Boston University
Institutional Biosafety Committee (IBC)
April 25, 2023 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:03 PM End time: 2:17 PM

Members Present:	R. Ingalls (left 1:32 PM), B. Slack, E. Muhlberger, R. Davey I. Afasizheva, X. Brown, W. Lu, V. Gouon-Evans, T. Winters (left 2:03 PM), E. Loechler (joined 1:59 PM), R. Morales (left 1:12 PM), C. Thurman, S. Niemi, J. Keeney, R. Timmerman, V. Britton, N. Dey, S. Ghosh
Guests Present:	N. Sullivan, J. Presedo, G. Madico, T. Killeen, M. Fitzgerald, K. Tuohey, P. Richmond, A. Ellis
Staff Present:	C. McGoff, L. Campbell

I. Review of March 21, 2023 IBC Meeting Minutes

No concerns were voiced.
Motion: Approve
For: 13; Against: 0; Abstain: 4; Absent: 1

II. New Business:

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

III. Chair Report

Dr. N. Sullivan, the new Director of the NEIDL, was introduced.

IV. Protocol Review

1. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2606	Nancy Sullivan	Storage of specimens from filovirus-infected NHP	4	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Rob Davey Additional Reviewer: Guillermo Madico
Applicable NIH Guidelines: N/A	

Meeting Comments: This protocol is from the [redacted]. The overall goal of this project is to store samples from the PI's previous research laboratory at USAMRIID consisting of Ebola and Marburg virus used in nonhuman primate models of infection. Samples will be shipped from USAMRIID to the NEIDL, cataloged, and stored in a secure repository. This protocol will also include propagation of virus for transfer to the PI's future protocols (which have not yet been submitted) and the distribution to other approved investigators. In terms of receipt and storage, this protocol describes how samples will be received, unpacked, barcoded, logged into the FreezerPro catalog, and deposited into a secure -80 or liquid nitrogen freezer. Cultivation of the virus will include propagation by a trained individual on the IBC protocol using cells inoculated inside a BSC. Committee requested changes to clarify the description of the virus cultivation work such as a detailed description of the cells that will be used, the cell culture protocol, as well as clarification of what personnel will be assigned to each procedure (or if this will be done by a future new hire). If viral culture is not yet planned for the immediate future, it recommended that the PI remove the proposal of this section of the protocol and let it remain as a protocol for the receipt and storage of these materials; an amendment can be submitted at a later date to add personnel and experimental details for virus propagation and distribution. It was also indicated that the inactivation step, if clarified, could remain if this is part of the validation and cataloguing process. The following will be communicated to the PI:

Based on the above discussion, it is recommended that the virus propagation work, and the work leading to inactivating the cultivated virus be on hold for now until the issues (listed below) are addressed and the facilities are updated. The following will be communicated to the PI:

