Boston University
Institutional Biosafety Committee (IBC)
October 22, 2024 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 1:32 PM

Members Present:	R. Ingalls, R. Davey, E. Muhlberger, W. Lu, P. Liu, J. Celenza, E. Loechler (Joined 12:59 PM), T. Winters, R. Morales, N. Dey, C. Thurman, J. Keeney, V. Britton, S. Ghosh
Guests Present:	A. Henderson, P. Richmond, A. Ahmad, A. Broos-Caldwell, A. Ellis, J. Wood
Staff Present:	C. McGoff, L. Campbell

I. Review of September 17, 2024 IBC Public Meeting Minutes

No concerns were voiced.
Motion: Approved
For: 13; Against: 0; Abstain 0; Absent: 1

II. Chair's Report

J. Celenza was introduced as a new member of the committee.

III. New Business:

A. Review of Revised BU Policy on Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in Research:

S. Ghosh provided an overview of recent changes to BU's Policy on Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in Research, and updates to the federal policy related to these revisions. Members were reminded to contact the IBC office before the meeting if there are concerns about responses to DURC questions, or are reviewing a protocol that may contain information to indicate DURC material. Members were also informed that the IBC office will be updating RIMS to reflect relevant policy changes; members should contact the IBC office with any questions about the DURC/PEPP Policy changes.

B. Research Occupational Health Program (ROHP) and Environmental Health and Safety (EHS) Report:

Members were provided with information on two (2) September 2024 incidents. Members were informed that EHS has established a policy for laboratories that have only used noninfectious BSL1 materials in their biosafety cabinets (BSCs). EHS will work with the IBC office on updating the Biosafety Manual with a description of this process.

IV. Protocol Review

1. Bhz –New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2661	[redacted]	Effect of antiretroviral therapy on mitochondrial function	2+	N/A	BUMC
Primary Reviewer: Andy Henderson (Adhoc)		Secondary Reviewer: Sajal Ghosh			
Applicable NIH Guidelines: N/A					
Meeting Comments: This new protocol that investigates how long-term use of antiretroviral therapy (ART) is related to wide range of metabolic abnormalities as well as aging and other HIV infection related illnesses. Since ART use is related to mitochondrial dysfunction of mitochondria, which is the organelle for production of cellular energy, reduced mitochondrial function maybe directly related to HIV-related illnesses. This protocol will investigate how different type of antiretroviral drugs such as nucleoside reverse transcriptase inhibitors (NRTIs); non-nucleoside reserve transcriptase inhibitors (NNRTIs); protease inhibitors (PIs); and integrase strand transfer inhibitors (ISTI)) interferes with mitochondrial function and capacity. They will treat human cell lines (CEM and SH-SY5Y) and PBMCs from HIV infected and normal healthy controls with various antiretroviral drugs and will assess changes in					

mitochondrial functions (ATP production, enzyme activities, respiration/membrane potential, DNA content, gene expression) and DNA sequencing. FACS analysis and cellular imaging will be done through BU core facilities. No blood samples from patients are collected at this time. PI will use previously collected blood sample (obtained through Yale University IRB protocol). The protocol clearly describes each major experimental approach, associated hazards and risk mitigation plans. Work with uninfected cells will be done in BSL2, whereas work with HIV-infected patient cells will be done with BSL2+ practices. HIV-infected and uninfected waste will be handled separately with special practices to dispose BSL2+ solid wastes. Bleach and Cavicide disinfectant spray will be used for surface disinfection. Storage of BSL2 and BSL2+ materials in entry restricted spaces are stated. There will be no HIV culture work and there will be no recombinant DNA work. It was noted that this was a well-written straightforward protocol.

The following will be communicated to the PI:

- The Overall Experience section for the PI describes research accomplishment, but we are looking for information on actual hands-on experience and expertise on the type of work proposed in the protocol.
- PI needs to complete rDNA/IBC Policy training and needs to secure ROHP clearance.
- Please clarify the need of using BSL2+ facility for your work. Are PBMCs from long-term ART users are still capable of making virus when cultured? If you wish to work in BSL2+ environment anyway, IBC has no concerns. We just need your rationale for such choice.
- Please clarify what are your control samples. Are they PBMCs from HIV+ patients but not with ART or PBMCs from healthy uninfected volunteers?
- If you are not going to be culturing HIV, please indicate so. If so, remove HIV from the hazardous biological agent list.
- Section VIII.8 – Bleach should be 10%, freshly made.
- For the transportation of biohazardous materials to the outside of the lab, please make sure they are packaged in leak-proof and shatterproof container so that wearing PPE outside the laboratory is not necessary. Please add appropriate commentary.

BUA Site Assessment: Dr. [redacted] lab is providing personnel training for working in BSL2+ facility. PI does not have any plan to culture any HIV and is not collecting any patient PBMC here in BU. PI needs to complete rDNA/IBC policy training.

