



Boston University
Institutional Biosafety Committee (IBC)
April 14, 2020 Meeting Minutes
Location: Zoom and/or by phone
Start time: 10:00am End time: 12:19pm

Members Present: I. Afasizheva, B. Slack, E. Muhlberger, R. Davey (left 12:18 PM), C. Abraham (left 10:55 AM, returned 11:07 AM, left 11:53 AM), E. Loechler (left 11:35 AM), R. Morales, T. Winters, R. Varada, S. Kurnick (left 12:11 PM), J. Keeney, R. Timmerman, X. Brown (left 12:14 PM), V. Britton, J. Barton
Guests Present: P. Urick, N. Yun, S. Benjamin, F. Ennever, M. Auerbach, A. Ahmad
Staff Present: J. Hutchinson, S. Ghosh, C. McGoff

I. New Business

LAI Subcommittee Recommendation (SARS-CoV)

Members were informed of a recommendation by the subcommittee to add Severe acute respiratory-syndrome related coronavirus to the list of Biological Agents with Potential to Cause Laboratory Acquired Infection. It was noted that the Agent Information Sheet covers SARS-CoV, MERS-CoV and SARS-CoV-2 and that agent specific training for coronaviruses is available in BioRAFT.

Motion: Approve recommendation

For: 15; Against: 0; Abstain: 0; Absent: 0

DURC Potential/DURRC Review

Members were reminded that if proposed research could possibly enhance the pathogenicity or transmissibility of an agent, that this should be noted during their review so further review can be coordinated by the Dual Use Research Review Committee’s subcommittee as needed. It was noted that SARS-CoV-2 (the novel coronavirus) is not on the federal list of select agents and toxins and SARS-CoV is.

II. Protocol Review

1. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus		
2363		Exploring molecular mechanisms of the immune system	2	2	BUMC		
Primary Reviewer: Carmela Abraham Additional Reviewer: Ron Morales		Secondary Reviewer: Rao Varada					
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1; Appendices B-II-D, G-II-B							
Meeting comments: The PI is proposing to use recombinant proteins (e.g. S-protein) of SARS-CoV-2 (BSL-1) and inactivated biological samples of SARS-CoV-2 infected cells and mice from the NEIDL. Members discussed the use of inactivated material derived from SARS-CoV-2 (provided by investigators at the NEIDL) and that it should be verified that the methods that will be used by the NEIDL investigators to inactivate the virus have been approved. It was noted that there is no animal work being proposed as part of this amendment. Members discussed that agent specific training is not needed for the use of inactivated material given that the material has been inactivated and is not infectious.							
<ul style="list-style-type: none"> Clarify if work that may produce aerosols will be done in a biosafety cabinet or a chemical fume hood – both are mentioned. Ensure that all of the requested information in Section I. Inactivated Biological Samples Use has been provided and, in the Application, make clear what inactivation methods will be used by the NEIDL PIs providing the inactivated material. Clarify if personnel have been cleared by ROHP for the proposed work. 							
Motion: Conditional Approval (Administrative Review)			For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

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 generation of recombinant SARS-CoV-2 clones: recombinant wild type SARS-CoV-2 viruses and virus encoding a reporter gene. BSL-2 work for handling plasmids encoding SARS-CoV-2 genome was added to IBC protocol 1409. Material is transferred to the BSL-4 lab in a shatterproof container. Nucleic acids are transfected using electroporation or lipofection only, the virus is then stored and used for other work. It was noted that the viruses produced will be as pathogenic or less pathogenic than the wild type virus and that work with wild type coronavirus was previously approved. It was noted that recombinant SARS-CoV-2 can be used safely in the BSL-4 using BSL-4 practices and procedures. Members discussed if there is a mechanism in place to monitor potential exposure for individuals working with virus; it was noted that work will be done in BSL-4 containment (including use of required PPE) minimizing exposure potential, and that ROHP's post-exposure protocol includes blood draws after an event and follow-up for 14 days (serum storage is not done). It was noted that once the lab rescues any virus, the lab will sequence its genome to ensure there are no mutations.							
Motion: Approve			For: 14	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

3. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2345		Identification of host factors controlling virus infection	4	N/A	BUMC
Primary Reviewer: Elke Muhlberger			Secondary Reviewer: Nadya Yun		
Applicable NIH Guidelines: Section III-F-1, III-D-2-a, III-D-1-a, III-F-8 - Appendix C-I, III-D-3-b, III-E-1					
Meeting comments: The PI is proposing to add new lab personnel and new viruses: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), Middle Eastern Respiratory syndrome virus (MERS-CoV), Severe acute respiratory syndrome coronavirus (SARS-CoV) and generation of recombinant viruses; no procedural changes are proposed. It was noted that BSL-4 practices and containment are sufficient to work with these agents and that K. Geoghegan-Barek and J. Patten are up to date with their training and are currently undergoing training to obtain independent access to NEIDL BSL-4 space. Members discussed that the PI has provided additional details to address if the proposed work could potentially enhance pathogenicity or transmissibility; it was noted that measures will be taken to ensure that the virus does not become more pathogenic and the steps that would be taken if this were to occur have been included. The Chair reported that the subcommittee of the Dual Use Research Review Committee (DURRC) met yesterday to discuss the proposed work and determined that full committee review by the DURRC is not needed given that the work does not meet the definition of DURC.					
<ul style="list-style-type: none"> SARS-CoV-2 and MERS-CoV are positive sense RNA viruses whose genomes can be used to generate infectious virus by transfecting cells. Describe precautions for handling RNA samples at BSL-2 (e.g. restricted access, no cell culture or transfection work). SARS-CoV genomic RNA is classified as a select agent and CDC regulations apply. If SARS-CoV work will be performed, more information about the BSL-2 logistics must be added. Clarify if work with recombinant SARS-CoV will be performed. Although it is stated that a separate BSL-2 protocol will describe the recombinant genome work, briefly describe procedures for the safe handling of plasmids encoding coronavirus genome in the BSL-2. Clarify if work will be done in a biosafety cabinet, what PPE will be used, what disinfectants will be used and contact time, and how will you handle waste. Indicate that no concurrent transfection work or in vitro transcription reagents are used or stored in the same laboratory and that no work with mammalian cell culture is conducted in the same laboratory space. 					

<ul style="list-style-type: none"> • Add a statement that the IBC and EHS will be notified after successful rescue of recombinant viruses in the BSL-4. • SARS-CoV is a select agent and must be registered with the CDC before work can be initiated. • Page 33, Section I. Inactivated biological Sample Use: add coronavirus to the table. 					
Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

4. 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: Section 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 proposing to add additional BSL-3 pathogens: Chikungunya virus, West Nile Virus, Yellow fever virus and MERS-CoV. It was noted that recombinant DNA work is also being added and that the listed applicable NIH Guidelines are appropriate.						
<ul style="list-style-type: none"> • VII. 3 Laboratory procedures: describe how the barcoded RNA for single cell sequencing will be removed from the BSL-3 lab. Is the RNA suspended in TRIzol or another lysis buffer? More details would be helpful. • VII. 3 Laboratory procedures: add that there are currently no plans to insert mutations into the SARS-CoV-2 genome. If there are plans to insert mutations, briefly describe which genes will be affected. • IV. Research Laboratory Facility Information: remove , this room is not currently available for proposed use. • Work with one virus at the time when doing work with cell cultures or in vitro transfections in the BSL-3 lab to avoid cross-contamination of cell cultures. • Aliquot and discard after use, transfection or in vitro translation reagents to prevent cross contamination of reagents. • For the BSL-2 portion of the study: recombinant nucleotide products should only be stored in BSL-2 and transported to BSL-3 for the transfection or in vitro translation studies. 						
Motion: Conditional Approval (Primary and Secondary Reviewer Review)		For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

5. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2439		Storage, Propagation and Distribution of BSL-3 Emerging Pathogens	3	N/A	BUMC
Primary Reviewer: Inna Afasizheva Additional Reviewer: Shannon Benjamin		Secondary Reviewer: Tom Winters			
Applicable NIH Guidelines: N/A					
Meeting comments: This is a new protocol that seeks to expand the NEIDL repository for viral stocks; eighteen (18) agents, including select agents are listed. The objective is to obtain, develop stocks, store, and distribute viruses to investigators with approved IBC protocols. It is essential to have all listed viruses in stock to expedite research on both human and animal pathogens. The current application is very similar to the PIs BSL-2 storage protocol (2172). Appropriately, PPE for the specific viruses is described. Listed personnel are experienced. Much of the work will be done by Broos-Caldwell, research technician and laboratory operations manager who maintains the NEIDL master stocks at BSL-2 and BSL-3. Research is not proposed under the protocol however, quantitation is required for distributing pathogens and providing investigators with information on virus concentration in stocks. Four basic methods in microbiology will be used: 1) Plaque assay: serial dilution of viral stocks to infect host cells in monolayer, quantitation of lysed by virus zones; 2) TCID50s: endpoint dilution of viral stocks to infect host cells in monolayer to measure 50% of killed host cells by virus; 3) Focus forming assays: serial dilution of viral stock, instead of colonies quantitation, infected host cells monolayers are probed with antibodies to viral antigens; and 4) Validation of the					

identity of the viral stock. This method is PCR based with complete deactivation of the virus by lysis in Trizol. Select agents and non-select agents will be separated and maintained in distinct rooms. Clinical samples will be obtained from a number of sources, IRB protocol numbers have been provided (approval is pending). The BSL-3 BSO indicated that many of her comments are intended to promote consistency between BSL-3 protocols and with relevant NEIDL SOPs. It was noted that personnel were not cleared by ROHP for work with Japanese encephalitis virus and yellow fever virus; ROHP staff indicated that this is because all of the travel clinics are currently closed (due to the SARS-CoV-2 outbreak) and that vaccinations should be provided before starting work. It was noted that ROHP clearance is required before personnel can engage in protocol related activities and that the PI has added Dr. Saeed as a Co-PI on the protocol.

III. Personnel Information

- #1, Add a co-PI to protocol. In the “Descriptive Role” column, indicate that the co-PI will be providing day-to-day lab supervision and oversight of lab activities.

VII. Research Project Description

- #3, storage: remove “or N95, and safety glasses or faceshield if using N95.” Add use of disposable scrubs to the PPE listed.
- #3, storage: remove “For example, flaviviruses and alpha viruses normally require N95 and safety glasses or a faceshield. However for coronaviruses and all select agents full PPE including PAPR are required.”
- #3, cell culture: remove “under BSL2 conditions”. Last sentence, re-word the following phrase “This room is equipped with centrifuges with sealed covers which are used for all centrifugation steps.” to “This room is equipped with centrifuges with sealed safety cups or sealed rotors which are used for all centrifugation. All sealed safety cups or sealed rotors will be loaded and uploaded in the biosafety cabinet.”
- #3, all sections that apply, indicate anticipated virus concentration or MOI
- #3, PCR and/or sequencing: reference the use of inactivation SOPs:
 1. Inactivating non-select agent BSL3 materials using TRIzol, TRIzol LS and other nucleic acid extraction buffers
 2. Inactivating non-select agent BSL3 materials using ionic and non-ionic detergents
 3. Inactivating non-select agent BSL3 materials using formalin or paraformaldehyde
- #3, virus quantitation: remove link and reference aforementioned inactivation SOPs
- #3, distribution to investigators: Add the following “Materials will be packed and transported in accordance with OPS-SOP-0198 Use of Pass-Through Boxes in NEIDL (A)BSL-3”
- #3, separation of select agents from non-select agents: add language which reiterates that equipment used for SA will be dedicated solely to SA and will not be shared.

