Boston University
Institutional Biosafety Committee (IBC)
May 20, 2025 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 12:59 PM
Meeting Open

Members Present:	R. Ingalls, R. Davey, E. Muhlberger, I. Afasizheva, W. Lu, V. Gouon-Evans, T. Winters, E. Loechler, X. Brown (joined 12:04 PM), N. Dey, C. Thurman, M. Mazur, J. Keeney, R. Timmerman (joined 12:14 PM), S. Ghosh
Guests Present:	P. Richmond, A. Ahmad, A. Ellis, J. Wood, T. Killeen, M. Fitzgerald
Staff Present:	C. McGoff, L. Campbell

I. Review of April 15, 2025 IBC Meeting Minutes

No concerns were voiced.
Motion: Approved
For: 9; Against: 0; Abstain: 4; Absent: 2

II. Chair's Report:

Members were informed that the LAI list has been updated following the discussion at the recent LAI meeting.

III. New Business:

A. IBC Office Updates: Members were informed that information regarding DURC and the Boston University DURC policy have been updated on the IBC website, based on a recent presidential executive order; new guidelines from the current administration are expected within 120 days.
B. Review of Research Occupational Health Program (ROHP) Report and Environmental Health and Safety (EHS) Report: One incident from April 2025 was reported and presented to members for review.

IV. Protocol Review

1. Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2640	Nancy Sullivan	Evaluation of medical countermeasures in non-human primates	4	4	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Valerie Gouon-Evans Additional Reviewer: Bob Timmerman

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol describes ongoing evaluation of vaccines and therapeutics for Risk Group 4 (RG4) pathogens. The work uses non-human primate (NHP) models including cynomolgus or rhesus macaques, and African green monkeys, following standardized ABSL-4 procedures. Vaccine efficacy will be assessed by pre-challenge immunization with candidate vaccines including vectored, protein subunit, nucleic acid, and live attenuated platforms. Antibody and small molecule therapeutics will be evaluated by administering them pre- or post-exposure of animals to the RG4 pathogens. Efficacy is evaluated via clinical monitoring, virologic and immunologic assays, and postmortem analysis. This amendment is to expand these studies to include Mpox Clade I virus which are normally RG3 agent but with increased human pathogenesis. PI requests to work with this virus at BSL4 according to the procedures detailed in IBC protocol 2620 where all ARS personnel are trained specifically at BSL4. This protocol appropriately focuses on procedures conducted by laboratory staff, including viral stock preparation and sample processing. These procedures adhere to BSL-4 standards and cite all relevant SOPs. The project does not meet DURC/P3CO criteria, and appropriate biosafety procedures and mitigation plans are in place. The following will be communicated to the PI:

- The BBP and Chem safety training need to be updated for [redacted].

- ROHP recommends vaccination for anyone working with Mpox virus and they have already communicated with all members of this protocol. Please make sure that all members communicate back to ROHP about this vaccine or sign declination form before starting the work.
- Remove the name of Dr. [redacted] as shared PI for the room [redacted].
- Please state that all additional laboratory personnel will be trained on agent-specific procedures by experienced mentors to ensure readiness and compliance.
- Plaques assays involve Vero cells, which are NHP-derived and should be listed under biohazardous materials.
- This protocol will not require annual renewal in the year 2026, but amendment may be submitted anytime as needed.

Motion: Conditional Approval (Admin Review)	For: 13	Recuse: 0	Against: 0	Abstain: 2	Absent: 0

2. rDNA/Bhz –Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2620	Colleen Thurman	NEIDL Animal Research Services: Animal Projects in A/BSL4	4	4	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Weining Lu

Applicable NIH Guidelines: III-D-4-a.

Meeting Comments: This protocol describes various procedures that Animal Research Service (ARS) provide to investigators in the NEIDL in various animal experiments involving risk group 4 pathogens. The ARS provides animal care, inoculation with the pathogen of interest, dosing or administration of a therapeutic candidate where applicable, clinical observation, *in vivo* sampling, clinical pathology analysis, euthanasia, and, in conjunction with the NEIDL Comparative Pathology Laboratory, necropsy and tissue sampling. The protocol also describes detail training that ARS members have gone through so that they can perform the experiments safely. This amendment updates the list of ARS personnel providing animal research support in the NEIDL ABSL-4 facility. The amendment also adds Mpox Clade I virus for planned studies in Fall 2025. Though an BSL3 agent, Mpox virus will be treated under BSL-4 containment for the purpose of having well trained staff performing the work who have been trained at BSL4. The protocol now also reference Non-clinical Study Unit SOPs (NSU-SOP) as part of institutional SOP management migration. The following will be communicated to the PI:

- Please update the biosafety cabinet certification dates.
- Please Indicate BSL for SARS-CoV-2 as BSL-2 in the hazardous biological agent list.
- Change the agent name Monkeypox virus to 'Mpox virus' or 'MPXV' in the agents list. The desired name or BSL status of an agent may be typed out instead of choosing from the drop-down available list.