- The descriptions of [redacted] and to a lesser extent, [redacted] experience do not provide much detail regarding their expertise with years of experience and actual pathogens worked upon as each relates to the submission. Please provide more detail on these experiences.
- The two listed rooms (#[redacted] and #[redacted]) are for storage of samples only. Which biosafety cabinets will be used for the virus cultivation work? Those rooms should be listed in the protocol.
- The very specific nature of the current title of the protocol will only allow very limited set of activities. It is recommended that the title be broader to allow new viruses to be added or samples from sources other than NHPs can be added.
- For clarification, please define the USAMRIID acronym.
- It is indicated in the brief description and line 1 of the procedures section that PI intend to work only with Ebola viruses, yet in the Hazardous Agents section both Ebola and Marburg viruses are indicated. Please make sure each section is consistent with each other. Please make sure the procedures description includes Marburgvirus.
- If other ebolaviruses such as Sudan, Bundibugyo, etc. will be collected, include them in this proposal as treatment options will change depending on which virus type is being used (while the protocol title remain broader).
- Please add specific language to state that transfer materials from outside sources will occur following approved methods with the oversight of EHS and permission granted by the RO.
- It is important to indicate that all staff on this protocol will have completed training on these SOPs with documentation on file with EHS and that the PI will verify the samples will have been appropriately processed by completion of an inactivation certificate that is also filed with EHS.
- Details are not provided in terms of what cells will be used for viral culture (there are no human or primate cells listed in the biohazard table); there is also no description what virus titer will be used, if or how virus will be otherwise manipulated, etc; and no SOPs are provided for viral propagation.
- Will purification of samples take place? If centrifuge is used, what safeguards are in place to limit aerosols? The scale of cultivation should be minimized to provide sufficient material for characterization but not generate excessive amounts of pathogen. Where will the cultivation take place?
- Please describe briefly how samples will be prepared for the process of inactivation by different listed inactivation methods (how it will be done and where it will be done).
- Use of vortex, homogenization of samples and centrifuge use are indicated in section VIII.1. For BSL4 protocols it is important to describe the processes and safeguards that will be used to prevent aerosolization of the material in the laboratory procedure section as well.
- It is stated in the procedures section that Microchem Plus will be used at 5% to clean up and decontaminate plasticware with an overnight treatment time. The standard time is at least 20 minutes, which is indicated in VIII.7A. Please make the statements consistent.
- In both procedures and in VIII.7 it is important to state that Microchem is only the first part of the decontamination process. To complete the decontamination process solid materials are then autoclaved or liquids are heated in the NEIDL cook tanks. Please make sure this is included in the protocol.
- The process in VIII.7B (disposal of solid wastes) is the material is double bagged, autoclaved and then placed in medical waste boxes after which it is transported for incineration. Please add this language.
- Q10. On storage. Indicate that storage tubes have a seal such as an o-ring to prevent liquid leakage.
- List all individual viruses to be used in the protocol as a separate item in the hazardous biological agent list in Section A (with protocol title still remaining broad).

BUA Site Assessment: EHS is already working on the detailed plans regarding the transport and receipt of samples at the NEIDL and storing them liquid nitrogen freezer. PI does not have immediate plan to start the virus culture work.

Motion: Conditional Approval (Administrative Review if culture work is removed, otherwise member review)	For: 17	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

2. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1888	Elke Muhlberger	Host Response to Filovirus and Henipavirus Infections	4	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Greg Viglianti Additional Reviewer: Guillermo Madico

Applicable NIH Guidelines: Section III-D-1-c, III-D-1A

Meeting Comments: The original goal of this protocol has been to study how cells react to filovirus infection and which cellular pathways involved in the antiviral defense are blocked or activated by filoviruses. The purpose of the current amendment is to add a new subproject in response to an antiviral drug discovery research request to determine if RNA viruses can develop resistance to 4' fluorouridine (4'-FIU) during culture and if so to define the specific phenotypic and genotypic changes. Ultimately this resistance profiling will enhance drug development by demonstrating where the viruses may be better targeted. Because remdesivir is a 4'-FIU analog used in clinical practice for treatment of a number of viral infections, although not for the treatment of Ebola or Marburg, this amendment has been reviewed by our internal DURC/P3CO subCommittee. It was noted that the DURC/P3CO subCommittee met on April 13, 2023 to discuss this amendment to IBC protocol. The subCommittee unanimously determined that since 4'-FIU is not currently a "clinically and/or agriculturally useful prophylactic or therapeutic intervention" the experiments do not meet the definition of DURC. Similarly, experiments proposed to construct recombinant viruses between Reston virus and Ebola virus are not, *a priori*, expected to "enhance the harmful consequences" of the virus and the subCommittee therefore unanimously felt that they do not meet the definition of DURC. It was noted that all experiments will be carried out under BSL-4 containment. It was also noted that, according to the procedures of the DURC/P3CO Committee, should any viral variant or recombinant virus prove to have enhanced replication kinetics or pathogenicity the PI will cease all experiments and report to IBC staff, EHS staff, and and the IBC will be notified immediately.

It was indicated that the NEIDL Scientific Safety Officer has contacted the Federal Select Agent Program (FSAP) Intragovernmental Select Agent and Toxin Technical Advisory Committee (ISATTAC) seeking their advice on whether the proposed experiments included in the amendment are "restricted experiments" under FSAP rules. A decision from the ISATTAC is expected in mid-May. Depending on the Committee's findings, the DURC/P3CO subCommittee will reconvene to discuss next steps.

PI recused herself from voting.

