Boston University
Institutional Biosafety Committee (IBC)
August 18, 2020 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 2:18 PM

Members Present: C. Abraham, B. Slack, E. Muhlberger, R. Davey, X. Brown, R. Morales, T. Winters, S. Kurnick (joined 12:14 PM), J. Keeney, R. Timmerman, V. Britton (joined 12:09 PM), J. Barton
Guests Present: P. Urick, F. Ennever, A. Ahmad, J. Davis, C. Bennett
Staff Present: J. Hutchinson, S. Ghosh, C. McGoff

I. New Chair: Members were informed that Carmela Abraham has been appointed as Chair of the IBC effective September 1st and will be leading today's meeting.

II. Review of July 21, 2020 IBC Meeting Minutes
No comments or questions were voiced.
Motion: Approve
For: 10; Against: 0; Abstain: 0; Absent: 2

III. New Business

A. LAI Subcommittee Recommendation: Members were informed of a recommendation by the subcommittee not to include *Prevotella intermedia*, *Peptostreptococcus micros*, *Streptococcus intermedia* or *Fusobacterium nucleatum* (new agents to BU) on the list of Biological Agents with Potential to Cause Laboratory Acquired Infection. It was noted that these are oral bacteria that are easily treated with penicillin. No questions or comments were voiced.
Motion: Not to include these four (4) agents on the list of biological agents with potential to cause LAI
For: 10; Against: 0; Abstain: 0; Absent: 2

B. Environmental Health and Safety (EHS) & Research Occupational Health Program (ROHP) Report: No incidents to report. It was noted that Pat Urick is retiring, this will be her last meeting and she was thanked for the support she has provided over the years.

IV. Protocol Review

1. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1949		Point of Care Tests for Cervical Cancer	2	N/A	CRC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Jim Keeney
Applicable NIH Guidelines: Section III-D-2-a	

Meeting comments: The PI is developing a diagnostic assay for Human Papillomavirus (HPV); pap smear samples obtained from BIDMC and BMC are used for assay development. DNA is extracted from these samples which are then used in specialized assays to ultimately design methods to quickly identify HPV infection. It was noted that the transport of samples is described in the PPE section and that all BSC's have recent certification. EHS staff indicated that they will follow-up with the PI regarding waste collection (per the comment below).

- Room : clarify if a BSL2+ lab is required for this work or if BSL2+ is required for other work performed in this room. If a BSL2+ lab is required for this work, clarify which pathogens are handled (in) and how personnel are protected.
- Clarify why decontaminated bacterial waste is transferred to the waste satellite area instead of being directly poured down the sink, consulting with EHS staff regarding appropriateness.
- Describe in the Research Project Description the work that requires a homogenizer/blender (this is checked in the PPE section).

- It is mentioned in the liquid waste section that blood will be disposed of. Use of blood is not described in the Research Project Description. Describe experiments with blood or remove blood from the liquid waste section.
- Remove *E. coli K12* from the Hazardous Biological Agents list.

Site Assessment: No findings; BSC's are certified and training and ROHP clearance are current.

Motion: Conditional Approval (Administrative Review)	For: 11	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

2. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1399		Control of embryonic development by CK2: CK2 as a core Wnt/beta-catenin component Effect of CK2 Dysregulation on Heart Morphogenesis Cardiac proliferation: Role of Protein Kinase CK2 Characterization of CSNK2A1 variants in Okur-Chung Neurodevelopmental Syndrome	2	2	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Susanna Kurnick

Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, Appendix B-II-D, G-II-B, Section III-D-4, III-E-1

Meeting comments: It was clarified that in section VI. that Xuemei Zhong is the correct spelling of one of the personnel listed.

- Federal funding should be checked.
- Indicate if there is RPO approval for P32.
- Update the BSC certification date.
- VIII.7: should be 10% bleach final concentration.
- Clarify why the protocol is marked ABSL2 in Section IV but ABSL1+ in Section IX; reconcile as appropriate.
- Indicate from which BU researcher cell lines are obtained.
- Replication competence: indicate if < or > than 2/3.
- Correct typographical errors throughout.
- Update requested IACUC information.

Site Assessment: PI needs to complete BSL1/BSL2 training.

