



Boston University
Institutional Biosafety Committee (IBC)
February 25, 2020 Meeting Minutes
Location: Medical Campus, B-406, 72 East Concord Street
Start time: 12:00pm End time: 2:01pm

This meeting is open to the public.

Members Present: I. Afasizheva, R. Ingalls, C. Abraham, B. Slack, R. Timmerman, J. Keeney, V. Britton, C. Sulis, R. Morales, S. Kurnick, R. Davey, J. Barton (arrived 12:35pm), T. Winters, R. Varada (arrived 12:02pm), E. Loechler (via Zoom)

Guests Present: P. Urlick, A. Ahmad, N. Yun, S. Benjamin, F. Ennever, R. Filler

Staff Present: J. Hutchinson, S. Ghosh, S. Jao, C. McGoff

I. Review of February 14, 2020 Meeting Minutes

No questions or comments were voiced.

Motion: Approve

For: 13; Against: 0; Abstain: 1; Absent: 1

II. LAI Subcommittee Recommendation

Members were informed that the LAI Subcommittee recommends adding Severe Acute Respiratory Syndrome Coronavirus 2 and Middle East Respiratory Syndrome Coronavirus to the list of Biological Agents with Potential to Cause Laboratory Acquired Infection.

Motion: Add Severe Acute Respiratory Syndrome Coronavirus 2 and Middle East Respiratory Syndrome Coronavirus to the list of Biological Agents with Potential to Cause Laboratory Acquired Infection.

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

III. New Business

A. Research Occupational Health Program (ROHP) & Environmental Health & Safety (EHS) Report

There were no incidents to report.

IV. Protocol Review

1. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
875		Genetics of Host Resistance & Susceptibility to Tuberculosis	3	3	BUMC
Primary Reviewer: Robin Ingalls		Secondary Reviewer: Susanna Kurnick			
Applicable NIH Guidelines: Sections III-D-1-a, III-D-1-b, III-D-2-a, III-E-1; Appendix B-III-A, G-II-C					
Meeting comments: The PI is adding GFP and mCherry expressing Mtb strains. These strains will help microscopic localization of the bacteria in infected cells under specific experimental conditions. It was noted that the appropriate sections of the application have been filled out, that there is no change in biohazard, and that the proposed experiments with these strains are for in vitro cell culture work. The BSL-3 BSO indicated that all safety training is current and BSCs certified.					
Motion: Approve		For: 14	Against: 0	Abstain: 0	Absent: 1

2. Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus	
2299		NEIDL Comparative Pathology Laboratory	2	N/A	BUMC	
Primary Reviewer: Inna Afasizheva			Secondary Reviewer: Nadya Yun			
Applicable NIH Guidelines: N/A						
<p>Meeting comments: The PI is requesting to receive inactivated biological samples from Rocky Mountain Laboratories (RML) that originated from risk group 4 agents. These samples will be used in the Biosquare III core facility, in immunohistological studies. The PI has provided published references for the inactivation procedures used at RML. The BSL-4 BSO indicated that EHS is working with RML to receive appropriate documentation. It was noted that these inactivated materials can be handled at BSL-1 containment as they are no longer infectious however, members discussed that the Biosquare III core facility is designated as BSL-2, this is why they will be used at BSL-2.</p> <ul style="list-style-type: none">• Include a statement to clarify that work is done in a BSL-2 space with materials that can be handled at BSL-1.• Clarify what disinfectant will be used including the procedure for instrument disinfection.						
Motion: Conditional Approval (Administrative Review)			For: 14	Against: 0	Abstain: 0	Absent: 1

3. Bhz - Annual Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2352		Propagation and characterization of viruses	4	N/A	BUMC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Nadya Yun		
Applicable NIH Guidelines: N/A					
<p>Meeting comments: Per reviewer request, the PI updated BSC certification information and added two (2) rooms. No further comments were voiced. The committee was asked to determine if this protocol should be reviewed next year, as it was previously determined that for BSL-3 and BSL-4 protocols, this determination would be made on a protocol specific basis. Members questioned whether this decision should be made on a protocol specific basis. It was noted that this requirement could be revisited by the committee if they so choose and that regardless, amendments that require full committee review and 3-year renewals will still come to the full committee for review. The Chair indicated that the protocol specific approach to determining if annual review is required can be discussed more generally at a future meeting. It was noted that BSL-4 laboratories are inspected by EHS quarterly and members discussed whether the inspection findings should be shared with the committee as part of the EHS report.</p> <p><i>Motion: Annual renewal of this protocol will not be required next year.</i></p> <p>For: 12; Against 2; Abstain: 0; Absent: 1</p>					
Motion: Approve		For: 14	Against: 0	Abstain: 0	Absent: 1

