Boston University
Institutional Biosafety Committee (IBC)
May 19, 2020 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 3:07 PM

Members Present: I. Afasizheva, B. Slack, E. Muhlberger (left 3:00 PM), R. Davey, C. Abraham, X. Brown (left 1:00 PM), E. Loechler (joined 12:06 PM), R. Morales, T. Winters, R. Varada (left 2:58 PM), S. Kurnick (joined 12:06 PM), J. Keeney, R. Timmerman, V. Britton, J. Barton (left 12:58 PM), R. Georgiadis
Guests Present: T. Killeen, N. Yun, S. Benjamin, M. Auerbach, A. Ahmad, J. Davis
Staff Present: J. Hutchinson, S. Ghosh, C. McGoff

I. Review of March 17, 2020 and April 28, 2020 IBC Meeting Minutes

No comments or questions were voiced.
Motion: Approve
For: 14; Against: 0; Abstain: 0; Absent: 2

II. New Business

A. Safety & Quality Assurance Program (SQAP) Report

i. Update on IBC protocol for 3-5-20 Splash to Nasal Mucus Membrane incident
As requested at the 4/28/20 IBC meeting, clarification was provided regarding IBC approval; EHS staff were consulted and the material and the individual involved in the incident are covered by the PIs approved protocol (2397).

ii. Administrative approval of amendment – 2439
Members were informed that as part of their review, the BPHC requested that information on an approved procedure be added to protocol 2439; the change was approved administratively.

iii. FAQs Regarding 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)
Members were informed that NIH OSP has issued new interim biosafety guidance for work with SARS-CoV-2 indicating that IBCs should consider the agent to be risk group 3 for the purposes of risk assessment; and updating guidance (previously shared with the IBC) on the appropriate biosafety level for handling SARS-CoV-2. A summary of BSL-2 and BSL-2+ coronavirus protocols recently reviewed by the IBC was presented to determine if members have any comments on the designated biosafety levels. The Chair requested that the list be shared with members via email for review and comment.

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

C. Presentation: Dr. Lydia Bourouiba (MIT): Dr. Bourouiba gave an educational presentation to IBC members about her work on viral transmission and fluid dynamics.

III. Protocol Review

1. Bhz – Three-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1788		Provide services related to the use of Flow Cytometer analyzer and cell sorting instruments.	2	N/A	BUMC
Primary Reviewer: Xin Brown		Secondary Reviewer: Jim Keeney			
Applicable NIH Guidelines: N/A					
Meeting comments: This is a three-year resubmission for the flow cytometry core facility (FCCF). The FCCF only allows samples that can be handled at BSL-1, BSL-2 or BSL-2 with special practices of BSL-3. Risk is assessed via the FCCF New					

User Form, each users' IBC FCCF Core Supplement Form will be reviewed before sorts can be initiated and agent training will be provided if necessary. The protocol covers procedures for material transportation, instrument operation and waste disposal. EHS staff noted that the use of disinfectants is appropriate (primarily 10% bleach otherwise EPA approved). Members discussed that checkboxes should be added to the cores user form to indicate if potentially infectious or rDNA material will be handled so staff are aware of potential hazards; all personnel should also complete rDNA/IBC training.

- III. Personnel Information:
  - There are four (4) personnel listed, but two (2) additional personnel (P. Autissier and M. Brudner) are mentioned in the research project description as dedicated personnel operating the cell sorter. Clarify if they should be listed as personnel and if so, list.
  - Anticipated work with rDNA and Infectious Agents is listed as "not applicable to this project". Cells brought into the facility by users may contain rDNA and infectious agents; the answers should be 'yes'.
  - B. Tilton's role is to perform large majority of sorting, his experience should not be listed as N/A.
  - Ensure that ROHP clearance is current for all.
- VIII. PPE and Safety Equipment: update the BSC certification date; and 70% ethanol should be added as it is mentioned in the research project description.
- Checkboxes should be added to the cores user form to indicate if potentially infectious or rDNA material will be handled so staff are aware of potential hazards and all personnel should complete the rDNA/IBC training.