Motion	For	Recuse	Against	Abstain	Absent
Conditional Approval (Member review once CDC comments are available)	16	1	0	0	1

3. Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2356	Anthony Griffiths	Testing medical countermeasures against high consequence pathogens in non-human primates.	4	4	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Sajal Ghosh

Applicable NIH Guidelines: N/A

Meeting Comments: The objective of the original protocol is to perform animal model development for risk group 4 pathogens and refinement, and medical countermeasure testing that will generate data that can be submitted to the FDA for support of licensure applications. The protocol has two objectives; a) non-human primates will be vaccinated against various RG4 pathogens before being challenged with the exposure to those pathogens; b) to test efficacy of therapeutics, animals will be treated around the same time as they are challenged with the pathogen. The protocol has been reviewed multiple times to evaluate safe handling procedures and practices. The current submission is an annual renewal that includes removal of one personnel and updating biosafety cabinet certification dates only. No concerns noted.

Motion	For	Recuse	Against	Abstain	Absent
Approve	17	0	0	0	1

4. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2443	Florian Douam	Investigating host-pathogen interactions regulating the pathogenesis and immunogenicity of BSL-3 viral agents	3	3	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Colleen Thurman Additional Reviewer: Guillermo Madico Aditi Broos-Caldwell

Applicable NIH Guidelines: Sections III-D-1-a, III-D-1-b, III-D-2-a, III-D-3-a, III-D-4-b, III-E-1; Appendix-B-II-D, Appendix G-II-B

Meeting Comments: The proposed work is to identify and characterize important virus-host interactions that regulate the infectious cycle of several BSL3 viruses, including members of the Flaviviridae and Coronaviridae family, and use this information to develop anti-viral countermeasures. In this amendment, additional flaviviruses are added. These are Powassan and Tick Borne Encephalitis virus Hypr. Powassan is a BSL3 agent. Tick Borne Encephalitis, Hypr strain is listed in the CDC BMBL as a BSL4 agent except when workers are vaccinated and then can be worked with at BSL3. The BMBL states, "Central European tick-borne encephalitis viruses (TBEV-CE subtype) as needing BSL-3 containment, provided all at-risk personnel are immunized. TBEV-CE subtype refers to the following group of very closely related, if not essentially identical, tick-borne flaviviruses isolated from Czechoslovakia, Finland, and Russia: Absettarov, Hanzalova, Hypr, and Kumlinge viruses." The following was discussed among IBC members, NEIDL BSO, NEIDL Animal Science Center management, and the Medical Director: the pathogenicity of CE tickborne encephalitis virus (Strain Hypr), biosafety concerns, containment requirement for in vitro and animal work, vaccine requirement, and the current availability of facilities in the NEIDL. The IBC recommended that the proposal of work with the Hypr strain be removed from the protocol for now. It was noted that either a dedicated suite will be required for such work or the work will have to be done in BSL4 containment only. The committee recommended that PI should discuss the specific concerns of NEIDL EHS staff, ROHP staff, and NEIDL animal research facility staff to address a plan to for the proposed work with Hypr; an amendment can be submitted to add back the work with the Hypr in the protocol once this is satisfied. No concerns were noted with the proposed work with the Powassan virus. The following will be communicated to the PI:

Specific Comments:

- Tick Borne Encephalitis, Hypr strain is listed in the CDC BMBL as a BSL4 agent except when workers are vaccinated and then can be worked with at BSL3. Here, "Central European tick-borne encephalitis viruses (TBEV-CE subtype) as needing BSL-3 containment, provided all at-risk personnel are immunized.
- Powassan virus in a risk group 3 virus and could be worked in BSL-3 containment without extra precautions.

<u>Virus sourcing:</u>

- EHS has confirmed that BEI (UTMB) works and store TBEV-CE strain hypr at BSL-4 and therefore is not suitable to be removed from BSL-4 to BSL-3 containment because of the risk of cross contamination with other BSL-4 agents. BSL-3 containment sources need to be identified.
- Both TBEC-EC and Powassan viruses will require Import permits to be transported to NEIDL

<u>Biosafety Requirements:</u>

To work in BSL-3 the following will be required:

1. Room [redacted] designated for work with TBEV will require a dedicated freezer to store samples. This freezer must have a combination lock. The combination only accessible to those vaccinated.
2. Storing samples in incubators with just signage will not be sufficient.
    a. Any time TBEV work is done, the room will be inaccessible to unvaccinated personnel. This will need to be done by locking the room down with a combination lock and chain (EHS has determined that this is possible and has the devices to do it)
    b. The room must undergo a surface decontamination by EHS when done working with TBEV in order to work with any other BSL-3 agents to continue or the wait until a gaseous decon during the annual

BSL3 decon. Verified documents will be posted before unvaccinated people have access to the room.