4. rDNA/Bhz - Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1902		Biological function of Epstein Bar Virus in dermal fibroblasts, endothelial- and immune -cells	2	N/A	BUMC
Primary Reviewer: Rob Davey			Secondary Reviewer: Tom Winters		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a; Appendix B-II-D and G-II-B					
Meeting comments: The PI is investigating the role of Epstein Barr virus (EBV) in causing scleroderma (systemic scleroderma or SSc). They plan to study EBV lytic infection in fibroblasts, monocytes and B lymphocytes obtained from a patient repository to understand the immune dysregulation in active systemic sclerosis patients					

<p>contributed by EBV infection. Some of the infection work will be done using recombinant EBV that expresses green fluorescence protein followed by fixation and microscopic evaluation of virus replication. It was noted that PPE appears appropriate for the work at BSL2; lab coat, eye protection and gloves are worn. Bleach is used as the preferred disinfectant with 30 minutes contact time; Wescodyne with one-hour contact time is also used. Recombinant work involves use of a bacterial artificial chromosome based vector that contains either the wild type virus or recombinant GFP encoding virus. It was noted that scalpel blades are used as sharps and there is no transport of the agent. A blood-borne pathogen program is in place as human tissue and blood are used. BUA Site Assessment: ECP is in place; BSC is certified; training is current; no findings.</p>				
Motion: Approve	For: 15	Against: 0	Abstain: 0	Absent: 0

5. Bhz - Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus	
1691		A high throughput screen for inhibitors of mammalian glycerolipid biosynthesis	2	N/A	BUMC	
Primary Reviewer: Carmela Abraham		Secondary Reviewer: Jim Keeney				
Applicable NIH Guidelines: N/A						
<p>Meeting comments: This is a straightforward 3-year renewal to perform HTS for inhibitors of mammalian glycerolipid biosynthesis. Primary screen will be done in CHO cells and secondary screens in human cell lines (HeLa and HUH-7) with the use of radioactive substrates. It was noted that there are no personnel being added (the PI is the only researcher listed); his training is current. Handling, storage and disinfection are appropriate. The BSC certification is current. Members discussed that it is appropriate for glass Pasteur pipettes to be discarded into sharps containers (not into biohazard boxes).</p> <ul style="list-style-type: none">• The responses to the DURC questions appear to be incorrect – the PI indicates that the project continues to be a non-DURC project but also that it was previously determined to be a DURC project.• Clarify if the purpose of using the inhibitors is as antiviral agents? Contradictory statements appear.• Liquid waste should be treated with bleach to a final concentration of 10% for 30 minutes and discarded in the sink. <p>Safety and Quality Assurance Program staff indicated that the PI addressed all comments in a resubmission received prior to the meeting.</p> <p>BUA Site Assessment: No Findings.</p>						
Motion: Approve			For: 14	Against: 0	Abstain: 0	Absent: 1

6. Bhz - Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
964		Molecular Systematics and Population Genomics of Birds	2	N/A	CRC
Primary Reviewer: Barbara Slack			Secondary Reviewer: Rao Varada		
Applicable NIH Guidelines: N/A					
Meeting comments: Genetic analysis of samples collected in the field is being done; no collection is planned. In response to concerns about bird flu, members discussed that samples are treated in the field and handled appropriately. It was noted that the IACUC protocol was approved in June 2019. <ul style="list-style-type: none">• Smith needs to update ROHP clearance.• Check “pipetting infectious liquid” (there is potential for pathogens to be present in tissue being extracted). BUA Site Assessment: At least one (1) person needs to complete shipping training.					
Motion: Conditional Approval (Administrative Review)			For: 14	Against: 0	Abstain: 0
			Absent: 1		