PI recused herself from the voting.

Motion: Conditional Approval (Admin Review)	For: 14	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

3. rDNA/Bhz –Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2375	Robert Davey	Evaluation of treatments for high containment viruses using animal disease models	4	4	BUMC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Sajal Ghosh Additional Reviewer: Jim Keeney

Applicable NIH Guidelines: Sections III-D-1-a, III-D-4-a, and III-D-4-b.

Meeting Comments: The objective of this protocol is to identify inhibitors of the most virulent high containment virus infections (including filoviruses, bunyaviruses, hantaviruses and pathogenic coronaviruses) using animal models, including rodents, ferrets, and possibly monkeys. The protocol provides detail step-by-step reviews of the collection

of these viruses and their storage. Steps involving inoculations with inhibitors into test animals; their treatments, observations, euthanizations, necropsies and methods of analysis of results are also described. Various NEIDL-specific SOPs incorporated into this research are described. Biosafety cabinets are used for both *in vitro* infection work as well as for animal inoculations and are done in either BSL4 lab or in ABSL4 lab, as appropriate. Disinfection techniques, such as use of either 10% bleach for 30 minutes or 5% Macrochem Plus, for 10 minute exposures, are well described and are appropriate for the proposed work. Personnel list has been updated in this 3-year renewal and detail training of individual members, as appropriate for this protocol, has been updated. The following will be communicated to the PI:

- Please remove [redacted] name from shared PIs name list in Section IV.
- Please correct the percentage number typos in the 1st paragraph of the Laboratory procedure section.
- It is not clear if the ferret work is covered by BSL-4 SOPs. Please clarify or provide appropriate SOP numbers for this work. If there are any distinct procedures that only apply to the work with ferrets in contrast to the work with rodents or NHPs, those should be described.
- A brief description of Bayou virus, Monongahela virus, and New York virus should be provided in the Laboratory Procedures section.
- Andes virus should be added to the Hazardous Biological Agents list. If it is not used, it should be removed from the Laboratory Procedures section.
- Recombinant DNA section – please specify in the Donor section which recombinant viruses will be used (for example, recombinant EBOV, MARV, etc.).

BUA Site Assessment: This lab has been inspected three times this year and there are no concerns. All biosafety cabinets associated to this protocol are duly certified and all certification dates are available in Scishield.

PI recused himself from voting.

Motion: Conditional Approval (Admin Review)	For: 12	Recuse: 1	Against: 0	Abstain: 2	Absent: 0

4. rDNA/Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2642	Nancy Sullivan	Propagation and Characterization of Risk Group 4 viruses	4	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Sajal Ghosh

Applicable NIH Guidelines: Section III-D-1 and Section III-D-1-c

Meeting Comments: The goal of this protocol is to grow stocks of highly pathogenic viruses such as Filoviruses, Arenaviruses, Bunyaviruses, Paramyxovirues as well as Mpox viruses and SARS-CoV-2 viruses in BSL4 containment and characterize their authenticity so that they are ready to be used for downstream experiments, particularly for the development of new therapeutics, as vaccine candidates, and for quantitation of neutralizing antibodies. Protocol also involves virus quantitation in blood or plasma from infected animals. No significant changes have been made in this annual renewal, except for the update on biosafety cabinet certification dates. The following will be communicated to the PI:

- It is stated in the section on SARS-CoV-2 that "SARS-CoV-2 is classified as a BSL-3 agent, so we plan to handle it in BSL-3 containment. However, some samples were originally generated in the BSL-4 and cannot be moved to lower containment levels. We would like to amend this protocol to include SARS-CoV-2 for processing these samples. All work and inventory management will be the same as for the Risk group 4 viruses." Please update to reflect that SARS-CoV-2 is now classified as a BSL2 agent.

• Since this is a BSL4 protocol, IBC recommends to keep all virus stocks (including that of Mpox virus and SARS-CoV-2 in the in BSL4 containing. But do refer that dedicated BSL2 protocol also exists to work with SARS-CoV-2 viruses that never entered BSL3 or BSL4 containment. • This protocol will not require annual renewal in the year 2026, but amendment may be submitted anytime as needed.					
Motion: Conditional Approval (Admin Review)	For: 15	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.