3. Inactivation and removal of samples
    a. Samples will only be able to be removed from the lab when using an inactivation method specific to TBEV-CE and approved by EHS and IBC.
    b. Removal of samples will only be allowed after a certificate of inactivation has been signed. The certificate of inactivation must follow the sample to BSL-2 containment.

Animal work:

- TBEV virus in mice is detectable at day2 post infection and animals stay positive until dead. This includes blood and other tissues with a concentration of ~1,000 virions per ml but in brain it could reach 10^8 - 10^9 (this is as high as in tissue cultures).
- Being a tick born virus it requires a tick or a needle prick for LAI so the risk in BSL-3 and ABSL-3 should be similar provided sharps are handled correctly.
- If there is a need to study mouse brains, a new SOP must be developed describing the collection of those samples to mitigate the risk.
- Maintaining mice cages in the next room [redacted] in HEPA cages is not enough to maintain the require level of safety. Cages are opened in the BSC to replenish food, remove dead animals, do cage changes. These activities require the same level of protection as for room [redacted] (see 1. above)
- If mice are housed instead in [redacted], husbandry of mice conducted by researchers instead of ARS personell will need to be approved. Alternatively, ARS technicians will need to be vaccinated to do husbandry duties.

Maintenance and Emergency response:

- To do repairs and maintenance, in [redacted] and [redacted], the rooms will need to be surface decontaminated see 2.b. above. Alternatively, Facilities technicians will need to be vaccinated.
- EHS inspections to the lab could only be performed by vaccinated personnel. Inspections by regulators will be performed online using video devices.

Waste disposal:

- Carcasses will need to be stored in a lockable dedicated fridge inside [redacted] or [redacted] (see above)

Cross contamination:

- If Powassan virus and TBEV-CE in the same lab ([redacted] or [redacted]) precaution described in NEIDL BSL-3 and BSL-4 Biosafety Manual need to be followed to avoid cross contamination. For safety reasons, Powassan virus that is worked in the same lab with TBEV-CE cannot be worked in other BSL-3 labs because of the risk of cross contamination. We suggest keeping backup vials of Powassan virus in [redacted] or another BSL-3 lab.

Training:

- Members of the lab will need to receive agent-specific training for TBEV.

Motion: Conditional Approval (Administrative Review with removing the work with Hypr)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

Dr. Barbara Slack chaired the rest of the meeting from this point on:

5. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2601	Kim Vanuytsel	Improving therapeutic options for patients suffering from blood disorders	2	N/A	BUMC
Primary Reviewer: Inna Afasizheva		Secondary Reviewer: Tom Winters			
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1; Appendix B-II-D, C-II, G-II-B					

Meeting Comments: This protocol aims to increase the efficiency and thus safety of hematopoietic stem cell (HSC) transplantations through the enhancement of HSC engraftment potential. Proposed methods will allow identification of ex vivo culture conditions that optimally support HSC repopulation capacity prior to transplantation. The second aim of the study is to use the disease-modeling capabilities of induced pluripotent stem cells (iPSCs) to generate patient-specific red blood cells from a diverse group of sickle cell disease (SCD) patients represented within in house SCD iPSC library. This approach will allow assessment of the therapeutic effect of novel drugs or gene editing approaches across the genetically diverse SCD patient population and find treatments that work for all patients. Human tissues, blood and cell lines are used in this protocol. iPSCs are derived from human somatic cells using five-plasmid-based lentiviral vector and have been tested to be free of both human pathogen and mycoplasma. The peripheral blood mononuclear cells (PBMCs) and hematopoietic stem and progenitor cells used in experiments are isolated from human sources. This study is based on patient-specific iPSCs from in house SCD iPSC library. iPCS will be differentiated into hematopoietic stem and progenitor cells and specified toward red blood cells. These differentiated cells will be used in preclinical trial to evaluate efficacy of compounds in upregulating fetal hemoglobin expression. Cells used in signaling pathway modulation experiment will be either purchased as CD34+ enriched products from commercial vendors or isolated via Ficoll centrifugation/magnetic bead separation from cord blood or volunteer donor blood obtained through National or local blood banks. PPE used are appropriate. Liquid waste and solid waste are disposed of appropriately. Disinfection is also appropriate with 10% bleach and 70% ethanol. Tissue culture cell lines are frozen and protected. Transport appears appropriate. It was clarified in the discussion that this new PI will get all the lentivirus particle preparation from the CReM facility. The following will be communicated to the PI:

