Boston University
Institutional Biosafety Committee (IBC)
June 16, 2020 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 2:48 PM

Members Present: I. Afasizheva, B. Slack, R. Davey, C. Abraham, X. Brown, C. Sulis, E. Loechler (joined 12:06 PM), R. Morales, T. Winters, R. Varada (left 2:00 PM), S. Kurnick (left 2:06 PM), J. Keeney, R. Timmerman, V. Britton (left 12:10 PM, rejoined at 12:16 PM), R. Georgiadis (left 2:02 PM), R. Ingalls
Guests Present: P. Urick, N. Yun, S. Benjamin, F. Ennever, C. Bennett, A. Ahmad, J. Davis, K. Tuohey
Staff Present: J. Hutchinson, S. Ghosh, C. McGoff

I. Update on Expedited Review Process

The Chair requested an update on the previously discussed SOP; SQAP staff indicated that the hope is to have the SOP ready for IBC review next month.

II. Retirement of Carol Sulis

Dr. Sulis is retiring, it was noted that this will be her last meeting; members expressed their appreciation for her time and contributions to the biosafety program.

III. Presentation – Resuming Research Activities

The Director of Research Safety presented on the resumption of research activities including the process for returning to laboratories and the implementation of research recovery plans. Each labs plan is reviewed to ensure that personnel are returning to work safely; EHS reviewed plans for tenant laboratories. Social distancing will be practiced, work schedules will be staggered, signage has been posted, proper hand hygiene is expected, and there will be regular cleaning of frequently touched surfaces. Personnel are expected to wear PPE as required (i.e., by approved protocols) – in addition, all personnel must wear a surgical mask. Pertinent federal, state, local and institutional guidelines are being constantly monitored. Members discussed that a COVID-19 testing facility is being established on the CRC at the Rajen Kilachand Center for Integrated Life Sciences & Engineering; PCR based testing will be done with projections of testing 5,000 samples a day, collection will occur on both campuses. It was noted that at some level, results will be shared with the BU community.

IV. Review of May 15, 2020 IBC Meeting Minutes

No comments or questions were voiced.

Motion: Approve

For: 16; Against: 0; Abstain: 0; Absent: 0

V. New Business

A. LAI Subcommittee Recommendation: Members were informed of a recommendation by the subcommittee to add: Bourbon virus, Eastern equine encephalitis virus, Japanese encephalitis virus, Louping ill virus, Murray valley encephalitis, Powassan, Rift Valley fever virus, Sin nombre virus, St. Louis encephalitis virus, Venezuelan equine encephalitis virus, Wesselsbron virus, and Whitewater arroyo to the list of Biological Agents with Potential to Cause Laboratory Acquired Infection. ROHP's Medical Director reported that the agent information sheets are being developed. No questions were voiced.

Motion: Approve

For: 16; Against: 0; Abstain: 0; Absent: 0

B. Safety & Quality Assurance Program (SQAP) Report - Follow-up on FAQs – Interim Laboratory Biosafety Guidance for Research with SARS-CoV-2 and IBC Requirements under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): Following discussion at the last meeting the FAQs and a list of protocols approved at BSL-2 and BSL-2+ were shared with the IBC for review; no questions, comments or concerns were voiced regarding the appropriateness of the designated biosafety levels.

C. Environmental Health and Safety (EHS) & Research Occupational Health Program (ROHP) Report: No incidents to report.

VI. Protocol Review

1. rDNA/Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
875		Genetics of Host Resistance & Susceptibility to Tuberculosis	3	3	BUMC

Primary Reviewer: Carmela Abraham Additional Reviewer: Shannon Benjamin	Secondary Reviewer: Susanna Kurnick

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

Meeting comments: The PI investigates a variety of Mycobacteria including Tuberculosis which causes disease in humans. Mice will be infected with the bacteria and tissues will be studied for genes of interest and cytokines. It was noted that *Francisella tularensis* Live Vaccine Strain (LVS), which causes human disease, will be used for respiratory infection in a mouse model and that infections with LVS will be performed by ASC personnel at ABSL-2 using intranasal methods; it was questioned whether this work should be done at ABSL-3 (like Mycobacterium tuberculosis). In response, it was noted that per the NIH Guidelines the strain is risk group two (2) and the BSL-3 BSO indicated that work at ABSL-2 is appropriate. ROHP's Medical Director noted that work is being done on an attenuated vaccine that is not yet available.