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

3. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1046		Molecular Pathogenesis of Vesicoureteral Reflux, Kidney and Urinary Development and Disease, SLIT2/ROBO2 and ZBE2 signaling pathway, novel therapeutics development	2	1	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Susanna Kurnick

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

Meeting comments: The lab studies reflux nephropathy, a type of chronic kidney disease. Deficiency in the cell signaling proteins, SLIT2/ROBO2 and ZEB2 may play roles in the disease. The work alters expression of each protein or mutates them and looks at impact on function and development of the kidney and nephrons in mice. No oncogenes are used. The PI is constructing plasmids encoding each gene with epitope tags, such as HA or His for the purposes of doing immunohistology or for detection of proteins that bind. Additionally, transgenic mice that lack expression of the SLIT2/ROBO2 gene will be used, transgenic mouse embryos will also be used. Yeast 2 hybrid assays will be done to detect binding partners for ROBO2 and related proteins such as Nck1 and SRGAP1. It was noted that: personnel are experienced; the project is non-DURC; human cell lines are used; and that sharps disposal and PPE seem appropriate.

- 70% ethanol is not an appropriate sterilant for cleaning surgical instruments, provide another method such as autoclaving.
- For use of BrdU and Tamoxifen, clarify transport procedures during shedding.

Site Assessment: No findings.					
Motion: Conditional Approval (Administrative Review)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1409		Replication strategies and host response mechanisms of RNA viruses with a focus on filoviruses	2	N/A	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Bob Timmerman
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 project's goal is to understand mechanisms of viral replication, infection, virulence and pathogenicity. Work involves use of minigenomes, replicons, genes, gene fragments and virus-like particles derived from filoviruses, henipaviruses, vesicular stomatitis virus, (VSV) and SARS-CoV-2. Replication incompetent lentiviral vectors, and a pseudotyped attenuated HIV vector are used in some experiments to construct virus-like reagents. All constructs and particles generated will be replication incompetent and/or incapable of causing infection. A variety of primary cells and cultured cell lines from humans, animals, non-human primates, and blood and tissue from bats will be used to express and propagate the various constructs and evaluate immune response. VSV will be used as a surrogate virus to establish conditions for inactivation of pathogens by gamma irradiation. All procedures are carried out using BSL2 precautions and procedures. It was noted that some of the listed training will expire soon, that the box for amendments should be blank, and that in Section IX. N/A should be checked for ABSL. Members discussed that the amendment and ABSL comments can be addressed at the time of next amendment and it was clarified that bats are regularly tested for pathogens such as rabies. Site Assessment: All trainings are current; and the BSC is certified. *The PI was not present for the vote.*	

Motion: Approve	For: 11	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

5. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1375		Apolipoprotein A-I and HDL; Structure, Formation and Function	2	N/A	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Jim Keeney
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a; App. G-II-B	

Meeting comments: There are two (2) specific aims: 1) the goal is to understand the molecular structure of apoA-I to provide details of the molecular features crucial to understanding the mechanisms of lipid interaction, LCAT binding and activation and HDL formation and function at a molecular level; and 2) the applicant will derive the structural details of ABCA1 and its interaction with apoA-I that are essential to understand the process of HDL biogenesis at a molecular level. cDNAs encoding apoliprotein A-1 and ApoA-1 domains and ABCA1 will be expressed in E. coli and insect cells and the resulting proteins purified for analyses. EHS staff clarified that as stated in the protocol, on the BUMC, it is appropriate for sharps containers to be disposed of in biohazardous waste boxes. It was noted that requested RPO information is provided and the BSC certification date is recent.

- In III. 1: training will be done by - Other; Dr. Xiaohu Mei, Mrs. Ildiko Akey. I. Akey is not mentioned anywhere in the protocol, please add her as personnel and/or clarify her qualifications to provide training.
- Ensure that trainings are current for all personnel. Talwar needs to be cleared by ROHP.
- VIII. 1: pipetting infectious liquid is marked, clarify what is infectious.
- VIII. 7A. Final bleach 10-20%, 10% is sufficient.
- Homosapient should be Homo sapiens.

Site Assessment: Some personnel are currently completing required training; and a ROHP questionnaire is being completed by one (1) personnel.

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

6. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1968		Modeling gastric mucus layer physiology	2	N/A	CRC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Valeda Britton

Applicable NIH Guidelines: N/A

Meeting comments: Helicobacter interactions with the mucus layer of the stomach are studied. Bacteria to be tested include: *H. pylori*, *H. suis*, and *Campylobacter jejuni* (human pathogens); *H. cetorum* (infects dolphins); and *H. mustalae* (infects ferrets). Bacteria will be cultured in the lab and mixed with mucin collected from pig stomach and purified. Bacterial motility will be examined microscopically, on slides, and in microfluidic devices. Members discussed that work with pig stomach, given the potential for aerosol generation and for transmission of pathogens from pigs to humans, should be done in a BSC or with additional PPE (such as a surgical mask resistant to particles and fluids and a face shield) and that EHS should be consulted prior to resubmission to advise. ROHP's Medical Director indicated that personnel should receive the influenza vaccine.