VIII. Personal Protective Equipment and Safety Equipment

- #3, de-select, laboratory coats, goggles, safety glasses, face shield, N95. Select disposable scrubs, other than enter “Sleeves, coveralls, and dedicated shoes”
- #7A, state “Any liquid waste will be handled as described in SAF-SOP-0190 (Biological waste handling and disposal in BSL3 laboratories). During experiments, cell media and supernatant will be discarded into a tray containing freshly prepared bleach to the final concentration of 10% inside the biosafety cabinet. After overnight incubation with bleach, liquid waste will be discarded into the sink”
- #7B, state “Any solid waste will be handled as described in SAF-SOP-0190 (Biological waste handling and disposal in BSL3 laboratories). During experiments, all tools and materials that come in contact with the virus, including serological pipettes, tips, etc, will be discarded into a tray with freshly prepared bleach to the final concentration of 10% inside the biosafety cabinet. After overnight incubation with bleach, the waste will be placed in medical waste boxes that will then be autoclaved following SAF-SOP-0102 (Autoclave use in BSL3).”
- #8, change “10% fresh bleach (EPA approved). Work surfaces are cleaned with 70% ethanol.” to “Work surfaces are disinfected using 10% bleach, made fresh daily, followed by 70% ethanol.”

Motion: Conditional Approval (Additional Reviewer Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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6. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus		
2261		Imaging and characterization of Heme/Hemozoin in SARS-Cov-2 infected tissue.	2	N/A	CRC		
Primary Reviewer: Ed Loechler Additional Reviewer: Ron Morales			Secondary Reviewer: Valeda Britton				
Applicable NIH Guidelines: N/A							
<p>Meeting comments: The PI is proposing to image slides made from tissues from COVID-19 patient autopsies. A novel microscopy technology will be used to image heme and hemozoin, two molecules believed to be highly related to organ damage and failure in COVID-19 patients. The tissues will be from lung or heart, and will be fixed, dehydrated with alcohol, and embedded in paraffin; this process kills the pathogen. Samples will be received from an external collaborator, Dr. Joerns (no samples have been received yet). Members discussed that the samples will be inactivated and considered BSL-1 material; given that the samples have been inactivated, agent specific training is not required.</p> <ul style="list-style-type: none"> • Ensure training and ROHP clearance is up to date for all personnel. • Per BU's Inactivated Biological Sample Use Policy, the source institution sending the samples must submit a certificate (e.g. a letter signed by the authorized institutional official) for each shipment attesting that the samples have been processed using their institutionally approved methods for inactivating and removing samples. • Since the samples have yet to be received, the past tense should not be used in the Application when referring to receipt/use of samples; this should be reconciled throughout. • It is indicated that this is a new project, however, in PI Comments (page #1) it is mentioned that this was an amendment, this needs to be reconciled. • The use of "double surgical masks and double head covers" is indicated, this is not necessary. • It is indicated that all PPE waste will be autoclaved; this is not necessary as the tissue samples that are mounted on the slides are fixed in formalin and histologically processed and stained. <p>BUA Site Assessment: Done remotely; has an ECP, BSM and CHP on file; the PI needs to update required training; and the BSC is certified.</p>							
Motion: Conditional Approval (Administrative Review)			For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

7. rDNA/Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2448		Studies with COVID19 proteins	2	N/A	BUMC
Primary Reviewer: Barbara Slack			Secondary Reviewer: Ron Morales		
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a and III-E-1					
<p>Meeting comments: The lab has extensive experience studying stress granule formation. This protocol will examine the effect of individual transiently expressed COVID-19 proteins on stress granule formation in cells stably transfected with RNA-binding proteins. If effects are seen, the experiment will be repeated in the presence of test compounds obtained from Aquinnah Pharmaceuticals.</p> <ul style="list-style-type: none"> • Ensure rDNA training is current for all personnel. • Procedures: add a brief description of procedures to be used/precautions taken while handling lentiviral vectors and transducing cells. • Section A lists human cell lines and plasmids encoding individual virus proteins and classifies them as 'virus' under 'Agent Class'; remove plasmids from this list and change classification from 'virus' to 'human cell lines'. • rDNA table: list species from which RNA binding protein cDNA was derived. • "Homogenizing, tissue grinding" is checked under Laboratory Procedures, information was not found that related to tissues being processed or grinded; provide details on what tissues are being grinded. What is the tissue source and is it from a known infected source? 					