Site Assessment: The BSC is certified; use of disinfectants is appropriate (primarily 10% bleach otherwise EPA approved); two (2) personnel need to be removed from the protocol; and ROHP clearance is not current for several personnel.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

2. 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 proposing to add equipment to evaluate stability and infectivity of SARS-CoV-2. The device is a nebulizer that will generate a defined size droplet aerosol. The aerosol disperses virus to mimic a sneeze plume. The aerosolized material then dissipates, and samples are collected from within a chamber on plates or through sampling tubes. The nebulizer is indicated to be sealed within an airtight chamber. After the machine is run, time is given to allow the aerosol to disperse before opening the chamber. The time ranges from ten minutes to hours, depending on droplet size . It was noted that caution should be taken to ensure that the droplet size and settling time are clearly understood by staff, developing a log sheet that shows that the correct time has lapsed before opening the chamber was mentioned. It was noted that decontamination of the chamber is appropriate and sufficient and that the risk associated with generating an aerosol containing infectious virus if offset by waiting before opening the chamber and given that the chamber will be housed inside a biosafety cabinet. The PI indicated that the settling time (number of hours) will be determined and documented in a SOP to ensure that the chamber is not opened until droplets have settled.

The BSL-4 BSO emphasized that all experiments will be conducted in the sealed chamber and inside a biosafety cabinet and that sealed chambers will be tested for airtightness prior to use including flow visualization and quantification (this data will be used to help ensure that the proposed time is sufficient for the aerosol to settle before opening the chamber); and that lab personnel will be trained on the procedure/equipment to ensure that the workflow is followed in a safe and consistent manner. It was emphasized that this work will be done at BSL-4 and that BSL-4 procedures and practices will be followed. It was noted that samples will be retrieved from the far end of the chamber and members discussed that the chamber will be flushed out after sampling. The PI indicated that gloves will be sprayed with Microchem and replaced each time the chamber is opened.

The PI was not present for the vote.

Motion: Approve	For: 13	Recuse: 1	Against: 0	Abstain: 0	Absent: 2

3. Bhz – Amendment

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

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Nadya Yun
Applicable NIH Guidelines: N/A	
Meeting comments: The PI is adding human cell lines of no concern and a source for SARS-CoV-2. Human cell lines will be received and stored in the BSL-2 laboratory (IBC protocol 2332) prior transfer to the BSL-4. • Transport of cells from the BSL-2 to the BSL-4 laboratory must be done via leak-proof, shatter-proof containers with biohazard symbols.	

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

4. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2361		Testing medical countermeasures against high consequence pathogens in rodents	4	4	BUMC

Primary Reviewer: Rob Davey Additional Reviewer: Nadya Yun	Secondary Reviewer: Rao Varada
Applicable NIH Guidelines: N/A	
Meeting comments: The proposed amendment adds Syrian hamsters as a disease model for SARS-CoV-2. Syrian hamsters' range in size from five to seven inches in length and are like Guinea pigs in size and behavior. Handling and precautions would be identical to Guinea pigs, for which the PI is previously approved; no further precautions are necessary. It was stated that the IACUC protocol for the proposed work is being drafted and that relevant SOPs are being updated to include hamsters. It was noted that hamsters will be inoculated intranasally. • Indicate the mode of virus inoculation in each animal species including hamsters. • Indicate that the SOPs for some of the procedures (i.e., blood collection and inoculation) are being revised to include hamsters.	

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

5. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2449		Analysis of coronavirus transcription and replication processes	3	N/A	BUMC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Shannon Benjamin
Applicable NIH Guidelines: N/A	
Meeting comments: The PI plans to do transcription and replication work with SARS-CoV-2 including cell culture experiments. It was noted that the PI is highly experienced at BSL-2 and that the protocol is similar to other protocols that have been reviewed by the IBC. It was noted that the completion of training requirements prior to engaging in protocol related activities will be stated in the approval letter. Site Assessment: The PI needs to be cleared by ROHP; and before conducting work, BSL-3 hands-on training, first aid and CPR training, and agent specific training need to be completed.	