- The lab space is Biosquare III room [redacted] (not [redacted]). Also, add room [redacted] as biological materials are being stored there. Add tissue culture rooms [redacted] and [redacted].
- Please update biosafety cabinet certification date.

BUA Site Assessment: The lab space is lab # [redacted] and not [redacted] as mentioned in the protocol. The lab stores their biological materials in room # [redacted] (and not [redacted] as mentioned in the protocol).Two tissue culture rooms -room # [redacted] and [redacted] are part of the shared larger lab space. The lab is not testing their human origin samples and cells for BBPs or their BBP status is unknown to them. All the lentivirus preparations are provided by the CReM facility.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 3

6. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2602	Daniel Dempsey	Molecular mechanisms of protein ubiquitination	2	N/A	BUMC

Primary Reviewer: Weining Lu	Secondary Reviewer: Jim Keeney

Applicable NIH Guidelines: Section III-E-1; Appendix B-1

Meeting Comments: This research project aims to understand how post-translational modifications regulate key proteins that promote the pathogenesis of several cancers and to develop new chemical tools to identify and characterize the deubiquitinase enzymes that interact with these key proteins and modulate their cellular function. The experimental laboratory procedures in this research project include peptide synthesis, protein expression, protein purification, cell culture, and molecular biology with DNA plasmid preparation. Protein expressions are done in bacterial cell lines, human cell lines, as well as in insect cells. All personnel will wear gloves, safety glasses, and lab coats when working in the laboratory. High Hazard chemical potassium cyanide will also be used in small quantities in the solid-phase peptide synthesis work inside a chemical fume hood wearing safety goggles, lab coats, nitrile gloves (double gloves), and face as per EHS safety guidelines. All waste contaminated with potassium cyanide will be placed in a separate labeled hazardous waste container. All other liquid and solid waste will be disposed of in labeled hazardous waste containers in their designated satellite accumulation area with secondary containment. The hazardous waste will be picked up as soon as the waste container is 2/3 full. All containers/flasks in contact with the bacterial or insect cultures will be treated with 10% bleach for 30 minutes before being washed in the sink. The protocol is clearly written with steps and procedures in place to limit the potential hazards. The Committee however,

noted that the PI has two other IBC protocols that have very similar laboratory experimental procedures and recommended that the protocols may be merged into one application in their future renewal. The following will be communicated to the PI:

The Committed recommended the PI consider merging all current IBC approvals in one application in the next submission of any of the other approved protocols. Multiple grant application titles may be listed on the title of the IBC application if the general laboratory procedures and biosafety risk mitigation plans are the same. The following will be communicated to the PI:

- PI should be listed in the personnel table.
- Add room [redacted] to the list.
- Please correct the typo 'HECT-293' cells in the Laboratory Procedures and the rDNA section.
- Update biosafety cabinet certification date.
- Update applicable NIH guideline to state: Sections III-D-1-a, III-D-2-a, III-E-1; Appendix B-I and B-II

BUA Site Assessment: The lab was advised to use the sonicator in a fume hood or in a BSC, although they rarely use it. BSC calibrated- 03/2023. The biological materials are stored in a separate shared room (room # [redacted]) which is part of the bigger lab space # [redacted].

