
- Please state that for storing any remaining body parts and tissues, the lab will make sure that the lab cold room is consistently operating at 4°C when used.
- IBC strongly recommends the lab to consult and observe all EHS recommendations for the safety of the associated personnel as well as for engineering control and cleanliness of the facility.
- The protocol does not appear to use any non-human primate material for bone collection or any other work. Please remove the use of NHP materials in the 'Other Potentially Infectious Material' section in RIMS.

BUA Site Assessment: All trainings are completed and current. No biosafety cabinet is needed for the work. Fume hood is certified. The lab needs to add [redacted] lab space and the off-site facility to the protocol and remove [redacted]. All liquid biological waste including human blood and other body fluids coming out of the body must be disinfected with bleach to a final concentration of 10% before they are disposed of down the sink. For transportation of bones between [redacted] and [redacted], leak proof, shatter proof plastic containers with tight shutting lids must be used. Since no non-human primate materials are used, its reference needs to be removed.

Motion: Conditional Approval (Admin Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

2. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2682	Chen Yang	Brain stimulation and recording in a deaf mouse model	2	2	CRC

Primary Reviewer: Valerie Gouon-Evans	Secondary Reviewer: M. Mazur

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol investigates how ultrasound treatment affects neuronal modification in the brain. As recent studies revealed that such treatment also activate peripheral hearing, determining true potential of ultrasound treatment of the brain has been difficult. This group will use a conditionally-deafened transgenic mouse model to study the auditory circuit in the brain during ultrasound and photoacoustic stimulation. The conditional deafening of the mouse will be induced using Diphtheria toxin (DT). The double transgenic mice will be obtained from a colleague at the Caltech. Because of lack of hands-on training of any of the listed members in the protocol on handling of DT, EHS and IBC recommended that the lab get such training from other PIs in BU who are currently working on DT in the lab. The committee discussed that the DT stock solution must be made directly in the vacuum-sealed vial in a biosafety cabinet and aliquoted inside the cabinet. The stock vial must be transported to the animal science center in sealed tube in a leak and shatter proof secondary container. The following will be communicated to the PI:

- Please write in the protocol and confirm that member of the protocol have taken hands-on training on the safe use of DT from current user of DT in mice.

- Please remove all references in the protocol that says training on handling of DT will be performed by zoom meeting with [redacted].
- [redacted] labs #[redacted], [redacted], [redacted] and [redacted] need to be added to the protocol.
- DT stock solution must be prepared in biosafety cabinet with double gloves and surgical mask at a minimum. Include this statement in the body of the application.
- Members should remain vaccinated with T-dep (mention in the protocol). Contact ROHP if members are not vaccinated.
- Remove Freeze drying/lyophilizing.
- Remove statements related to nanoparticles from this application as those are not part of this application. If you plan to use nanoparticles in relation to the DT work, please submit an amendment after the current IBC protocol is approved.
- Complete the biohazard material transport question for transporting DT stock solution from [redacted] lab to the ASC.

BUA Site Assessment: Remove Freeze drying/lyophilizing and add double gloves. Both biosafety cabinets and fume hoods are duly certified. The lab needs to add labs #[redacted], [redacted], [redacted] and [redacted] to the protocol. N95 respirator is not required if the lab plans to use DT inside of a fume hood/BSC. The lab plans to conduct DT injection procedure in mice in the BU animal science center. In section VIII, please describe transportation of DT from the lab to the ASC procedure room. The lab is not making any nanoparticle conjugate with diphtheria toxin. They also plan to use 70% alcohol as another disinfectant.

Motion: Conditional Approval (Admin Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

3. rDNA/Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2442	Mohsan Saeed	Investigating the role of viral proteins in disease pathogenesis	3	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Jim Keeney

Applicable NIH Guidelines: Sections III-D-1-b, III-D-2-a, III-D-3-b; Appendix B-III-D and G-II-C