- III. in the table the PIs BSL-3 training is 2015, in the training dates table it is 2020, correct 2015 to 2020.
- For liquid waste decontamination, reference the applicable NEIDL waste handling SOP.
- 'Nonmaterial' should be corrected to nanomaterial.
- Check off animal handing and cage changing.
- Update the BSC certification date.
- Update the IACUC approval information (# AN 15276) for the F. tularensis work.
- Personnel section: confirm whether E. Brownhill is still in the lab working on this protocol.
- IV. Research Laboratory Facility Information, #1, : this is the anteroom area of the suite; there will be no tissue culture, bench work, or centrifugation taking place in this area. Remove as none of these spaces will be used for animal work. All animal work that requires ABSL-3 practices will take place in , update this section accordingly.
- VII. Research Project Description, #3: update all language in this section that references the use of the "NEIDL ABSL-3 Suites" for animal work. All animal work will be taking place in 604D which is located within the NEIDL BSL-3 suites. Remove language that references the transfer of materials from the ABSL-3 to the BSL-3. All work will be contained to the suite, therefore, there will be no need for the use of the pass-through window.

A motion was made not to require annual review of this protocol.
For: 15; Against: 0; Abstain: 1; Recuse: 0; Absent: 0

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

2. Bhz – Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2375		Testing medical countermeasures against high consequence pathogens in rodents	4	4	BUMC

Primary Reviewer: Inna Afasizheva Additional Reviewer: Nadya Yun	Secondary Reviewer: Rao Varada

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol screens small molecule drugs for their ability to block infection of cells by high consequence risk group 3 or 4 pathogens in animal models. The PI has removed one (1) personnel. It was noted that personnel are current with training, that IACUC approval is in place, and that the BSC certification date has been updated.

A motion was made not to require annual review of this protocol.
For: 14; Against: 0; Abstain: 0; Recuse: 1; Absent: 1
The PI was not present for the vote.

Motion: Approve	For: 14	Recuse: 1	Against: 0	Abstain: 0	Absent: 1

3. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2286		Biomolecule Production Core – Propagating BSL4 pathogens	4	N/A	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Nadya Yun

Applicable NIH Guidelines: Section III-D-1-a, III-D-1-b, III-D-1-c

Meeting comments: The PI is adding recombinant work for generating recombinant SARS-CoV-2 viruses with changes in the S protein that adapts the virus to mice and in proteins that suppress the innate immune response as well as the polymerase complex. It was noted that the changes requested will likely lower virus pathogenicity. Adapting the virus to mice through changes in the S coding sequence, de-adapts it to humans. The changes are well defined and published. The other changes include those in the polymerase complex, which are indicated by name. Changes are likely to result in defective viruses. Other changes are in non-structural proteins that suppress the innate immune response. It was noted that rescue of recombinant SARS-CoV-2 with introduced mutations will be done at BSL-4 using BSL-4 procedures and practices and that all recombinant viruses will be added to the recombinant virus list. Members were informed that the amendment was sent to the Chair of the DURRC for review and he determined that DURRC subcommittee review is not required given that the change in the sequence of the S protein that the PI wants to make has been published and is in the public domain – hence not DURC. He also noted that the other mutations in the polymerase are most likely going to inhibit virus replication and they will destroy virus if they see the opposite. Given this and the fact that they are working at BSL-4 he determined that subcommittee review is not needed.

- Identify the potential target genes by name so that such viruses can be identified later on.
- It should be mentioned that genetic material will not be transfected into cells to generate infectious virus in a BSL-2 laboratory and they will be generated and stored well away from mammalian cell cultures.

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

4. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2352		Propagation and characterization of viruses	4	4	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Nadya Yun

Applicable NIH Guidelines: N/A

Meeting comments: The PI is adding two (2) new sources of SARS-CoV-2: Boston Children's Hospital and Brigham and Women's Hospital, he has already been approved to obtain SARS-CoV-2 from local hospitals. No comments or concerns were voiced.