Motion: Approve	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

6. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2442		Investigating the role of viral proteases in disease pathogenesis	3	N/A	BUMC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Shannon Benjamin

Applicable NIH Guidelines: Sections III-D-1-b, III-D-2-a, III-D-3-b; Appendix B-III-D and G-II-C					
Meeting comments: The PI is adding virus mutations (SARS-CoV-2); the additions are well described. It was noted that the PI responded to the DURC questions and that the DURRC subcommittee reviewed the submission and determined that the research did not meet the criteria for DURC. • VII. 3 Laboratory procedures: add incubation temperature for Triton X-100 inactivation; If the relevant language is that samples will be "incubated at 4 degrees C for 2 hours for virus inactivation" this language should be added to the protocol; and indicate that an SOP will be developed describing this inactivation method.					
Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

7. rDNA/Bhz – Three-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1285		Insulin regulation of cell nutrition; Regulation of lipolysis; Regulation of leptin production	2	1	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Rao Varada
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1; Appendix B-II-D, G-II-B	
Meeting comments: This protocol investigates the molecular defects associated with obesity and diabetes. Mouse or rat adipocytes, human HEK 293 cells and other non-human cell lines will be purchased and will be used for studying the trafficking of Glut4 protein in adipocyte cells by introducing exogenous proteins using retroviral, lentiviral or adenoviral vectors. It was noted that there is an IACUC approved protocol covering this work. • For Dr. Meriin, indicate how many years of experience, when and where. • Ensure that all personnel are current with training requirements, it appears that Dr. Zaarur's rDNA/IBC training is not current. • Viral waste inactivation should be done by adding bleach to a final concentration of 10%. • Correct phosphorus radioisotope designation from P23 to P32 • It was noted that animals will be euthanized to harvest adipocytes, clarify if this protocol includes animal handling, if so, this should be indicated. • For epididymal fat pad collection, clarify the method of euthanasia. • Sharps containers should not be autoclaved, please remove this statement. • In the rDNA section answer whom, when, and where for question 5 (marked 'Yes') and answer question 14. • For ASC entry, the animal PPE section should be completed to include shoe covers, gloves, lab coat, eye protection and surgical mask. Site Assessment: The lab has an Exposure Control Plan (ECP); one (1) personnel member is in the process of being cleared by ROHP; and several personnel have been notified of required training.	

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

8. rDNA/Bhz – Three-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1853		The role of the innate immune system in autoimmune kidney disease	2	2	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Susanna Kurnick
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1; Appendix B-II-D, G-II-B	
Meeting comments: This protocol compares gene expression in cells from patients with autoimmune disease and normal healthy individuals. An animal model of autoimmune disease is used. Materials used in the study include cultured human cell lines, urine and biopsy samples. Biopsy materials come from the Lupus and autoimmune disease registry at BMC. Lentivirus vectors expressing relevant proteins or appropriate shRNAs will be used and transduced in cell lines as well as in TLR or IRF5 deficient animals. Some experiments include transfer of hematopoietic cells to irradiated mice. • This is a 3 year-renewal, not an amendment, revise the protocol accordingly leaving the amendment space blank. • Section III.1: add the PI to the list of personnel and indicate where personnel received training.	

- Section VII.3-Lab Procedures: indicate how transformed hematopoietic stem cells (HSCs) will be introduced into mice; provide a brief description of procedures.
- Section IX. Materials Used in Research: check the first box (human cell lines, viruses) and fill out the table. If mice will be irradiated as part of this protocol, check Radiation and X-ray or clarify what protocol irradiation is being done under. ABSL-1 is checked, if lentivirus-transformed cells are injected into mice ABSL-2 should be indicated.
- rDNA table: under animal experiments, table lists pHAGE2 vector expressing mouse or human IRF5. The lab procedures section states that no virus will be injected into mice at any time, reconcile. Provide the current requested IACUC information.
- VIII: check off animal handling, cage changing.

Site Assessment: The lab has an ECP; two (2) personnel need to be cleared by ROHP; training is current; and the BSC is certified.