7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2211		Delineation of an immune gene regulatory network and rewiring in disease	2	N/A	CRC
Primary Reviewer: Barbara Slack		Secondary Reviewer: Rob Davey			
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1, Appendix G-II-B					
<p>Meeting comments: The PI is investigating cytokine gene regulatory networks, study protein-DNA interaction, and functional perturbation to evaluate how virally encoded transcription factors perturb the cytokine network. They are using a number of commercially available cell lines as well as pCDNA series vectors for expression of specific proteins. Lentivirus vectors as well as a CRISPR-lenti library will be used for introduction of short-hairpin RNAs for making specific mutations.</p> <ul style="list-style-type: none">• ROHP clearance for Liu needs to be updated.• Clarify whether the CRISPR-Cas9 lentiviral vectors will be used to introduce transcription factors into the genome, or just for gene knock-out.• Check pipetting in Section VIII.1.• Some of the cell lines mentioned in the protocol are not listed in the hazardous biological agent list (section A; add HT-29, A549, SK-MEL28 cells to the table.• Use of Lentiviral vectors (e.g. CRISPR lenti-V2) is indicated in the laboratory procedures section; add them to the rDNA table (Prokaryotic and Eukaryotic experiments). <p>BUA Site Assessment: The BSC is certified.</p>					
Motion: Conditional Approval (Administrative Review)		For: 15	Against: 0	Abstain: 0	Absent: 0

8. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1217		Melanopsin Signal Transduction Studied by FTIR Spectroscopy Structure and Function of Microbial Sensory Rhodopsins The Analysis and Bioengineering of Optogenetic Rhodopsins	1	N/A	CRC
Primary Reviewer: Ed Loechler		Secondary Reviewer: Ron Morales			
Applicable NIH Guidelines: Section III-E, Appendix I-I-A-I					
Meeting comments: It was noted that hazards are adequately addressed. <ul style="list-style-type: none">• The PI needs to complete Chemical Safety Training.• The protocol states that work will be performed in a dedicated BSL1 lab, yet it is also stated that the E. coli bacteria used for expression are infectious through injection, ingestion, and autoinoculation. Clarify if an infectious E. coli strain will be used. In the rDNA Section, E. coli K12 is indicated (this strain is typically used under BSL1). This should be reconciled throughout.• PPE: uncheck "Surgical mask."• VIII. Personal Protective Equipment and Safety Equipment: Question 2 indicates that "Work that produce/or potentially produce aerosols are done in the Biological Safety Cabinet or other containment equipment" however, question 5 states that a BSC will not be used; this should be reconciled.• VIII. Personal Protective Equipment and Safety Equipment –Q7: should state that "liquid waste will be treated to a final concentration of 10% bleach." BUA Site Assessment: Remove the personnel who no longer work in the lab; and the fume hood needs to be certified.					

Motion: Conditional Approval (Administrative Review)	For: 15	Against: 0	Abstain: 0	Absent: 0
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9. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1151		Mechanisms regulating megakaryocyte endomitosis and polyploidy	2	2	BUMC
Primary Reviewer: Robin Ingalls		Secondary Reviewer: Rao Varada			
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-E-1, appendix B-I					
Meeting comments: The PI states that she is using a second generation lentiviral vector system. Members discussed that she should be encouraged to transition to a 3 rd generation or later system. It was noted that the IACUC protocol is approved through May 2020.					
<ul style="list-style-type: none">• VIII. Personal Protective Equipment and Safety Equipment –Q4: check “Shoe Cover” – PPE in animal containment requires shoe covers to be worn.• VIII. Personal Protective Equipment and Safety Equipment –Q7: indicate that liquid waste is treated to a final concentration of 10% bleach.• The Animal Biosafety Level should be changed from ABSL2 to ABSL1 throughout.					
BUA Site Assessment: Some lab personnel need to be cleared by ROHP; an ECP needs to be adopted; and W529 should be removed.					
Motion: Conditional Approval (Administrative Review)		For: 15	Against: 0	Abstain: 0	Absent: 0

10. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2426		H-33380: ANCHOR Study: Anal Cancer/ High-grade squamous intraepithelial lesions (HSIL) Outcomes Research Study. H-36335: AMC 088: A Randomized, Phase III Study of Intra-Anal Imiquimod 2.5% vs. Topical 5-Fluorouracil 5% vs. Observation for the Treatment of High-Grade Anal Squamous Intraepithelial Lesions in HIV-Infected Men and Women. H-35739: AMC 092: A multicenter observational and feasibility study of excision of superficially invasive squamous cell carcinoma (SISCCA) of the anal canal and perianus in HIV-infected persons.	2	2 (should be N/A)	BUMC
Primary Reviewer: Inna Afasizheva		Secondary Reviewer: Ron Morales			
Applicable NIH Guidelines: N/A					
Meeting comments: The committee was informed that the activities covered by this protocol have been taking place without IBC approval. When the PI became aware that IBC approval was needed, she submitted this protocol. An investigation will be done by EHS to identify the root cause of the noncompliance, corrective actions taken, and steps to prevent recurrence. The Institutional Official recommended that the projects be kept open, and that everyone listed on the IBC application complete the Lab Safety Training, BBP Training and ROHP clearance as soon as possible since stopping the study could cause harm to study participants and no federal requirements were broken (the NIH Guidelines do not apply). BMC's Research Compliance Officer was made aware of the noncompliance. It was noted that EHS will be doing a training with BMC investigators on what activities require IBC approval. Safety and Quality Assurance Program staff are also looking at opportunities to streamline the IRB ancillary review process to ensure that work being proposed to the IRB is receiving IBC					