Motion: Approve	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

5. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1932		Rel Homology Domain Signal Transduction Pathways in Basal Invertebrates	2	2	CRC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Susanna Kurnick

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1, III-E-3

Meeting comments: The PI studies the NF-κB signaling pathway. The genes used are in the form of cDNAs cloned from a variety of eukaryotic species: mouse, human, chicken, sea anemone, coral. These cDNAs are generally genes in the NF-κB signaling pathway, or mutant versions of such genes from animal and human sources, cDNAs will be infected via viral delivery to a number of cell lines.

- Ensure that ROHP clearance is current for all personnel.
- It is noted that "Bacterial cultures and tissue culture plates are routinely disinfected with 10% fresh bleach before disposal". Change to 10% final concentration in all places 10% fresh bleach is mentioned.

- Clarify why ABSL-2 is checked, it appears that no animals will be used. Sea anemones are not considered animals so it should be indicated that no transgenic animals will be used; section III-E-3 Experiments Involving Transgenic Rodents is marked but use of transgenic rodents is never mentioned.
- Provide additional information regarding the use of yeast (it is mentioned only once with no information otherwise).
- IX A: clarify from which BU and MIT researchers' viruses are received.
- Clarify if IRB approval is needed for this work (it seems that the answer should be 'no').
- Describe which molecules are pathogenic (it is noted that the experiments involve rDNA molecules capable of expressing a pathogenic polynucleotide or polypeptide).
- Describe the use of the biosafety cabinet in VII #3 and indicate which procedures will be performed in a BSC.

Site Assessment: An ECP needs to be adopted; training is current; ROHP clearance is needed for a few personnel; and the BSCs are being recertified.

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

6. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
848		Uncoupling obesity from breast cancer in African American women; Mechanisms of BET bromodomain metabolic reprogramming in triple negative breast cancer	2	N/A	BUMC

Primary Reviewer: Xin Brown	Secondary Reviewer: Bob Timmerman

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

Meeting comments: The long-term goal of the project is to understand the immunological basis of insulin resistance and cancer risk. Lab procedures include isolation and analysis of cells from human blood and fat biopsy samples and transduction of human or murine cell lines with VSVG pseudotyped lentivirus. All procedures are done in a BSL-2 lab and sufficient safety measures are described. It was noted that Dr. Sulis was not contacted, she indicated that further consultation is not needed. A member expressed that it is not necessary to test tissue samples for COVID-19, the use of universal precautions when handling samples was mentioned.

- III. Personnel Information: Denis and Shafran need to complete BSL 1/2 training and Lab Safety Training. Jafari and Shafran need to update their ROHP clearance. Clarify if Jafari and Shafran are still in the lab.
- VII.3.: it is indicated that "Primary blood and fat biopsy samples are obtained from the Plastic Surgery Department", clarify if the COVID-19 status of the tissue samples is known and what precautions will be used.
- VIII.7A. Liquid Waste: it is indicated that "the liquid will be overlaid with a large excess of freshly prepared 10% bleach. The biological materials will be inactivated for five to ten minutes." Time should be increased to 20 minutes.
- Sharps containers should not be autoclaved (will melt).
- The protocol indicates that liquid waste will be disinfected with Wescodyne, include contact time before dumping down the drain.

Site Assessment: The lab has an ECP; the personnel list is being updated; and the BSC and fume hood are certified.

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

7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1340		Neuromodulation and Cortical Memory Function	2	2	CRC

Primary Reviewer: Rosina Georgiadis	Secondary Reviewer: Rao Varada

Applicable NIH Guidelines: Section: III-E-1 and III-D-4-a; Appendix B-II-D; G-II-B, Appendix M-II-A, M-II-B

Meeting comments: It was noted that there have been no changes made to the laboratory procedures, only administrative changes. The lab uses rat and mouse models for studying anatomical and physiological properties of subpopulations of neurons and are studying memory function of healthy brains with attention to microstructural

connectivity in specific brain areas using replication incompetent rabies virus vector and AAV. Procedures, including animal procedures, are well described. It was discussed that if training and ROHP clearance are not current, that language should be included in the approval letter indicating that these requirements must be met before personnel can engage in protocol related activities. It was noted that there are two (2) IACUC approved protocols covering this work. Site Assessment: No findings.					
Motion: Approve	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

8. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
835		Diversity of Redox Enzymes	2	N/A	CRC
Primary Reviewer: Ed Loechler		Secondary Reviewer: Jim Keeney			
Applicable NIH Guidelines: Section III-F-3, Appendix G-II-B					
Meeting comments: The PI investigates properties of a variety of iron-containing redox enzymes which he previously molecularly cloned out from various microorganisms. He is now creating specific mutations in those proteins and expressing them in other common laboratory microorganisms such as E. coli or Salmonella which are not typically hazardous. The PI also expresses the cloned redox enzymes in other exotic microorganisms to investigate their biochemical properties in a different biological environment with an ultimate of goal of using this knowledge to develop fuel cell technology. It was noted that the hazards in the work are low, a BSC will be used, and the safe use of methane gas is addressed. It was noted that social distancing measures are included, and that training is current. • Ensure that all personnel have current ROHP clearance. • Update the BSC certification date. Site Assessment: All personnel need ROHP clearance (and have been notified); the personnel list needs to be updated; and the BSC will be recertified in July.					
Motion: Conditional Approval (Administrative Review)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

9. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1314		Cellular Imaging Core	2	N/A	BUMC
Primary Reviewer: Rosina Georgiadis		Secondary Reviewer: Valeda Britton			
Applicable NIH Guidelines: N/A					
Meeting comments: This is a core facility protocol, advanced microscopy services are provided to users on a fee for service basis; the core facility manager provides services to users and individual research PIs and their lab personnel are also permitted to use equipment in the core. In the application the core facility manager indicates that the application is confusing to fill-out as a core facility manager. It was noted that not all of the boxes under the Agreement Policy are checked. Members discussed that the application is geared toward PIs (not core facility managers) and that adjustments within the application may be needed. Members discussed whether the core has a screening tool or user form to collect information about planned work, training, IBC approval, etc. as is the case for other cores. EHS staff indicated that they will meet with the PI to provide guidance. • The boxes under the Agreement Policy should be checked for the core facility manager and listed personnel. Users should be trained on core procedures. • Clarify if a screening tool or other user form exists to collect information about planned work (i.e., nature of the materials that will be used), training, IBC approval, etc. – such a form is used by other research cores and is recommended, EHS staff can provide guidance. A copy should be provided upon resubmission. Site Assessment: All researchers who use the core have an IBC protocol and are given equipment specific training by core staff, a copy of the equipment SOP is available at each piece of equipment; the ECP needs to be updated; training and ROHP clearance is current; and the core facility manager is seeking guidance from the IBC on how to safely accommodate agent specific work.					

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 16	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

10. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1583		Pathway-Focused Real-time PCR Arrays, Metabolic Arrays, and Protein/cytokine Arrays	2+	N/A	BUMC

Primary Reviewer: Ed Loechler | Secondary Reviewer: Ron Morales

Applicable NIH Guidelines: N/A

Meeting comments: This protocol is for the Analytical Instrumentation Core (AIC) where approximately forty (40) cutting-edge analytical instruments are used. The AIC consists of a central location and seven (7) satellite locations on the BUMC. Instruments are managed by managers located near the instrument site, the core director, and/or a lab safety coordinator. When services are performed, prior to materials coming into the core, a material safety form is completed to disclose the nature of the materials (the highest biosafety level being BSL-2). It was noted that solid waste and sharps use is properly described. Human and animal blood samples from patients and animals infected with COVID-19 will be analyzed; it was noted that the enhanced practices required for safely handling these samples are described in the protocol.

- Ensure that all personnel have completed all required training including Laboratory Safety Training and Bloodborne Pathogens Training.
- Indicate if there are SOPs in place for disinfecting and cleaning equipment after use.