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

9. rDNA/Bhz – Three-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
753		Quantitative Analysis of Tumor Cell Migration in 3D Environments Noninvasive Quality Control of Malaria Rapid Diagnostic Tests	2	N/A	CRC

Primary Reviewer: Ed Loechler | Secondary Reviewer: Jim Keeney

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

Meeting comments: This protocol has two (2) distinct objectives: 1) to investigate the mechanism by which tumor masses break away and migrate to distant locations by a process called metastasis (tissue culture models expressing suspected players will be manipulated to understand their contribution in tumor metastasis); and 2) testing the validity of various rapid diagnostic test kits (available to field workers in rural Africa) for malaria via comparison against gold standard validated test methods (such as PCR or microscopy) to provide guidance to test manufacturers to improve reliability. Members discussed that the protocol to understand mechanisms of tumor metastasis and to improve rapid diagnostic tests for malaria are unrelated to each other and that these two (2) projects should be covered by two (2) separate protocols; it was noted that both are low risk but the risks differ. It was observed that work on cancer cells is straightforward and that decontamination is appropriate; cell work will be done in a BSC and centrifugation appropriately performed. It was noted that personnel have adequate experience or will be trained.

- Separate the two (2) projects into two (2) separate protocols (the risks are completely different).
- For the work being done in Tanzania, clarify if samples have already been shipped/received. If they have yet to be received, elaborate on shipping procedures and if any of the personnel in the lab have shipping training.
- Ensure that required training is current for all personnel.
- The protocol states that “no lentivirus work will be performed in the lab” however, lentivirus storage is mentioned elsewhere, and a lentivirus marker and a lentivirus packaging system are mentioned – clarify and reconcile.
- Provide the sources of cancer cell lines.

Site Assessment: There are personnel that need to be removed; a few personnel have been notified of required training; and the BSC is certified.

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

10. rDNA/Bhz – Three-year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1190		1. Regulation of topoisomerase I in the response to CPT; 2. Developing a predictive bio-marker for topoisomeraseI inhibitors; 3. Developing an E3 ligase inhibitor for combination therapy	2	N/A	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Bob Timmerman

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

Meeting comments: The PI is studying resistance mechanisms to CTP analogous (drugs inhibiting activity of topoisomerase I) in about 30% of patients with cancer. Determination of mechanisms will lead to development of predictive tests and drug screens to overcome drug resistance. It has been shown that four (4) of the CTP analogs inhibit activity of TOPOI and are effective for cancer treatment. The lab has developed an ImmunoHistoChemistry (IHC) test that detects levels of TOPOI-phosphorylated serine in human cells. The goal of the project is identification and validation of small molecules that specifically inhibit TOPOI activity in response to CTP.

- Ensure that rDNA/IBC training is current.
- Ensure that the PIs ROHP clearance is current.
- Update research experience, including an appropriate description of experience conducting work done at BSL-2.
- Include procedures for co-localization study on live cells. All procedures producing aerosols must be done in a BSC, the protocol should reflect this.
- Provide the current BSC certification date.
- Included procedures for genome editing using CRISPR/CAS9 technology.
- Include the source of cells from the Department of Pathology, including the name of the PI/lab.
- Compounds should be listed as non-toxic drugs.
- Section IV indicates that material will be stored in room , with room used for tissue culture however, Section VIII paragraph 10 says material will be stored in rooms and – clarify and reconcile.

Site Assessment: Lab has an ECP; the PI is updating ROHP clearance; the BSC is certified; eye wash and fire extinguishers are up to date; and should be removed.

Motion: Conditional Approval (Primary Reviewer Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

11. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2450		Lsd1 in oral cancer; Regulation of osteoarthritis by Loxl2 and other proteins	2	2	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Rao Varada

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1

Meeting comments: This protocol investigates the role of lysyl oxidase like protein 2 (LOXL2) in osteoarthritis and oral cancers. For the osteoarthritis project, they will transduce commercially available primary human chondrocytes or similar cells from transgenic mice with adeno or lentiviral vectors expressing LOXL2. Animal models will be used, viral vectors will be injected in experimentally created wound or xenograft tumors induced by implantation of cartilage from human patients followed by analysis of tissues for cancer-specific changes. The second project investigates the role of lysyl-specific demethylase 1 (Lsd1) in transgenic mice where Lsd1 is conditionally expressed using tamoxifen inducible Cre/lox system. The role of Lsd1-specific inhibitors will be tested under differential Lsd1 expression conditions. In some experiments, inhibitors encapsulated in nanoparticles will be injected into animals. It was noted that the PI has IACUC approval. The secondary reviewer will share any comments following the meeting.