- It is indicated that “sonication and tissue grinding will be done in a chemical fume hood”. Clarify tissue source (comment above) and why the sonication will be performed in a chemical fume hood and not a biosafety cabinet. Indicate how waste from tissue sonication/grinding procedures are treated and disposed and how the equipment is cleaned and disinfected.
- Throughout the application the virus should be referenced as SARS-CoV-2 (not COVID-19 which is the disease).

BUA Site Assessment: Done remotely; has a BSM and CHP on file, updating ECP; ROHP clearance and training are current; and the fume hood and BSC are certified.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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8. 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: Barbara Slack		Secondary Reviewer: Ed Loechler				
Applicable NIH Guidelines: III-D-2-a, III-D-3-b, III-E-1, III-F, Appendix B-II, Appendix G-II-B, G-II-C						
Meeting comments: The PI is adding DNA encoding the SARS-CoV-2 virus, and plasmid DNA encoding SARS CoV-2 replicons with or without reporter genes. These will be transcribed to genomic RNA or RNA fragments (these are BSL-2). The Viral RNA will be transported to BSL-3 or BSL-4 facilities for further investigation under a different protocol. The CoV-2 replicons (which cannot make infectious particles) will be transcribed and used to transfect cells under BSL-2 conditions. The replicons are cloned into bacterial-yeast shuttle vectors and will be propagated in E. coli K12 or yeast BL6-48 strains (BSL-1). It was noted that RNA will not be infectious and will be kept away from any cell culture work, and that the cell lines are classified by ATTC as BSL-1. Members discussed if the RNA could potentially be infectious; it was noted that nucleoprotein would also need to be added to the RNA to get infectious virus, but nevertheless personnel should take care when handling RNA, particularly if they have cuts or skin damage. Further it was noted that stabilizing material is needed to produce infectious RNA and that the PI is not using such material, making the work low risk.						
Motion: Approve		For: 14	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

9. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus	
1522		Virus - Host interactions during HIV-1 pathogenesis	2+	2	BUMC	
Primary Reviewer: Xin Brown		Secondary Reviewer: Susanna Kurnick				
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-D-3-b; Appendix G-II-C, B-III-D						
Meeting comments: The PI studies HIV-1 interaction with macrophages and dendritic cells. This amendment seeks to determine the infection efficiency of SARS-CoV-2 in macrophages using HIV pseudotyped with SARS-CoV-2 S protein in a single round infection assay. The ability of these pseudotyped virus to bind, fuse, and enter macrophages will be determined by FACS analysis of fixed cells or luciferase activity in cell lysates. The lab has done extensive studies on virus entry and he is aware of the biohazards associated with his research. All procedures will be performed in a BL2+ suite, PPE, disinfection procedures and other safety precautions are described in detail.						
<ul style="list-style-type: none"> • Section VII, 3, #13: it is indicated that mice will be used in experiments but no ABSL level is checked in the protocol. This should be clarified and corrected throughout to include IACUC #, ABSL level, locations of housing and necropsies, etc. • Ensure training is current for all personnel. • Update the biosafety cabinet certification date. 						
Motion: Conditional Approval (Administrative Review)		For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

10. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus	
2355		Material transfer to NEIDL/BUMC New Title: Characterization of cellular proteins cleaved during virus infection	2	N/A	BUMC	
Primary Reviewer: Inna Afasizheva		Secondary Reviewer: Bob Timmerman				
Applicable NIH Guidelines: III-D-1-a, III-D-2-a, III-D-3-a, III-E-1						
<p>Meeting comments: This amendment proposes: 1) to add new coronavirus strain (SARS-CoV-2) plasmid DNA and yeast to propagate plasmids (BSL-1); 2) RNA synthesis in vitro by T7/SP6 transcription using SARS-CoV-2 plasmid DNA (BSL-2); and to add Murine Coronavirus Mouse Hepatitis Virus (MHV) as hazardous agents (BSL-2). The PI is proposing to use SARS-CoV-2 cDNA cloned into plasmid that the lab will receive from collaborators for synthesis of viral RNA by in vitro transcription. This RNA will be used to infect cells and produce virions. The protocol has been updated accordingly. Cells will be infected in the NEIDL BSL-3 suite; the PI's BSL-3 protocol is referenced.</p> <ul style="list-style-type: none"> Update the work experience for Dr. Kapell on page 6; it is not clear what training he/she has received during postdoctoral training. The addition/use of Coronavirus Mouse Hepatitis Virus needs to be explained. Clarify if animal work will be done; an ABSL is not indicated. Update the biosafety cabinet certification date. 						
Motion: Conditional Approval (Administrative Review)		For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

11. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus	
487		Initiation and regulation of RSV mRNA transcription and genome replication (NIH) A structure analysis of the intact virion and replicative complexes of human respiratory syncytial virus (MRC, UK) Treating respiratory syncytial virus infection by targeting the viral polymerase (The Hartwell Foundation) The B cell repertoire as a window into the nature and impact of the lung virome (NIH) Mechanism of action of an RSV N protein inhibitor (Enanta Pharmaceuticals) Mechanisms of Marburg virus gene expression (NIH) Developing combination therapies against pneumo- and paramyxoviruses causing severe respiratory infection (NIH subcontract) Analysis of coronavirus transcription and replication machinery	2	N/A	BUMC	
Primary Reviewer: Xin Brown		Secondary Reviewer: Jim Keeney				
Applicable NIH Guidelines: Sections III-D-1a; III-D-2a; III-D-3a; Appendices B-II-D; B-V; G-I; G-II-B						
<p>Meeting comments: The PI is interested in the regulation of RNA polymerase activity of RNA viruses. Polymerases are expressed in either a T7 system or a baculovirus system, purified, and their activities analyzed in mini-genome or amplicon systems. The amendment proposes to add SARS-CoV-2 RNA dependent RNA polymerase and N protein to the study. The study does not involve use of live virus, only viral RNA polymerases. The safety precautions described in the protocol are reasonable.</p> <ul style="list-style-type: none"> If shipping is being done under this protocol, ensure that all personnel who will be responsible for shipping have current shipping training. Update the biosafety cabinet certification date. 						
Motion: Conditional Approval (Administrative Review)		For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

12. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus		
635		Biospecimen Archive Research Core	2+	N/A	BUMC		
Primary Reviewer: Rob Davey Additional Reviewer: Ron Morales			Secondary Reviewer: Tom Winters				
Applicable NIH Guidelines: N/A							
<p>Meeting comments: Work is being proposed with nasopharyngeal swabs collected from COVID-19 positive and negative patients to evaluate a rapid PCR-based device for the detection of the virus SARS-CoV-2 in a BSL-2 setting. Three (3) personnel have been added and lab space in 670 Albany, room (as an overflow area for sample processing or if manual preparation of histological material is required) the room has a BSC. The PI oversees the biospecimen archive at BU (BARC). He will supervise a group of three (3) scientists to collect and archive material from COVID-19 patients from BMC and local hospitals. Each is a trained physician working with infectious material daily. Blood as well as nasopharyngeal swabs will be taken. For blood work, the group is well experienced, and procedures are established; the nasopharyngeal work needs refinement. It was noted that the PI contacted EHS to do a risk assessment.</p> <ul style="list-style-type: none"> • The PI should be listed on the protocol. • Clearly state what BSL-3 practices will be followed and coordinate with EHS to ensure that appropriate BSL-3 practices will be followed, including proper donning and doffing of PPE. • In section 3 of the PPE and safety equipment responses, state clearly what is meant by “BSL2 with BSL3” and then later “Advanced BSL-2 practices” as each is not the same and means different things to different people. It would be preferred that an a) N95 (samples are not expected to be large and no procedures are indicated that would generate a strong aerosol); b) disposable lab coat; c) disposable pair of gloves; and d) face shield, be used and should not leave the immediate lab area. • Provide additional procedural details regarding the nasopharyngeal work, noting relevant experience. • It is indicated that the swab will be placed in “lysis buffer”. Is this known to inactivate SARS-CoV or other enveloped viruses? Clarify efficacy. If not, it is preferred that an inactivating lysis mixture be used. • It is stated that after each test, “the pre-filled tubes will be fully decontaminated by adding ethanol to the tubes, bleaching the outside of the tubes, and then discarding”. It would be simpler and more effective to immerse the tube in 10% bleach in a tub for 30 minutes, then drain and drop the tube in a biohazard box. • For remainder sample storage, does the vial seal well? If not, use an air-tight sealable vial. • Indicate that vials will be transferred to the freezer in a shatterproof container. • Agent specific training (coronaviruses) needs to be completed. • Room was indicated as one of the storage locations for frozen blood products and tissues; add this room to the laboratory locations on page 11. • Clarify if safety precautions are the same in room . 							
Motion: Conditional Approval (Administrative Review)			For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 2

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: Inna Afasizheva			Secondary Reviewer: Tom Winters		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendix B-II-A.					
<p>Meeting comments: The PI is adding two (2) COVID-19 studies: 1) serological study: use of discarded human blood from the BMC pathology lab. The task is to create a fast and sensitive ELISA-based testing system with antibody to SARS-CoV-2 or specific protein that can be used to coat ELISA plate. The PI proposes to use a recently published assay that allowed minimizing the amount of plasma samples. Developing plasmids for expression of full size or truncated</p>					

spike protein genes and production of monoclonal antibody is planned in established collaboration with Sigilon Therapeutics. All manipulations with specimens will be done in a BSC; and 2) COVID-19 NP swabs study: collection of samples negative and positive to COVID-19 from BMC in transport media. They propose to understand the impact of SARS-CoV-2 on the microbiome. DNA will be extracted from samples obtained from the Discarded Biospecimen repository at BUMC. All procedures involved in DNA studies are covered by the currently approved protocol. Discarded human samples will be collected from BMC pathology with no patient contact. Members discussed concerns about the efficacy of the inactivation methods (heat) provided, indicating that additional details are needed about the methods that will be used and their efficacy. It was noted that relevant literature should be referenced to indicate that methods being used are effective and that inactivation literature for SARS-CoV is a good proxy for SARS-CoV-2. It was stated that heating samples to 50°C is insufficient for inactivation using heat. Members discussed the appropriate biosafety level for the proposed work. It was noted that other investigators working with live virus do so in BSL-3 space, using BSL-3 practices and procedures. When human samples are used that are known to be infectious, work has been done in BSL-2 space with BSL-3 practices. Members discussed that the BSL for the proposed work should be BSL-2 with special practices of BSL-3. EHS staff indicated that they will work with the lab to ensure that appropriate BSL-3 practices will be followed.

- Clearly indicate what samples will be received and what will be done with the samples.
- Detail the inactivation methods that will be used and provide evidence that methods have been validated (i.e., referencing literature indicating that the method is valid for other viruses such as SARS-CoV).
- Add SARS-CoV-2 to the hazardous biological agents table.
- Proposed work should be done with special practices of BSL-3. Coordinate with EHS to ensure that the appropriate practices will be followed and are listed in the application and note the highest biosafety level accordingly.

Motion: Conditional Approval (Primary and Secondary Reviewer Review)	For: 10	Recuse: 0	Against: 0	Abstain: 0	Absent: 5
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