- Provide training experience for Liao.
- Training and ROHP clearance need to be updated for Bansil.
- Section VIII.1: centrifugation should be checked (used for mucin purification).
- Section VIII.2: additional engineering controls to protect against aerosols (e.g. centrifuges with sealed rotors or sealed cups) should be used.
- Section VIII.5: when working with pig stomach, given the potential for aerosol generation and for transmission of pathogens from pigs to humans, EHS should be consulted to determine if a BSC should be used or if additional PPE is sufficient.
- Section VIII.6: describe how sharps containers will be disposed of.
- Section VIII.7: liquid waste should be decontaminated with fresh bleach at a final concentration of 10%, not "mixed with a 10% bleach solution".
- Section A. *C. jejuni* is listed in the project description and procedures sections and should therefore be added to the table.
- IX: check off potentially infectious materials, there is a reference to blood and other animal tissues in VII (3) amendment 3/16/18.

Site Assessment: The PI needs to be cleared by ROHP and needs to complete required training; the lab does not have a BSC but has a fume hood and should use a centrifuge with rotors.

Motion: Conditional Approval (Review by R. Morales and T. Winters)	For: 12	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2248		Artificially manipulating memories in healthy and maladaptive states	2	2	CRC

Primary Reviewer: Xin Brown	Secondary Reviewer: Rao Varada

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

Meeting comments: The project utilizes genetic manipulation, immunohistochemistry and behavioral assays to study how memories are formed and whether memory manipulation can relieve the effect of stress. Adeno associated viruses are used to incorporate light sensitive proteins and fluorescent proteins into mouse brains. The viruses are not generated in the lab. The surgical procedures, histology analysis and waste disposal are described in sufficient detail. It was noted that the work is covered by an IACUC approval protocol, that animal study procedures are clearly described, and that PPE and disinfection methods seem sufficient.

- III. Personnel Information: ensure that training is current for all including BSL1/2 training. ROHP clearance is listed as inactive for E. Merfeld and N. Murawski, ensure they are cleared to work on this protocol.

- VI. DURC: the answer to the first question "Enhances the harmful consequences of the agent or toxin" is 'yes'. The work (introducing light sensitive proteins into mouse brains) does not seem to qualify as DURC. Clarify and update the response appropriately.
- IX. Materials Used in Research: Clarify what the highest BSL required for this project should be indicated as. AAV is used at BSL1.
- Under recombinant DNA, E. coli K-12 is listed as a host for plasmid vectors however, the protocol does not mention any bacterial work (it is used at UMass to generate AAV), therefore it does not need to be listed here.

Site Assessment: The personnel list needs to be updated; and the BSC is certified.

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

8. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1395		Role of the NCoR corepressor complex in the regulation of inflammatory responses and insulin resistance in the adipose tissue and immune system.	2	2	BUMC

Primary Reviewer: Rob Davey | Secondary Reviewer: Susanna Kurnick

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

Meeting comments: The PI studies the role of GPS2 for control of diabetes and obesity related disease. The PI works with mouse and human cell lines transiently transfected to express wild-type or mutant forms of GPS2, they construct plasmids encoding each gene with epitope tags and make CRISPR knockout cell lines. Transgenic mice have been made that lack or exogenously express GPS2. Transgenic mouse embryos will be worked with. Lentiviruses are used to introduce genes into cell lines; these are not used in animals. The pLKO-puro vector (Mission, Sigma-Aldrich) is used; this appears to be a 3-part, generation 3 vector and so has good safety aspects. Personnel have a range of experience and trainees are trained by Dr. Cardamone (who has 9 years' experience). This is a non-DURC project, human cells lines are used, 10% fresh bleach is used as a disinfectant, sharps are disposed of in sharps containers, and PPE is sufficient.

Site Assessment: The lab has an ECP; some members are working on ROHP clearance; training is current; and the lab has a BSC.