- Section III.1- Personnel: add the PI to the list and describe experience of personnel (when and where). Ensure that required training is current for all (Alhousami rDNA training is overdue).
- Section IV.1- facilities: only space listed ( ) is BSL-1 but proposal is BSL-2; clarify where BSL-2 work will be performed.
- Section VII.2- Project Description: define LSD1 and LOXL2.
- Section VII.3- Lab procedures: define OSCC. This section mentions nanoparticle encapsulated LSD1 inhibitors. Describe the nature of the nanoparticles, and how the waste will be managed. (Can it be disposed of in the general biohazard waste container, or is a separate waste receptacle required?)
- Section VIII.3: PAPR is checked; indicate when a PAPR will be used.
- Section VIII.5.: A BSC is needed for virus preparation and tissue culture work; if the BSC in is being used, indicate its use and provide requested information throughout.

- Section IX.: Clarify why 'Field Study with animals' is checked (this appears to be an error). Uncheck 'synthetic DNA'.
- Section A.: Adenovirus and lentivirus and 293 cells in which viruses will be packaged should be added to the table.
- The protocol indicates use of human chondrocytes obtained from BUMC oral surgery department, fill out table in Section B. (Other Potentially Infectious Material) and provide IRB number if applicable.
- Section F. Hazardous chemicals: 4NQO (CCL2) and tamoxifen (CCL3) will be used. The table describing procedures, storage and handling of these chemicals should be filled out.
- Section H.1-rDNA table: Clarify if the adenovirus particles encoding LOXL2 described in the lab procedures section will be obtained from other labs/cores or prepared in the lab? If the latter, indicate the packaging system used.
- Section H.16: confirm that viral vectors are NOT replication competent (rDNA table indicates use of a commercial 3-plasmid lentiviral packaging system from Addgene).

Site Assessment: Room numbers need to be updated including shared space with Dr. Trackman, BSL-2 rooms and need to be added; has a BSC; adenovirus and lentivirus vector viruses will be added to the protocol; hazardous chemicals are listed on the IACUC protocol; and the lab mistakenly checked PAPR, will use N95.

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

12. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2453		Kidney Precision Medicine Project (KPMP); Renal Biobank; VEGF Biomarkers	2	N/A	BUMC

Primary Reviewer: Tom Winters | Secondary Reviewer: Valeda Britton

Applicable NIH Guidelines: N/A

Meeting comments: The goal of the study is to use deep molecular phenotypes of kidney biopsies and longitudinally collected clinical phenotypic data to develop new disease ontologies, classification systems, and treatments for acute kidney injury and chronic kidney injury. Biopsies will be done at Brigham and Women's Hospital. Blood and urine samples will be collected during the participants' baseline visit. A phlebotomist will collect blood in a vacutainer tube, and urine will be collected in a urine cup. A study coordinator will carry the specimens in a biohazard bag from the Menino building to the Evans Biomedical Research Center; samples will be processed, spun in the centrifuge, and stored in a freezer located in the same room.

- Indicate adherence to the blood borne pathogen standard.
- Include the use of needles to collect blood in the sharps section and provide requested information – information on sharps is provided in two different places in the application, reconcile.
- Clarify if Llori should be listed as Associate PI or Sponsored Personnel.
- The PI should be listed as personnel.
- Training Dates for Colona should be updated. Llori needs training. Clarify who is trained in shipping.
- ROHP clearance for Llori needs to be updated.
- It is indicated that blood and urine will be collected at BMC/BU. Should Box #2 be placed in Box #1? Should Phlebotomy or the General Clinical Research Unit (GRCU) be indicated as well?
- Research Project Description, paragraph 2: clarify why there is a reference to stool (does not appear elsewhere), clarify and reconcile throughout.
- Boxes should be checked in the Agreement Policy.

Site Assessment: The lab has an ECP; two (2) personnel need ROHP clearance; training is not current for a few personnel; and the lab does not have a BSC (the lab has been advised to use a BSC if generating aerosols).