Motion: Conditional Approval (Admin Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

2. rDNA/Bhz – 3-year Renewal (Re-review)

BUA	(PI)	Title	BSL	ABSL	Campus
1670	[redacted]	Synthetic biology and automated culture platforms for cellular systems	2	N/A	CRC

Primary Reviewer: John Celenza	Secondary Reviewer: Sajal Ghosh Additional Reviewer: Ron Morales

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-5, III-E-1; Appendix L-II-A (BSL1-P)

Meeting Comments: The three-year renewal of this protocol already had been reviewed in the September 2024 IBC meeting, but it was suggested that this protocol receive a second review in line with the IBC program self-assessment that will be reviewing processes and procedures, as well as ensuring compliance with all relevant state and federal regulations. This protocol investigates how cells make decision on how to regulate its global transcription based on environmental cues or epigenetic memory. To do this the regulatory regions in DNA sequences and coding regions of genes obtained from variety of prokaryotic and eukaryotic species including plants, are modulated *in vitro* using viral vector or CRISPR/Cas9 technology and then introduced back in yeast or human cell lines or model plants to study how cells adapt to the changes in phenotype. For the plant rDNA work they do whole plant transformation in model plants *Arabidopsis thaliana* Col-0 or *Nicotiana benthamiana* using *Agrobacterium tumefaciens* bacteria as a vector and grow them in a dedicated [redacted] room in Charles River Campus. EHS has also reviewed the [redacted] room and found

the room to be clean and nicely maintained for their work. Any spill of water or soil are promptly cleaned. All used plant and soil hand put in red biohazard bag and marked for incineration. The grow the both wild type and hybrid plants to the stage of flowering and seed formation. They use HEPA-filter attached vacuum pump to clean dusts and flower petals and also sticky pad for blocking spread of fungal gnats. The methods and risks involved are described adequately with the necessary precautions given.

The following will be communicated to the PI:

- ROHP clearance (BSL2 level) update necessary for [redacted].
- Please specify which specific members have plant research experience.
- Brief Project Description needs to include short statement of plant work.
- Plase state briefly, what plant genes will be modified for what additional genes will be expressed in plants.
- Since seeds will be collected from genetically modified plants, please clarify if there could be any gene-drive effect.
- Please use PPE (lab coat and gloves in the plant room and leave them their before exit).
- Please mop any liquid spill with detergent soap as appropriate.
- Develop a [redacted] Operations Manual. The manual should describe cleaning of the room, disposal of whole plants, personal protective equipment used and role of Facility and Management for that room..
- Ensure PPE are available and used. Recommend use of disposable gowns, gloves, and safety glass (as necessary)
- Use wet vacuum equipped with HEPA to vacuum floor after working with flowering plants.
- Post BSL1-P sign on entrance door and indicate “Authorized Personnel”.
- Implement a pest control program by a contract and licensed pest control vendor.
- For the recombinant DNA experiments, can the specific Agrobacterium strain be listed? Most researchers use GV3101; plants vectors are not listed.
- Since the *E. coli* ATCC 35150 produces shiga toxin 1 and 2, it is considered a laboratory acquired infection agent. Its use will require special safety training for the lab members. Dr. [redacted] provide this training to the lab.

Motion: Conditional Approval (Admin Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

3. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2468	[redacted]	Biomechanics of Proximal Femur	2	N/A	CRC

Primary Reviewer: Pinghua Liu	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: N/A

Meeting Comments: This lab studies proximal (neck of femur) femur fracture etiology. They will perform mechanical testing of cadaveric femurs to capture its stiffness and failure load during sideways falls. Digital Image Correlation (DIC) will then be employed to compute surface strains and displacements, which will be compared with the simulation results to observed regions in the femur that are experiencing high strain concentrations. They obtain hip models from orthopedic surgeons who performed arthroplasty and cadaver femurs that are anonymized.
This data will help predict risks from patients with osteoarthritis. They will use all bloodborne pathogen standard precautions applicable as they are working with unfixed tissue. Personal protective equipment proposed for the work is appropriate. Liquid and solid waste are disposed of properly. Disinfection of instruments is done by soaking in 10% bleach for 30 minutes and 70% ethanol is used to clean surfaces. It was noted that this protocol is straightforward and well-described. The following will be communicated to the PI:

- Please complete the Overall experience, where and when and project related experience section for the PI.
- Please describe briefly where are these unfixed human tissue samples are obtained and how they are brought to the laboratory.
- It is stated in the protocol that X-ray MRI scanning will be used. However, there is no description of those activities in the procedure section. Please provide a brief description of their use and the use of personnel protection in those procedures.

BUA site Assessment: The lab uses X-Ray for x-ray diffraction studies. They have a steel bench for their work with bone samples. They use Tyvek coverall, safety glasses and face shield, but they do not use any additional shield in front of them. [redacted] rDNA/IBC policy training have expired.

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

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.