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

9. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1957		Longevity and endoplasmic reticulum stress resistance	2	N/A	BUMC

Primary Reviewer: Elke Muhlberger | Secondary Reviewer: Bob Timmerman

Applicable NIH Guidelines: Section III-F-8

Meeting comments: This protocol investigates genetic and environmental factors that affect longevity and aging using yeast as a model organism. They also analyze iron homeostasis in yeast at BSL1. At BSL2, they investigate the role of MAPK in ER stress in melanoma cells. It was noted that some of the training listed will expire soon.

- Provide the current BSC certification date.
- It seems that the lab performs cloning work with bacteria, add a sentence in the research project description briefly describing the bacterial cloning work.

Site Assessment: The BSC's are certified; some training needs to be completed; and the PI needs ROHP clearance.

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

10. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2440		Corneal collagen crosslinking studies	2	N/A	BUMC

Primary Reviewer: Tom Winters	Secondary Reviewer: Valeda Britton
Applicable NIH Guidelines: N/A	
Meeting Comments: This new project will study a new treatment for people with corneal ectasia, a non-inflammatory disorder caused by thinning of the cornea. The cornea will be treated with a non-toxic solution containing riboflavin (vitamin B2) and exposed to a beam of UV-A light which will provide cross-link collagen in the cornea. Corneas will be obtained from pig and human sources. The human donor eyes have been screened for blood-borne pathogens such as hepatitis B, hepatitis C, and HIV. Treated and control samples will be transported to BMC where they will be tested with a inverse spectroscopic optical coherence tomography (ISOCT) device. Surfaces will be cleaned with antiseptics. Storage and transport with tertiary containers are controlled. Liquid and solid waste disposal is appropriate. 70% ethanol and oxavir wipes will be used to clean surfaces. It was noted that IRB approval is not required for working with postmortem cornea samples. • Indicate whether L. Gibson is a BU employee. • The PI needs to be added to the personnel list. • Clarify if space in the Yawkey building is being used, if so, indicate. • Clarify where eyes are treated before being transported to BMC. • If any aerosol generating procedures (such as centrifugation) are being performed, check appropriate boxes in Section VIII.1. • Update the biosafety cabinet certification date. Site Assessment: Not complete, PI was unavailable.	

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

11. rDNA/Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2471		A Randomized Controlled Trial of Quetiapine for the Treatment of Youth with Co-Occurring Substance Use Disorders and Severe Mood Dysregulation	2	2	CRC

Primary Reviewer: Xin Brown	Secondary Reviewer: Rao Varada
Applicable NIH Guidelines: Sections III-D-1, III-D-4-a, Appendix G-II-A, G-II-B, M-II-A, M-II-B	
Meeting Comments: This new protocol uses transgenic mice and organoids to investigate how different neuronal populations and pathways (e.g., nitric oxide or neuropeptide Y) contribute to the regulation of cerebral blood flow and oxygen consumption and to better understand neuroimaging data. The protocol provides detailed information on the manipulation of mice and organoids before they are used for imaging and electrophysiology studies, as well as on the imaging study itself. Adeno-associated viral vectors (rAAV) obtained from commercial sources will be used to introduce optogenetic proteins either directly into mouse brains through craniotomy surgery, or intravenously. Human induced pluripotent-stem-cell (hIPSC) derived organoids will be transduced with lentivirus vectors to express optogenetic proteins and will either be implanted into mouse brains or used directly in an *in vitro* imaging chamber. Tamoxifen will be used to induce conditional gene expression of Cre recombinase variants in transgenic mice. Tetrodotoxin will be used to block action potential firing during *in vitro* experiments with organoid cultures. Proposed safety measures including animal work procedures and waste disposal procedures are well described. It was noted that a very small amount of Tetrodoxin (a select agent) is being used (1mg); EHS staff indicated that the cumulative amount of Tetrodotoxin in the lab must be known to ensure that limits are not exceeded. • N. Formin-Thunemann's ROHP clearance needs to be updated. • It is stated in the protocol that recombinant adeno-associated viruses will be stored in a -80 freezer in (shared with X. Han). These viruses are no longer stored in ERB623; update this information. • Uncheck 'synthetically derived DNA' in Section IX. • Provide the cumulative amount of Tetrodotoxin (a select agent) that may be in the lab at any given time. Site Assessment: The lab has a ECP; ROHP clearance needs to be updated for few members; and training is current.	

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

12. rDNA/Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2464		Cell Line Engineering with Genomics Tools	2	N/A	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Ron Morales

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

Meeting comments: The PI provides purified proteins (including antibodies) expressed in various cell lines to collaborators and uses standard molecular biology techniques. It was noted that X. Zhong is a BUMC faculty member with whom the PI collaborates.