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 1	Absent: 2

13. Bhz/rDNA – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2455		Transcription Factor Profiling for SARS-CoV2 Tolerance/Symbiosis Regulation	2	N/A	CRC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Rosina Georgiadis
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendix B-II-D, G-II-B	
Meeting comments: This protocol proposes to compare cellular transcription factor activities in a bat cell line model in association with SARS-CoV-2 infection and how that translates to immune status of the species. Bats are immune to infection of a variety of viruses which can otherwise cause disease in other species when transmitted. No live virus will be used in this study; only plasmid expression vectors that express individual viral proteins will be used. Human cell lines such as HEK293 will also be used. • Ensure that ROHP clearance is current for all listed personnel (appears to be outdated for two (2) graduate students). • Bleach solution should be a final concentration of 10% bleach; correct throughout. • It is indicated that "All needles will be capped after using"; needles should not be recapped. • Solid waste: disposal should be when ¾ full, not full. • rDNA: "Will the experiments involve rDNA molecules capable of expressing a pathogenic polynucleotide or polypeptide?" The answer is indicated as 'Yes', clarify if this is correct (should it be 'No', consistent with other information provided); and for question 11, should it be 'Yes' or 'No'? Site Assessment: A student needs to be added to the protocol; training is current; and the BSC is certified.	

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

14. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2457		Automated Large Scale SARS-CoV-2 Testing Scale Up with DAMP Lab for BU Community	2+	N/A	CRC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Ron Morales
Applicable NIH Guidelines: N/A	
Meeting comments: This protocol is an extension of approved protocol 1528 from the same lab (reviewed at the March 2020 IBC meeting). It proposes to use discarded clinical samples already in hand, and new samples from a collaborator at Boston Children's Hospital (both described in the previous protocol), to develop automated methods for high-throughput testing for SARS CoV-2. Positive controls include synthetic and genomic RNA from SARS-CoV-2 (BSL-2) and heat-inactivated SARS-CoV-2 virus (BSL-1), all obtained from BEI. • Section I, Inactivated Biological Samples Use: NP swabs from BCH are listed in this table, but these are not inactivated before receipt. According to the protocol the swabs are suspended in saline and shipped on dry ice to BUSM. However, the table should include heat-inactivated viral RNA obtained from BEI. Inactivation should be better described so it is clear if/what samples will be inactivated. • The PI needs to renew the following training: BSL1/2; BBP; Chemical Safety; and rDNA/IBC. • Indicate if the specimen samples from Boston Children's Microbiology laboratory will be labelled with the microbiological agents that they tested positive for. • Indicate that samples received from Boston Children's Microbiology laboratory will be packaged according to IATA/DOT standards. • Describe how the samples that are positive for SARS-CoV-2 are stored in the laboratory. • The use of an EPA registered disinfectant against SARS-CoV-2 should be added to the protocol. • Provide additional details on when the PPE checked in the protocol will be used. Specifically, goggles, safety glasses, and face shield were indicated, explain when each would be used. Surgical masks and respirators are also indicated, explain when each will be used. Laboratory coats and back-fastening gowns are indicated, explain when they will be used. • Provide additional information on how sharps will be safely handled. • Procedures for treating and disposal of solid and liquid waste should be adjusted. Contaminated solid waste (i.e. pipettes, tips) should be treated with a freshly prepared household bleach solution to a final concentration of 10% for 30 minutes (or any other EPA approved disinfectant) before discarding in a biohazard bag with a lid. Liquid waste is similarly treated with bleach solution to a final concentration of 10% for a minimum of 30 min prior to disposal in the sink.	

