Boston University
Institutional Biosafety Committee (IBC)
August 19, 2025 Meeting Minutes
Meeting is Open
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 2:00 PM

Members Present:	R. Ingalls, R. Davey, I. Afasizheva, P. Liu, W. Lu (joined 12:14 PM), J. Celenza, N. Dey, C. Thurman, M. Mazur, J. Keeney, R. Timmerman (joined 12:06 PM), V. Britton, S. Ghosh
Guests Present:	C. Fernald, J. Wood, P. Richmond, M. Fitzgerald, B. McKinney, T. Killeen
Staff Present:	C. McGoff, L. Campbell

I. Review of July 15, 2025 IBC Meeting Minutes

No concerns were voiced.
Motion: Approved
For: 10; Against: 0; Abstain: 1; Absent: 2

II. Chair's Report: Nothing to report.

III. New Business:

A. IBC Office Updates: Members were encouraged to attend the IBC Public Meeting, which will be held on September 16, 2025.
B. Review of Research Occupational Health Program (ROHP) Report and Environmental Health and Safety (EHS) Report: One incident from July 2025 and the corrective action that was taken was reported and presented to members for review, and the incident was reported to the BPHC. No concerns were voiced.

IV. Protocol Review

1. rDNA –New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2581	Diane Joseph-Mccarthy	Bioengineering Technology & Entrepreneurship Center (BTEC): Molecular, Cellular, & Tissue Engineering Suite	1	N/A	CRC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Sajal Ghosh		
Applicable NIH Guidelines: Section III-E-1 and Section III-F-8 (as detailed in Appendix C).					
Meeting Comments: This protocol from Bioengineering Technology & Entrepreneurship Center (BTEC) is linked to the course work that will train students in standard cloning techniques in bacteria and yeast, such as isolation of genomic DNA, restriction enzyme digestion, plasmid transformation, and SDS-PAGE electrophoresis. Only BSL1 organisms are being used for the rDNA work, including lab E coli strains and Saccharomyces. Members were reminded that this protocol was previously reviewed at the July 2025 IBC meeting and was reviewed again in this meeting to clarify the role of Dr. Brown in the protocol and earlier review assignment for this protocol. It was noted that Dr. Brown will provide training for personnel unfamiliar with the techniques, but is not part of BTEC or teaching in the course; the IBC Chair and members were asked to					

review and vote again on the protocol to ensure the integrity of the vote. One modification was requested as a result of this re-review. The following will be communicated to the PI:

- Please complete the question on where and when the experience was received and the question on experience relevant to the current protocol.

BUA Site Assessment: The site assessment for this laboratory was already completed in the July 2025 meeting indicating appropriate compliance with all safety requirements.

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

2. rDNA/Bhz –New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2698	Nadia Storm	Non-Clinical Studies Core- BSL2/ABSL2 support	2	2	BUMC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Colleen Thurman Additional Reviewer: Jim Keeney

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

Meeting Comments: This protocol provides procedural support for both preparatory and post response laboratory work required for evaluating new medical countermeasures against highly pathogenic risk group 4 viruses. The countermeasures will be tested in both cell culture work and in animal models including mice, guinea pigs and hamsters. No live RG4 viruses will be handled in this protocol. The protocol includes immunizations with VSV vectors expressing viral components, blood sampling and monitoring as well as downstream processing of inactivated cell and tissues derived from animals infected with RG4 agents in other approved ABSL4 protocols. Individual laboratory procedures are described in detail. All cell culture work will be done in biosafety cabinets in BSL2 containment. Disposal of liquid and solid wastes are described and are appropriate. The following will be communicated to the PI:

