



Boston University
Institutional Biosafety Committee (IBC)
June 17, 2025 Meeting Agenda
Open to public
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 1:39 PM

Members Present: R. Ingalls, R. Davey, E. Muhlberger, I. Afasizheva, P. Liu (joined 12:05 PM), T. Winters, X. Brown, R. Morales, N. Dey, C. Thurman, M. Mazur, J. Keeney, R. Timmerman (joined 12:04 PM), V. Britton, S. Ghosh
Guests Present: P. Richmond, A. Ahmad, C. Fernald, J. Wood
Staff Present: C. McGoff, L. Campbell

I. Review of May 20, 2025 IBC Meeting Minutes

No concerns were voiced.

Motion: Approved

For: 12; Against: 0; Abstain: 1; Absent: 2

II. Chair's Report:

Members were informed that Dr. Nancy Sullivan has stepped down as Director of the NEIDL, and IBC Vice Chair, Dr. Rob Davey, is now the interim Director of the NEIDL.

III. New Business:

- A. IBC Office Updates: Members were informed of changes made to the IBC application in RIMS. Members shared their thoughts about the questions in the new section on collaboration with countries outside the U.S.
- B. Review of Research Occupational Health Program (ROHP) Report and Environmental Health and Safety (EHS) Report: Two incidents from May 2025 and the corrective actions taken were reported and presented to members for review. Both were reported to the BPHC.

IV. Protocol Review

1. rDNA/Bhz – 3-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
662	Maria Kukuruzinska	The Role of E-cadherin N-glycans in Oral Cancer	2	2	BUMC
Primary Reviewer: Elke Muhlberger			Secondary Reviewer: M. Mazur		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a; III-D-4-a; III-E-1					
Meeting Comments: The goal of this study is to have a better understanding of molecular interactions between Wnt/beta catenin signaling and cancer stem cells in the development of oral squamous cell carcinoma (OSCC) and their progression to metastasis. Lentivirus mediated expression of small hairpin RNA is also used to block expression of putative key regulators of signaling pathways of their interest. Work with biohazardous materials including use of 4-nitroquinoline-1-oxide (4NQO) in animals are done in biosafety cabinets wearing lab coat, double gloves, eye protection and face shield/surgical mask as appropriate. Liquid wastes are treated with bleach to a final concentration of 10% and solid wastes are placed in red biohazard boxes, which are sent for incineration by outside vendors. The following will be communicated to the PI: • Please add “Where and When Experience” and “Related Experience” also for all listed members. • [REDACTED] needs to update his rDNA/IBC policy training. If he is not going to be working in the protocol, please remove his name from the list. • Will any animal work be done in any [REDACTED] rooms ([REDACTED] or other)? If so add, add that in the list of rooms. • The layperson’s section is overly technical. Please use simpler language without technical details.					

- Please provide more information in the laboratory procedure section about the used lentivirus system. pINDUCER11 is a plasmid that requires co-transfection with packaging plasmids to generate viral particles. Please describe briefly which other plasmids will be used and how recombinant lentivirus particles will be made indicating replication incompetency. Should be briefly described in the laboratory procedure section and added to rDNA section.
- State which animal work will be done where. Provide information on what animal work will be done in [REDACTED], if any. Confirm that [REDACTED] room doors for animal work and tissue culture work will remain closed while working.
- Since 4NQO is a carcinogen and mutagen, reproductive toxicology concerns and availability of counsel through ROHP need to be mentioned briefly in the laboratory procedure.
- Cloning work and work with *E. coli* K12 should be added to the laboratory procedure section.
- HEK293 cells and lentivirus should be added to hazardous biological agents and in rDNA eukaryotic host.
- 4NQO should be removed from the biological agent list and add in high hazard chemical list.
- Additional plasmids necessary for the pINDUCER 11 system should also be listed in the rDNA prokaryotic and eukaryotic system.

BUA Site Assessment: Personnel list needs to be updated as [REDACTED] will not work in the protocol. Biosafety cabinet is duly certified. Cell lines and lentiviruses needs to be added in the hazardous biological agent list; 4NQO should be removed from this list.

Motion: Conditional Approval (Admin Review + BSO will check animal work space in E-building)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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2. Bhz – 3-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2388	Elisha Wachman	Wachman Perinatal Research Lab 1) COVID-19 Perinatal Project (H-40096 and H-40270) 2) H-43822 - POD (Placental Markers of Opioid Exposure on Development) Study 3) H-43249 - PRIME Study 4) H-32553 - NAS Genetics 5) H-45965 - Discarded Perinatal Sample Project 6) H-45966 - Neonatal Nasal Swab Study	2+	N/A	BUMC

Primary Reviewer: Robin Ingalls

Secondary Reviewer: Pinghua Liu

Applicable NIH Guidelines: N/A

Meeting Comments: This is an umbrella protocol to cover a number of research studies that utilize human samples, specifically mother and newborn samples related to Covid-19, opioid use disorder, genetic mutations, and preterm birth medical complications. Human samples collected in the protocol include infant saliva; infant and maternal urine; breast milk; placenta; infant and maternal blood; infant nasal swabs. No new Covid-19 samples are being collected. All collections take place in BMC space or in the General Clinical Research Unit. They also culture human airway epithelial cells from nasal swabs, and conducts *in vitro* infections of cell lines (HeLa) with RSV and rhinovirus. All research work is carried out in BSL2 lab with BSL3 practices. The committee requested clarification on the virus infection work and experience of the personnel in virological studies. The following will be communicated to the PI:

- Please update 'Related Experience' question to clarify who in particular have experience on working with RSV and rhinovirus. If none have such experience, individuals must get hands on experience from PIs who work on RSV. If the PI has such experience, it must be clearly stated and assured that the PI will train other

members of the protocol on handling RSV and rhinovirus. ROHP is also available to provide such training. Vaccination of the laboratory members may be necessary. Please contact ROHP for clarification.