Site Assessment: The PI has been notified of required training that needs to be completed; the lab has been notified that work being done outside of the BSC requires use of a N95; and the BSC is certified.					
Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

15. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2332		Investigations of negative-strand virus and alphaherpesvirus biology	2	N/A	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Ron Morales				
Applicable NIH Guidelines: III-D-1-a, III-D-2-a, III-E-1, III-F-1, Appendix B-II-D and G-II-B					
Meeting comments: The proposed work adds human immortalized cell lines and primary lung cell types to support work on virus infection mechanisms. The work covered in this protocol is for cell cultivation only and is BSL-2; cell types are handled at BSL-2 with use of a BSC which is appropriate. • Documentation with the lung cells should indicate that they have been checked for common human pathogens. A comment should be made that blood-borne pathogen precautions will be used. • Specify the source of materials.					
Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

16. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
698		Analysis of human tumor xenograft models and frozen blood samples from stroke patients	2	2	BUMC

Primary Reviewer: Tom Winters Additional Reviewer: Ron Morales	Secondary Reviewer: Jim Keeney
Applicable NIH Guidelines: N/A	
Meeting comments: This is an amendment to study disinfected blood samples from COVID-19 positive acute respiratory distress syndrome (ARDS) patients to look for the presence of DEspR (dual endothelium – 1\signal peptide receptor) on neutrophils. In addition, NETs (neutrophil extracellular traps) will be studied for presence in this population. Cytokine storm during ARDS and multi organ failure is often the cause of death in COVID-19 patients. The PI plans to study whether DEspR positive neutrophils and NET's are elevated in COVID-19 positive patients. They will study DEspR expression on neutrophils/WBCs in NET's presence in fixed whole blood from COVID-19 positive ARDS and COVID-19 negative ARDS patients. All blood samples are disinfected and fixed with 4% PFA (paraformaldehyde) for 60 minutes with 4% PFA added to blood immediately after blood draw (the literature supports 3.5% PFA killed SARS-CoV in five minutes). A review of the neutralization of SARS-CoV-2 blood samples in the GCRU lab is described. Samples are then moved to 700 Albany St. (lab) in double bagged protected containers. Work is done in a BSC where smears are made and fixed with 100% methanol. The remaining blood is stored in sealed micro tubes and frozen. Meticulous cleaning processes are explained. No recombinant DNA work is done. Blood processing is well explained. It was clarified that BMC's Epidemiologist (Dr. Sulis) does not need to be consulted given that work is being done at the GCRU. Members discussed their understanding that inactivation is being done at GCRU; the PI needs to clarify if he is receiving inactivated samples and if so, provide pertinent details. • Clarify if shipping will be done, if so, all personnel who are shipping materials need to complete shipping training. • Provide the certification date for the BSC. • Clarify if personnel have been cleared by ROHP for use of COVID-19 positive samples. • Indicate if there is a biosafety cabinet in the GRCU that is used when the specimen container with blood is opened and treated with 4% PFA. • The following PPE are listed in the amendment: lab coat, disposable gloves, safety glasses, face shield, surgical mask, and double gloves; provide additional details on when the PPE listed would be used (for what procedures). • Clarify where the inactivation of materials is being done – the protocol should specify if inactivated samples will be received and from whom.	

• Personnel need to complete agent specific training.					
Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 3

17. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2113		Zika virus growth and characterization; development and evaluation of diagnostic tests for positive and negative sense RNA viruses.	2+	N/A	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Bob Timmerman				
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, and III-D-3-a; Appendix B-II-D, and G-II-B-3					
Meeting comments: The PI is proposing to test environmental samples collected on Teflon filters at Hebrew Senior Life Facility for the presence of SARS-CoV-2. Samples will be sent to the NEIDL in sealed containers, defrosted, diluted in PBS, and deactivated by addition of AVL/RLT buffer. All procedures will be performed inside a BSC. Sealed rotors will be used for centrifugation. Members discussed that the listing of materials as potentially infectious material is sufficient. • Clarify who is doing the environmental sampling collection and if lab personal are involved. • Provide current IRB information requested in the application.					
Motion: Conditional Approval (Administrative Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4

18. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
983		Role of Intercellular Communication in Pathogenesis of Diabetic Retinopathy	2	2	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Valeda Britton				
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1; Appendix B-II-D, Appendix G-II-B.					
Meeting comments: The amendment is to change the PI, the new PI was previously listed as an Associate PI on the protocol. • Personnel experience should be detailed; number of years of experience is insufficient. • Included titles for new personnel. • Ensure all personnel have current ROHP clearance. • Personnel who will be shipping materials must have current shipping training.					
Motion: Conditional Approval (Administrative Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 4