- It is stated that inactivated material will be used for plaque assays; inactivated material won't contain infectious virus and therefore plaque assays cannot be performed. Please clarify.
- Please confirm that recombinant VSV will only be used for infection studies and not for cell culture studies, such as titration assays.
- It is indicated in the sharps section that DNA will be excised from agarose gels, but this protocol does not cover any cloning work. Please clarify or modify the response to the question in PPE section VIII.6
- Will the samples from the BSL2 animal studies be analyzed as described for the inactivated BSL4 samples? If this is the case, please add analysis of BSL2 animal samples to the protocol.
- Please add all recombinant VSV clones that will be used (pseudotyped with filovirus, henipavirus surface proteins – anything else, e.g., arenaviruses, nairoviruses?).
- Since there are concerns that replication-competent VSV pseudotyped with NiV glycoproteins F and G might target neurological tissue potentially leading to disease, the following information should be added: "Additional precautions will be taken with all work done with VSV expressing henipavirus F+G glycoproteins. These include the use of N95 face masks and face shields as well as restricted access to the space during the procedures."

- Committee recommends adding statement on “test substance administration” in addition to vaccination procedures as because the summary statement includes therapeutic candidates as well as vaccines.
- Please note that normally lab coats and disposable gloves are all that is required for ABSL2 work in appropriate containment equipment (downdraft table or BSC). Since this is for rodent studies, they would be performed on or in one of those types of equipment. Head cover, masks or eye protection may be added on a project-specific basis, but would not be standard. Facility scrubs and shoes are used in lieu of disposable scrubs and shoe covers by ARS personnel working with animals.
- Uncheck “Eukaryotic experiments” if rVSV is exclusively used for animal experiments. If it is also used for cell culture experiments (e.g. titration assays), the “Eukaryotic experiments” section must be completed.
- Committee recommend unchecking “Vector Packaging System” to avoid confusion. rVSV is a recombinant virus expressing glycoproteins from other viruses. It is not a typical vector packaging system used to transport genetic material into cells.
- It is checked that defective viral vectors will be used in this study. It is not clear which defective vectors will be used. Please clarify or uncheck this box.

BUA Site Assessment: Most of the proposed work will be done in NEIDL BSL2 rooms that have appropriate engineering controls and duly certified biosafety cabinets. Biosafety training for all listed members are current.

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

3. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
690	Vladimir Botchkarev	Molecular mechanisms of skin development, growth, and regeneration	2	2	BUMC

Primary Reviewer: Weining Lu	Secondary Reviewer: Colleen Thurman

Applicable NIH Guidelines: Section III-D-2, Appendix B-II-D, G-II-B

Meeting Comments: The goal of this protocol is to study skin cell gene expression regulation and DNA methylation using *in vitro* and *in vivo* animal studies to uncover molecular mechanisms that support efficient skin regeneration, prevent fibrosis and resist carcinogenesis. They study transcriptional control, chromatin remodeling and cytoplasmic signal transduction using inactivated CRISPR-based epigenome editing, working with hazardous chemical 7,12-Dimethylbenz[a]anthracene (DMBA), analysis of RNA/DNA modifications as well as other molecular biology techniques. The protocol describes each laboratory procedures associated safety concerns and mitigation plans in great detail, which are all appropriate. All procedures involving carcinogens DMBA are performed in chemical fume hoods and biological safety cabinets, with proper decontamination and disposal of contaminated materials. In addition, staff training and supervision are regularly monitored to ensure compliance with safety practices and to reduce exposure risks. N95 respirators are worn while transporting animal cages from their rack to the fume hood. Other safety protocol includes washing hands immediately after procedures and potential exposure, and decontamination of work surfaces after each use. The following will be communicated to the PI:

- BBP training needs update for [redacted], [redacted], and [redacted].
- ROHP clearance update needed for [redacted].

- Multiple entry for Lentivirus vector is not necessary in the Hazardous biological agent list. The lentiviral packing plasmids, gRNA expression vectors or d-Cas9 constructs are better placed in the rDNA section only.
- IACUC [redacted] is now [redacted] approved through 3/7/2027. Please update this information in the protocol.
- Animal experiments in Section H should include updated IACUC numbers and approval dates (5 currently approved protocols: [redacted], [redacted], [redacted], [redacted], [redacted]).