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 3

7. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2211	Juan Fuxman Bass	Delineation of an immune gene regulatory network and rewiring in disease	2	N/A	CRC

Primary Reviewer: Valerie Gouon-Evans	Secondary Reviewer: Rob Davey

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

Meeting Comments: The goal of this project is to identify the gene regulatory networks including transcription factors and their cis-regulatory elements that control immune gene expression and determine how viruses and more specifically viral genes can affect immune responses. In addition, the lab investigates how viruses affect cellular pathways and immune response in infected cells by examining the interaction between the viral gene regulatory network with that of the infected host cells. The protocol involves mostly recombinant DNA work with plasmids being made expressing various reporter genes (luciferase, etc.) under control of host and virus promoter elements. Constructs are transfected into yeast and multiple human cell lines and reporter activity measured. Cells are challenged with different BSL2 viruses and changes in reporter expression are measured. Biohazards include number of human cancer cell lines and four viruses (Epstein-Barr virus, human cytomegalovirus, herpes simplex virus and Sendai virus), all obtained from commercial sources such as ATCC and Sigma. Third generation lentivirus vectors and CRISPR/Cas9 technology are also used. The following will be communicated to the PI:

- Please provide research experience of all the listed members relevant to the work described in the protocol. Currently it only lists how many years and from where, but does not indicate what experience they have and if those are relevant to the current protocol.
- Please update the personnel list. Remove those who have left and add if there are any new members working in the protocol.
- PI must update the rDNA/IBC policy training.
- Except one, none of the listed members have current BBP training.
- Provide recent biosafety cabinet certification date (should be less then an year old).

BUA Site Assessment: Personnel list needs to the updated. PI's rDNA/IBC policy training needs update. Biosafety cabinet is duly certified.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 3

8. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1296	Lawreen Connors	In vitro studies of the amyloidogenic natures of transthyretin and immunoglobin light chain proteins	2	N/A	BUMC
Primary Reviewer: Xin Brown		Secondary Reviewer: Bob Timmerman			
Applicable NIH Guidelines: Section III-D-1, Appendix B-2, January 2011					

Meeting Comments: The goal of this protocol is to understand the amyloid-forming nature of the normally occurring plasma proteins. By understanding the amyloid disease process, the group wants to develop therapeutic strategies which will interrupt, halt, and/or eradicate amyloid formation. They characterize amyloid proteins purified from clinical samples including cells, plasma/serum, urine, and tissue specimens obtained on patients with various types of amyloidosis. Their in vitro investigations of the biochemical and biophysical properties of amyloidogenic proteins include test tube and cell-based studies using cardiac, renal, hepatic, and bone marrow plasma cells (mouse and human) purchased from commercial sources. They also investigate strategies for inhibiting the amyloid process, including developing and testing small molecule drug candidates. In this 3-year renewal PI requests the transfer of this IBC protocol to two of the senior members of her group who have been associated with this protocol and the BU Amyloid Center for many years. There are also updates to material used, for example, expression vector pET21 and host cell E. coli BL21 are added, pCMV expression vector and HEK 293 cell are also added. No concerns were noted with the added research material since this research project already uses human tissue samples and other E. coli strains and expression vectors. The added material does not require any additional safety measures besides the ones that are already in place. The following will be communicated to the PI:

- Please make sure safety trainings are updated for all members of the protocol. Especially Dr. Prokaeva has no current training record.
- Please update the personnel list as appropriate. Add new members and remove those that are no longer active.
- IBC protocol can only have one PI (all communications will be with that faculty). Others can be Co-PI if appropriate.
- The revision to this 3-yr renewal must come from Dr. Connors. IBC will then arrange transferring the protocol in RIMS to whomever Dr. Connors will designate to be the PI.
- Please check the BMC clinical space use box since the lab receives samples from BMC clinic.
- Please remove E. coli strains from the Hazardous Biological agent list as they are not hazardous material. However, they should stay in the rDNA section.
- Add human cell lines HEK293, Expi293 cells and U266 in the Hazardous agent list.
- Is IRB protocol [redacted] still active? It appears closed.

BUA Site Assessment: Dr. Connors has retired therefore this protocol should have another PI. Dr. Gareth Morgan has agreed to be the PI. The personnel list is not up to date. Two lab personnel are missing in the protocol. Since the lab routinely receives samples from the BMC amyloidosis clinic, therefore in section IX of the protocol, the lab should mention the use of BMC space.