review/approval as required. Members discussed that it is important that new BMC PIs are informed by BMC administration of IBC requirements.

The PI is taking part in an ANCHOR study (clinical trial) initiated by NCI to determine if treatment of HSIL (High-grade Squamous Intraepithelial Lesion) in HIV-infected individuals can prevent anal cancer from developing. The objective is to improve treatment by replacing major surgery with local surgical removal of the effected area in combination with onsite drug treatment. The protocol describes collection, transportation, storage, and shipping of HIV-infected blood specimens and anal swabs. Members discussed that it is not clear if a BSC is being used and if so, for what procedures. Members discussed whether a BSC should be used and it was noted that study procedures and use of PPE during study procedures needs to be clarified. It was noted that use of centrifuges with sealed rotors or sealed cups is indicated in the protocol.

- Clarify if a BSC is being used and if so, for what procedures (i.e., for procedures other than blood centrifugation). Check “Work that produce/or potentially produce aerosols are done in the Biological Safety Cabinet or other containment equipment” if appropriate.
- Contact Dr. Carol Sulis and provide the information requested in the application.
- Clarify what PPE will be used for which procedures.
- Clarify if this protocol is only to collect and ship specimens or if research will be done in the PIs lab with these samples. If research will be done, clarify what research/procedures will be done.
- B. Passarelli needs to complete Lab Safety Training.
- J. Lukish and B. Passarelli need to complete Chemical Safety Training.
- J. Baez, B. Passarelli, and I. Pokuaa need to complete ROHP medical clearance.
- Clarify if patient samples are obtained directly from patients by clinicians and/or lab research personnel listed in the protocol.
- Lab personnel who are responsible for packaging and shipping patient samples need to complete Shipping of Biologicals training.
- Liquid waste must be treated to a final 10% bleach concentration; the protocol should be updated accordingly.
- Clarify if ABSL-2 has been indicated in error. If so, this should be corrected.

BUA Site Assessment: Shipping training needs to be completed; 504 is an office, true locations are 670-520,522,331.

Motion: Conditional Approval (Reviewers to Review)	For: 15	Against: 0	Abstain: 0	Absent: 0
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11. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2428		Predicting and Optimizing Language Outcomes in Minimally Verbal Children with Autism Spectrum Disorder	2	N/A	CRC
Primary Reviewer: Carol Sulis		Secondary Reviewer: Valeda Britton			
Applicable NIH Guidelines: N/A					
<p>Meeting comments: This project is part of a Clinical Research Center program in partnership with the University of California, Los Angeles. The team will be collecting saliva samples from participants with Autism spectrum disorder and their immediate family members using “Oragene Discover” kits for the collection of human DNA. Those able to spit on command will use Oragene Discover OGR 500. Those unable to spit on command will use assisted-collection kits, OGR 575. The primary reviewer indicated that she was unable to review the IRB protocol, it was noted that this is because the protocol would have been reviewed by the CRC IRB (not the BUMC IRB).</p> <ul style="list-style-type: none">• Clarify where saliva samples will be collected.• For routine samples, clarify how tubes are handled after collection is complete (i.e., wiped with a disinfectant, stored in a biohazard bag, etc.)• For the “assisted collection kits” clarify what PPE will be worn by technicians. A face shield should be used.					