BUA Site Assessment: Biosafety cabinets and fume hoods are duly certified. Lab [redacted] needs to be added to the protocol as a -80°C freezer there is in use The lab mentioned that they decontaminate their instruments by dipping them in 10% bleach for a short time and then they autoclave them. The lab mentioned that they use N95 respirator for transporting animal cages from rack to the fume hood. Some personnel training needs to be updated.

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

4. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
734	Ella Zeldich	Neurogenetic Processes in the Fetal Neocortex	2	N/A	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Sajal Ghosh

Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-E-1

Meeting Comments: The goal of this protocol is to investigate how chromosomal trisomy found in individuals with Down's syndrome (DS) affects the development of the brain. They are using different approaches in their protocol which include use of a) differentiated iPS cells that originated from individuals with DS, 2) 3D organoid culture derived from DS iPS cells, and 3) fixed frozen brain tissues from DS and Alzheimer's Disease patients. AAV and lentiviral vectors are used to overexpress or downregulate proteins of interest in their studies. CRISPR editing as well as deltaCas9-mediated transcriptional activation technique will also be used. All work involving lentiviral vectors and human frozen brain samples will be performed in a biosafety cabinet by trained personnel using appropriate personal protective equipment. Sources of iPS cells, frozen brain tissues, viral vectors are clearly described. Disposal of solid and liquid waste, including that of brain tissues are described and are appropriate. Personnel training for working in BSL2 lab, with viral vectors, human brain tissues seem appropriate. The following will be communicated to the PI:

- BBP training required for [redacted].
- Scalpel blades are not used in cryostat machine. Please correct this statement.
- Please indicate that disinfection of human brain tissue wastes will be done by treating them with 1N sodium hydroxide or 40% bleach solution for 1 hour or longer.

BUA Site Assessment: Biosafety cabinet and fume hoods are duly certified. Human brain samples are not disinfected with 1N NaOH or 40% Bleach. EHS recommended the lab to dispose of these brain samples properly packaged in a double red lined Biowaste box and mark the box for incineration. Disposable blades were used in the cryostat instead of scalpel blades as mentioned in the protocol.

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

5. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2562	Philip Strandwitz	Discovery and development of therapies and consumer products derived from the human microbiome	2	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: Section III-D-1-a and Section III-D-2-a.

Meeting Comments: This renewal is from a tenant company Holobiome in the [redacted] building who plans to build a map of how gut bacteria affect human health to develop new microbiome-based drugs and functional foods. Biohazards include human feces; the bacteria isolated from human feces samples, some of which could be human pathogens; and human cells and cell lines. Rodent tissues from collaborators that contain mouse/rat feces are also used. The protocol lays out the biohazards, associated risks, and precautions taken in terms of PPE. This is mostly handling human feces and growing bacteria in small broth cultures. Experimental approaches are logical and described well. Some bacteria will be prioritized for additional studies. The rDNA work involves knocking out genes in bacteria using standard molecular biology techniques. Changes in this renewal include additional bacteria that will be studied, none of which change the risks associated with the protocol, which remains BSL2. The following will be communicated to the PI:

- If additional researchers are working in the protocol, please add them in the personnel list.
- Please update the 'Overall Experience', 'Where/When Experience' and the 'Related Experience' section for all listed members.
- Please add room [redacted] (for autoclave and dishwashing).

BUA Site Assessment: Biosafety cabinets are duly certified. All safety trainings are current. The principal investigator will update the list of laboratory personnel on the protocol application and may add room [redacted] (autoclave/dishwashing room) for procedures relevant to this application. PPE, including lab coats, gloves, and eye protection, will be worn as appropriate, and the lab is equipped with a fume hood, spill kit, safety shower, and eyewash station for emergency response.

Motion: Conditional Approval (Admin Review)	For: 13	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.
No opinions were voiced.