Site Assessment: Some personnel need to complete training and ROHP clearance; the BSC is certified; and enhanced practices will be used when analyzing COVID-19 positive samples.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 3

11. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2231		Genomic and biochemical studies of Piwi proteins and piRNA regulation mechanisms.	2	2	BUMC

Primary Reviewer: Inna Afasizheva | Secondary Reviewer: Susanna Kurnick

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

Meeting comments: The PI seeks to uncover the role of Piwi-interacting RNAs in the regulation of transposons metabolism in cell culture and in an animal model. The project involves manipulations with rDNA, insect, and human cell lines. The PI is proposing to use a CRISPR-Cas9 system for editing of piRNA to disturb normal regulation of transposable elements by downregulation of Piwi proteins in frog embryos.

- Provide relevant experience for personnel.
- Provide details regarding the concentration of bleach used for disinfection.
- Provide clarity regarding the use of human blood and brain materials and clarify if IRB approval is needed, providing the requested IRB information as appropriate.
- Update the lab procedures to include a rationale for using human material and the procedures that will be used.
- Include additional details describing the CRISPR-Cas9 work and use of insect cell lines.
- Clarify if adult Xenopus will be handled and if so, describe these procedures and check animal handling and cage changing.
- Describe the specific use of human and macaque brain tissues; this use may require the use of respirators if any of the procedures generate aerosols, clarify if procedures will generate aerosols.
- Contact Dr. Sulis and provide information requested in the application.

Site Assessment: Some personnel need to complete training; and the BSC and fume hood are certified.

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4

12. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2460		Cerebrospinal Fluid Analysis in COVID-19	2	N/A	BUMC

Primary Reviewer: Rob Davey Additional Reviewer: Ron Morales	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: N/A

Meeting comments: The PI is proposing to examine the presence of SARS-CoV-2 in cerebro-spinal fluid (CSF). RNA will be extracted from CSF for PCR, IgG, IgM, and inflammatory cytokines will be measured by immunoassays. Samples will be stored in the -80C freezer in Dr. Zhou's lab. PPE is gloves, goggles, lab coat and surgical mask and a BSC will be used. Screw cap tubes will be used and IRB approval information is provided. EHS staff indicated that they will follow-up with the PI to ensure that enhanced practices (BSL2+) will be followed when working with COVID-19 positive samples.

- Provide relevant experience for Dr. Wang including the pathogens worked with previously and the type of work, including biosafety level.
- Clarify if any of the lab space is shared (i.e., with Dr. Zhou's lab) if so, this should be indicated in the protocol and personnel should be informed of the work being done (access should be restricted when work is ongoing).
- Provide the requested details for use of a biosafety cabinet, including the certification date.
- Confirm if screw cap tubes have O-rings to ensure an airtight seal.
- The biosafety level is indicated as BSL-2 - working with COVID-19 positive samples should be done at BSL2+ (enhanced). The lab will need to follow enhanced practices (BSL2+) when working with COVID-19 positive samples; BSL-2 with special practices of BSL-3 should be checked as the highest biosafety level. Consult with EHS staff to ensure that appropriate practices will be followed and are indicated in the protocol.
- Indicate what concentration of bleach will be used as a disinfectant.

Site Assessment: An ECP is in place; training and ROHP clearance is current; and the BSC and fume hood are being certified.

Motion: Conditional Approval (Administrative Review)	For: 11	Recuse: 0	Against: 0	Abstain: 0	Absent: 5

13. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2145		rDNA Protocols for Molecular Cloning in Pediatric Infectious Diseases; COVID-19 studies	2+	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendix B-II-A.

Meeting Comments: This protocol investigates the gene necessary for S. pneumoniae-mediated middle ear infection, develops testing protocols for detecting the presence of antibodies to COVID-19, and tests protocols for microbiome analysis of clinical samples from COVID-19 patients. This amendment adds a new clinical study to test the efficacy of four (4) RNA vaccines against COVID-19 in healthy individuals. Only blood and nasopharyngeal swabs will be brought back to the PI's lab where blood will be centrifuged and serum removed and frozen, NP swab media will also be frozen. Serum and swab/viral culture media will then be shipped. For these clinical samples, lab procedures for collection, processing, aliquoting, and evaluation of immune response will remain the same and will be done in the GCRU. GCRU staff will transport blinded samples in a spill proof and shatterproof container to the Maxwell Finland Lab for shipping to an outside laboratory. Personnel will complete appropriate safety training, including agent-specific SARS-CoV-2 training. It was noted that there is a very low risk of exposure to SARS-CoV-2 when administering the vaccine and collecting the samples.