- It is indicated that "No animal or human samples are used, just cell lines to express proteins. Nothing infectious is involved." If the cell lines are human, they were isolated from human sources (HEK, Jurkat); clarify.
- Clarify if bacterial waste treated with 10% fresh bleach is solid or liquid waste. If liquid, final concentration of bleach should be 10%.
- Confirm and clarify that following use, scalpel blades are discarded directly into sharps containers.
- The PI needs to complete the BBP training (given use of human cells).

Site Assessment: No findings.

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

13. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1750		Role of myo1c in adaptation in the inner ear	2	2	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Ron Morales

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

Meeting comments: The PI is adding procedures to generate recombinant adenovirus expressing myosin 1 to be used in rescue experiments in a rat insulinoma cell line.

- Section A: add adenovirus to list of hazardous biological agents (BSL2).
- Section VIII.1: animal handling and animal inoculation should be checked.
- Section VIII.5: update the certification date for the BSC.
- Section H-17: checked 'no' to transgenic/knockout mice, the lab procedures section describes use of knockout mice (Myo1c f/f/ x inducible Cre); reconcile.

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

14. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1530		A Systems Biology Approach to Tuberculosis Biosensors for Physiological Monitoring Identifying Molecular Signatures of Drug Susceptibility A Diagnostic for Viral DNA	2	2	CRC & BUMC

Primary Reviewer: Tom Winters	Secondary Reviewer: Inna Afasizheva

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

Meeting comments: The lab uses non-pathogenic relatives of *Mycobacterium tuberculosis* – BCG and *Mycobacterium smegmis* as well as Actinomycetes, non-pathogenic, as models to decipher gene regulation. The amendment includes a plan to acquire plasmids with cDNA for portions of the coronavirus RNA genome. This will be used to model this DNA to test different DNA recognition strategies. No live virus or SARS-CoV-2 proteins are used. Members discussed that the submission could be approved without the following clarifications (based on a reviewers comments): 1) to provide source information for SARS-CoV-2 genome containing plasmids; and 2) to provide information about the bacterial strain and method for isolation of SARS-CoV-2 genome containing plasmids. It was clarified that they are proposing to encode a portion of the genome.

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

15. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1459		Uremic vascular disease and cancer biology	2	2	BUMC

Primary Reviewer: Carmela Abraham Additional Reviewer: Ron Morales	Secondary Reviewer: Tom Winters
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendix B-II-A.	
Meeting Comments: The PI is requesting approval to conduct experiments with plasma obtained from patients with COVID-19 (C-19) at BSL2+. No live virus experiments will be performed. The experiments aim to determine the detrimental effects of C-19 plasma on kidney and renal microvasculature by treating commercially available human endothelial and kidney epithelial cells with C-19 plasma. Plasma will also be used to examine tissue factor activity and activity of signaling pathways. C-19 plasma is from the BU-BMC biorepository. Members discussed that Trizol treatment of biological samples is a commonly used, EHS approved method of virus inactivation. EHS staff indicated that the PI requested guidance to upgrade their lab from BSL2 to BSL2+ (which EHS has already provided). It was noted that the PI indicated that he will be the only person handling C-19 plasma samples. • In Section IX mark the highest biosafety level of this protocol as 'BSL-2 with special practices of BSL-3'.	

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

16. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
1788		Provide services related to the use of Flow Cytometer analyzer and cell sorting instruments.	2+	NA	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Ron Morales
Applicable NIH Guidelines: N/A	
Meeting Comments: This amendment requests the addition of serum or plasma from COVID-19 patients that have been found to have undetectable antibodies against the nucleocapsid protein as measured by the Abbot SARS-CoV-2 antibody ELISA emergency use authorization (EUA) kit. The goal is to determine if there are other SARS-CoV-2 antibodies that can be detected by ELISA using other highly sensitive ELISA protocols and additionally to measure cytokines and cellular phenotypes. Samples will be obtained from BMC. The flow cytometer is a closed system limiting contamination of the environment by any aerosols generated during operation of the machine. All samples will be decontaminated using 10% bleach per core protocols. Members discussed that according to published literature, only low copy numbers of COVID-19 virus RNA are detected in blood and that the potential for virus transmission through aerosol during handling of COVID-19 plasma is very low, but possible. Given this, it was recommended that handling of COVID-19 plasma samples be done at BSL2+ containment. It was noted that all proposed manipulation of serum will be done in a BSC using BSL2+ PPE.	

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