- [REDACTED] needs to update BBP training.
- [REDACTED] and [REDACTED] need ROHP clearance.
- Please add room [REDACTED] as a laboratory location. Since SARS-CoV-2 is now considered as BSL-2 pathogen for laboratory work and culture work, this protocol no longer require BSL2+ containment.
- Please indicate the concentration of RSV and rhinovirus virus stock that you are receiving from commercial sources and state what MOI you are using in your infection studies.
- Fresh 10% bleach should be used with a contact time of at least 30 minutes instead of 10.
- Please change the highest BSL for the protocol to BSL2 (instead of BSL2+) in Materials Used in Research section.
- Please remove two RSV strains and human rhinovirus 16 from the 'Other Potentially Hazardous Materials' and add them in the 'Hazardous Biological Agent' list.

BUA Site Assessment: BSO communicated to lab personnel that they must wear appropriate PPE (lab coat, gloves and eye protection) while handling BSL-2 samples in the lab and during transportation. Centrifuges are in working condition. Biosafety cabinets and fume hoods are certified. Sharps containers and spill kits are available. As per updated NIH guidelines, this should be a BSL2 protocol. The lab needs to add [REDACTED] as a location. Fresh 10% bleach should be used with a contact time of at least 30 minutes instead of 10. The lab has biowaste box designated for incineration for the disposal of human tissue wastes. RSV and human rhinovirus should be mentioned in the Part IX, section A of the protocol, instead of section B.

Motion: Conditional Approval (Admin Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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3. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2026	Paola Divieti Pajevic	Osteocytes, hematopoiesis, and fracture repair, and Musculoskeletal Cell Core (P30)	2	1	BUMC
Primary Reviewer: Inna Afasizheva			Secondary Reviewer: Colleen Thurman		
Applicable NIH Guidelines: Section III-D-1-a, Section III-D-2-a, Section III-E-1					
Meeting Comments: This protocol investigates role of osteoclast cells in variety of functions of the bone such as bone formation, resorption or during hormonal changes. They perform both <i>in vitro</i> studies on cultured bone cells and <i>in vivo</i> studies on cells isolated from mouse bones. They manipulate expression genes interest by using shRNA, lentiviral vectors or by CRISPR/Cas9 mediated gene editing. In this amendment, they propose to study subset of tissues in transgenic mice using diphtheria toxin. Protocol provides details of the preparation of DT stock solutions, storage, transport of the toxin for the animal studies and disinfection of any spill. The committee requested clarification on disposal of unused toxin solution. The following will be communicated to the PI: • Please specify who has the experience working with diphtheria toxin (DT) in the overall and related experience section. • ROHP clearance is needed for [REDACTED] and [REDACTED]. Update needed for [REDACTED]. • The ROHP recommends users must remain up-to-date with their Tdap vaccination. • Please state if any of the DT injected animal or tissues will be brought into [REDACTED] lab. • State if you have IACUC approval for working with animals in [REDACTED] or any kind of animal work will be done in [REDACTED] for this protocol. • Please check the proposed DT dilution plan. The concentration of the final working solution does not appear to match stated dilution steps. • State if there is any potential for DT exposure to the researchers in the proposed work and if so, what are the mitigation plans.					

• Provide updated biosafety cabinet certification date. • Include statement of bleach treatment for the disposal of unused liquid DT stock or working solution in the liquid waste section. • Include statement of bleach treatment for the disposal of absorbent wipes used in cleaning spilled DT in the solid waste section.					
Motion: Conditional Approval (Admin Review)		For: 15	Recuse: 0	Against: 0	Abstain: 0 Absent: 0

4. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus		
2547	Brianne Connizzo	Matrix Remodeling and Biosynthesis in Fibroblasts	2	2	CRC		
Primary Reviewer: Xin Brown			Secondary Reviewer: Colleen Thurman				
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1							
Meeting Comments: The overall goal of this protocol is to understand the molecular mechanism of regulation of collagen synthesis and turnover in connective tissues and how these processes are altered in injury, disease or natural aging. In this amendment new personnel and two sets of experiments have been added: one set of experiments will selectively eliminate tendon cells in transgenic mice via diphtheria toxin (DT) administration to determine role of specific cell types and one set of experiments will genetically manipulate tendon cells using lentiviral vectors or engineered virus-like particles. The stock solutions of DT will be prepared in biosafety cabinet inside PI's BSL2 lab wearing disposable lab coat, double nitrile gloves and appropriate face mask. All mice injections will be done in biosafety cabinet in the animal facilities. All waste materials contaminated with DT will be disposed of in biohazard waste containers. Liquid waste will be inactivated with 10% bleach for at least 30 minutes prior to disposal. Viral vector particles and virus-like particles will be prepared by departmental colleague who already has appropriate IBC approval. The following will be communicated to the PI: • Please indicate PI's professional title. • Please state who specifically has hands-on experience on the use of DT. • [REDACTED] and [REDACTED] need to complete BBP training in Scishield. • Please note that all members handling DT should have their Tdap vaccination current. • Please double check the DT dose for mouse. Standard dose is 0.5 to 50 microgram/kg body weight. With average mouse weight being 20 grams, the dose is typically 50 to 1000 nanogram per mouse and not as stated in the application. • Check 'Animal handling and cage changing' box. • Complete the Animal PPE questions in section VIII.4 • Mention DT-related disposal processes in both solid and liquid waste disposal sections.							
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.