Motion: Approve	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4

14. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus

2388		1) H-37773: MOM NEST Study: Safety, Efficacy, Pharmacokinetics, and Pharmacogenetics of Naltrexone in Pregnant Women with Opioid Use Disorder 2) NIDA Clinical Trial Network Protocol 0080: MOM Protocol - Randomized Trial of Buprenorphine for Pregnant Women with Opioid Use Disorder. 3) COVID-19 Perinatal Project (H-40096 and H-40270)	2+	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Bob Timmerman				
Applicable NIH Guidelines: N/A					
Meeting Comments: Clinical specimens are obtained to test treatment efficacy in pregnant and post-partum women with opioid use disorder (OUD) for optimal management of women with OUD. Cord blood is collected from pregnant women infected with COVID-19 during childbirth to test virus transmission. In this amendment the PI is adding collection of additional materials from COVID-19 infected mothers and their newborns including breast milk, cord blood, infant blood, and infant urine for investigating mother-to-infant virus transmission. It was noted that the lab is experienced in collecting these materials and additional safety measures required for handling COVID-19 infected materials are described; enhanced BSL-2 practices will be followed. BMC's Hospital Epidemiologist indicated that BMC infection control issues were discussed at the time of initial submission of the protocol and further discussion related to this amendment is not needed.					
Motion: Approve	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4

15. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2092		Analysis of small RNA processing during vertebrate embryogenesis	2	1	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Ron Morales				
Applicable NIH Guidelines: Section III-D-1-a; III-D-2-a, Section III-E-1					
Meeting comments: The PI is proposing to examine RNA and proteins from cells infected with nidoviruses (specifically SARS-CoV2). Plasmid DNA encoding SARS-CoV-2 replicons (truncated and non-infectious) will be obtained from a lab in Switzerland and will be transcribed in vitro to RNA and introduced into cultured cells under BSL-2 conditions. No infectious viruses can be formed by these replicons. The cDNA plasmids will be propagated in *E. coli, K12* strains or yeast. Additionally, the PI is proposing to clone plasmid DNA encoding the entire SARS-CoV-2 genome, and transcribe it into positive sense RNA (which is classified as BSL-2). The RNA will be transported to the Muhlberger lab at the NEIDL and used to infect cultured cell lines (in BSL-3 space). All material is then inactivated using inactivation procedures approved by NEIDL EHS and BU IBC, returned to BSL-2 space, and analyzed by RNA-Seq, Northern Blot, and Western Blot to detect small RNAs derived from the virus and the host cells. Per CDC guidelines and the current BEI classification of similar material, the generation of the SARS-CoV-2 positive sense genomic RNA appears to qualify as a BSL-2 procedure. • Confirm that generation of complete RNA genome of SARS-CoV-2 (transcribed from cDNA) qualifies as a BSL-2 procedure under current CDC guidelines. • Section VIII.11-Transport: update to describe transfer of SARS-CoV-2 RNA to the NEIDL, clarifying if material is being transported to a BSL-3 or BSL-4 lab, and describe transfer of inactivated cell culture material to the BSL-2 lab (this section currently states that there will be no transport of biohazardous material between and fish facility). • Add SARS-CoV-2 genomic RNA to the list in Section A. A. Mora Martin needs to complete BSL 1/2 training.					
Motion: Conditional Approval (Administrative Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4

16. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1409		Replication of and host responses to negative-sense RNA viruses with a focus on filoviruses	2	N/A	BUMC

Primary Reviewer: Xin Brown	Secondary Reviewer: Jim Keeney				
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-3, III-E-1, III-F-8; App. B-II-D, App. G-II-B					
Meeting Comments: The overall goal of the project is to identify and characterize virus and cell-specific factors that contribute to the virulence and pathogenicity of highly pathogenic negative sense RNA viruses. The current amendment seeks to add GFP expressing murine hepatitis virus as a surrogate for pathogenic coronavirus for inactivation studies. This is a mouse coronavirus that does not infect humans. It was clarified that no shipping is being done as part of this protocol.					
Motion: Approve	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4