Motion: Conditional Approval (Administrative Review)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

9. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2397	Florian Douam	Host and viral determinants regulating Flaviviridae pathogenesis and immunogenicity	2	2+	BUMC
Primary Reviewer: Barbara Slack		Secondary Reviewer: Steve Niemi Additional Reviewer: Aditi Broos-Caldwell			
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-3-a, III-E-1; Appendix-B-II-D, Appendix G-II-B					

Meeting Comments: This protocol investigates how the mosquito-borne members of the Flaviviridae family such as Hepatitis C Virus, Dengue virus or Zika virus interact with their host and vectors, and how these interactions regulate virus replication, cellular tropism, host range, disease and immune response. In this project, they are studying specific viral and host determinants, as well as virus-host interactions and immunoregulation, that define the infectious cycle and clinical outcome of these viruses. They will also investigate how immunodeficiency, such as the one induced upon HIV-1 infection, can compromise these interactions and immunoregulation. This amendment adds two new investigators, and two additional lab spaces and a new RG2 virus. In the amended procedures, human mononuclear cells will be obtained from a commercial source, and hematopoietic stem cells (HSC) will be purified from this suspension and used to generate induced-pluripotent stem cells (iPSC). HSC or iPSC will be injected into mice. The protocol has also been expanded to included infection of mosquitos with Zika and West Nile virus in the insectary, in addition to the pathogens which were described in the original protocol. Approved IACUC protocols performed in ABSL2 with ABSL3 practices are in place for their animal work. These additions to not require additional precautions from those already thoroughly described in the previously approved protocol. The following will be communicated to the PI: • West Nile Virus should be included in the list of pathogens in the Layman's Summary and Brief Project Description section. • It is stated in Section VII, 3B (1.4 Describing Stem Cell work): “Biological materials will be guaranteed negative for HIV-1, HIV-2, hepatitis B, and hepatitis C”- How will these materials be guaranteed to be negative?

Motion: Conditional Approval (Administrative Review)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

V. List of Protocols reviewed by DMR (not discussed in the meeting)

List of protocols (below) that are currently being reviewed by DMR was displayed in the meeting.

Three-Year Renewals to be review by DMR:

10. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1125	Ian Rifkin	The Role of Interferon Regulatory Factor 5 in the Pathogenesis of SLE	2	1	BUMC
Primary Reviewer: Barbara Slack		Secondary Reviewer: Steve Niemi			
Applicable NIH Guidelines: Section III-D-1; Section III-E-3; Section III D-2					

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

11. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1904	Jan Blusztajn	BMP9 as a juvenile protective factor in cognitive aging	2	1	BUMC
Primary Reviewer: Valerie Gouon-Evans		Secondary Reviewer: Colleen Thurman			
Applicable NIH Guidelines: N/A					

Motion: Approval	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

12. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1459	Vipul Chitalia	Uremic vascular disease and cancer biology	2+	2	BUMC
Primary Reviewer: Weining Lu		Secondary Reviewer: Elke Muhlberger			
Applicable NIH Guidelines: Sections III-D-1-a and IIID-2-a and Appendix B-II.					

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

13. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2402	Elizabeth Stier	H-38555 AMC-103: A Phase 2 Evaluation of VGX-3100, a Synthetic DNA Immunotherapy Targeting Human Papillomavirus 16 and 18 E6 and E7 Proteins, for Anal High-Grade Squamous Intraepithelial Lesions (HSIL) in HIV-Positive Individuals.	2	N/A	BUMC
Primary Reviewer: Tom Winters		Secondary Reviewers: Sajal Ghosh			
Applicable NIH Guidelines: Section III-C-1					
Motion: Approval	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

14. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
658	Joseph Zaia	Center for Biomedical Mass Spectrometry; High-Throughput De Novo Glycan Sequencing (R01GM132675); Developing new glycosylation analysis techniques and software to enable generation of more effective Influenza A virus vaccines, sponsored research agreement from Waters Corporation to Boston University; Selecting HA glycosylation for improved vaccine responses (R01 AI155975); Cerebrovascular Remodeling and Neurodegenerative Changes in Alzheimer's Disease (R01 AG075876); Methods for measuring matrisome molecule similarity during disease processes (R35 GM144090)	2	N/A	BUMC
Primary Reviewer: Ed Loechler		Secondary Reviewer: Inna Afasizheva			
Applicable NIH Guidelines: N/A					
Motion: Conditional Approval (Administrative Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 0