Meeting Comments: The current submission is an annual renewal of a BSL3 protocol that has the objective to study role of viral and cellular proteins in the pathogenesis of risk group 3 viruses, which include flaviviruses, togaviruses and coronaviruses. They will study viral replication, screen for small molecule antivirals, and genetic determinant of SARS-CoV-2 variants. The protocol has been reviewed by the DURC subcommittee and has been determined to be non-DURC project. Additionally, PI stated that they will monitor and stop work if any of the mutants replicate better than the wild-type viruses and report to the EHS, IBC, and DURC subcommittee. In this renewal PI removed their previous plan of working with poliovirus and added use inactivated lysates from cells infected with SARS-CoV-2, MERS-CoV, Chikungunya and Yellow Fever Virus. Work is done with each virus separately so that the possibility of cross-contamination is eliminated. It was noted that SARS-CoV-2 culture work may now be carried out in BSL2 containment, but the PI decided to carry out culture work with previously created chimeric or mutated SARS-CoV-2 still in BSL3. Detailed project description also lists information on PPE and waste disposal (SOPs), which all are appropriate. ROHP confirmed that vaccines for chikungunya and yellow fever virus are available and all members of the lab have been offered the vaccines. The following will be communicated to the PI:

- Please add list of the genes to be manipulated in mutant viruses (as listed in the body of the project description section) in response to the first question of the eukaryotic experiments.

Motion: Conditional Approval (Admin Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

4. Bhz-Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1823	Nancy Sullivan	Storage, Propagation, and Distribution of BSL3 Select Agent Emerging Pathogens	3	N/A	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Robin Ingalls

Applicable NIH Guidelines: N/A

Meeting Comments: The original objective of this protocol was to store and distribute risk group 3 select agents of both viral and bacterial origin. In this amendment PI's group have proposed expansion of this protocol to include propagation and characterization work for the select agent MPOX virus of undetermined or Clade I origin. They will conduct assays to test viability and purity of the stock and their suitability for future antiviral and therapeutic candidate testing. All personnel working with the MPOX Clade 1 virus have strong BSL3 training. All SOPs for waste disposal are listed, and agent-specific inactivation procedures are also listed. The PPE to be used during handing the listed agents are also appropriate. The committee requested clarification on whether they plan to propagate all select agents listed on the protocol or just the MPOX viruses. The medical director clarified that ROHP offers 2 doses of Jynneos vaccine to anyone working with MPOX which needs to be renewed every 2 years. For anyone working with replication competent vaccinia virus, the same Jynneos vaccine is also offered by the ROHP (instead of ACAM2000 vaccine) but in that case it needs to be renewed every 10 years. The following will be communicated to the PI:

- Please state briefly in the project description what type of studies are planned for the "characterization of the virus".
- PI needs to state that Jynneos vaccine provided by the ROHP offers protection against the MPOX.
- Please state that the Lab will post signage when MPOX work is being done, so that any unvaccinated personnel do not enter the work area.
- The description of the virus propagation work appears to be non-specific. Is the PI also planning to grow other listed RG3 agents? Please state specifically which virus or viruses or bacteria will be propagated.
- Since EHS/IBC/BPHC approval is necessary for the establishment of an inactivation protocol for MPOX virus, please state that no MPOX virus-associated material will be taken out of the BSL3 suite before the approval of MPOX virus inactivation protocol.

Motion: Conditional Approval (Admin Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

5. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2387	Andrea Geisz	Mechanisms of trypsin activation in Pancreatitis	2	1	BUMC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: M. Mazur

Applicable NIH Guidelines: Sections III-D-4-a and III-E-1

Meeting Comments: This protocol studies the pathogenesis of acute and chronic pancreatitis at the molecular level using transgenic mouse model specifically looking at the role of trypsinogen activators. This amendment is to add the use of recombinant DNA techniques, particularly adeno-associated viral vectors for the expression of recombinant protein in mouse model. PPE and chemical reagent handling descriptions appear adequate for the risk level. The rDNA work is described with appropriate disinfection and safety mechanisms in place. No safety concerns were identified. The following will be communicated to the PI:

- For [redacted], please complete the Overall experience, Where and When experience and Experience related to the current work sections.
- [redacted] also needs to complete the rDNA/IBC policy Training.

● It is not clear how liquid waste will be disposed of. In the liquid waste section, it only describes how surgical instruments are disinfected. Treatment of liquid waste, disinfectant percentage, exposure time and mode of disposal must be mentioned. ● If you are using HEK293 cells in the lab, it must be mentioned in the Hazardous biological agent list. ● In the Recombinant DNA section, prokaryotic and eukaryotic experiments, donor section, please list names of the human and mouse genes to be used in the project. ● AAV must be added to vector packaging system (to detail the source, name of the vector, replication competency and how they are packaged). ● Answer questions 15 and 16 to indicate the defective and replication-incompetent nature of the viral vector. ● Add "Sections III-D-1-a, III-D-2-a, III-D-4-a and III-E-1" to the Applicable NIH guidelines question.

Motion: Conditional Approval (Admin Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

V. 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.