<ul style="list-style-type: none"> Clarify how the collection area will be cleaned between participants. It is stated that samples will be stored at room temperature in a locked file cabinet for 1-2 months prior to shipping to UCLA. Clarify where the cabinet is located. Is the cabinet marked with a biosafety label? Harvey and Licht should complete shipping training. Describe the response if there is an unprotected exposure to saliva. Both BSL-1 and BSL-2 containment are referenced; this should be consistent throughout. Clarify what CARE stands for throughout. 				
BUA Site Assessment: One (1) individual is scheduled to attend shipping training in March.				
Motion: Conditional Approval (Primary Reviewer Review)	For: 14	Against: 0	Abstain: 0	Absent:1

12. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus	
2421		A Phase I study to evaluate the pharmacokinetic and pharmacodynamics profile of intramuscular or subcutaneous injections of levonorgestrel butanoate (LB) for female contraception. (LB Study)	2	N/A	BUMC	
Primary Reviewer: Tom Winters		Secondary Reviewer: Bob Timmerman				
Applicable NIH Guidelines: N/A						
<p>Meeting comments: The PI is investigating a new injectable birth control called levonorgestrel butanoate. They will draw blood to look at surrogate markers such as steroid hormones, gonadotropins, and sex binding proteins. In addition, they will perform ultrasounds and follow bleeding patterns and test the tolerance and safety of the medication. Blood draws are done at the OB-GYN clinic (Yawkey 5). The methodologies are well described. The PPE appears appropriate. Solids are disposed of properly.</p> <ul style="list-style-type: none">• Contact Dr. Carol Sulis and provide the information requested in the application.• All lab personnel listed need to have ROHP clearance.• Provide the requested IRB information (no protocol number is provided).• VIII. Personnel Protective Equipment and Safety Equipment –Q6: check “yes” as blood draws will be done.• VIII. Personnel Protective Equipment and Safety Equipment –Q7: The MSDS for D-125 includes cautions on irreversible eye damage from exposure. Use of safety glasses should be indicated.• VIII. Personnel Protective Equipment and Safety Equipment –Q8: update this section to clarify a final 10% bleach concentration.• The timing of sample collection and processing is inconsistent. One paragraph states that the samples are transported within one hour of collection. The next paragraph states that the samples are allowed to stand for 30 minutes to allow the blood to clot. The protocol states that the samples should be centrifuged 30 to 60 minutes after collection. If a sample is transported the maximum of 1 hour after taking it, plus ten minutes to transport it, plus sitting at room temperature for 30 minutes, that is one hour 40 minutes. The wording could be clarified to state whether time after drawing blood is included in the 30 minutes to allow for clotting. <p>BUA Site Assessment: The lab has an ECP; a few personnel need to complete Chemical Safety Training; the use of safety glasses is checked; and the fume hood and BSC are certified.</p>						
Motion: Conditional Approval (Administrative Review)			For: 15	Against: 0	Abstain: 0	Absent: 0

13. Bhz – New Protocol

BUA	(PI)	Title	BSL	ABSL	Campus
2425		NSF Nanosystems Engineering Research Center for Directed Multiscale	2	N/A	CRC

		Assembly of Cellular Metamaterials with Nanoscale Precision: CELL-MET			
Primary Reviewer: Ed Loechler		Secondary Reviewer: Bob Timmerman			
Applicable NIH Guidelines: N/A					
Meeting comments: How cardiac cells grow on their scaffolding will be investigated using a unique microscope technique designed and developed at BU’s Photonics Center. Samples will be prepared by personnel in Dr. Chen’s lab at CILSE. Transport of these cells from Dr. Chen’s laboratory to the PI’s laboratory is appropriately described. It was noted that D. Beaulieu is experienced, and his training is current. <ul style="list-style-type: none">• The PI needs to be added to the personnel list. BUA Site Assessment: ECP is in place; training is current; no findings.					
Motion: Conditional Approval (Administrative Review)			For: 15	Against: 0	Abstain: 0 Absent: 0

14. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
897		Ah Receptor, Androgen Receptor and Estrogen Receptor: Controlling Receptor Activation and Breast Cancer Growth	2	N/A	BUMC
Primary Reviewer: Ron Morales			Secondary Reviewer: Jim Keeney		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a; Appendix G-II-B					
Meeting comments: The PI would like to add new plasmids: pcDNA-DEST40, pDONR221_SLCO1B1, pDONR221_SLCO1B3, pDONR221_SLCO2B1. These are standard cloning plasmids that will be used to express proteins being studied in E. coli K12 bacteria and mammalian cell lines.					
Motion: Approve			For: 15	Against: 0	Abstain: 0 Absent: 0

15. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2063		Lung injury and sepsis	2	2	BUMC
Primary Reviewer: Carol Sulis			Secondary Reviewer: Valeda Britton		
Applicable NIH Guidelines: Section III-D-2-a					
<p>Meeting comments: In order to develop potential biomarkers to detect bacterial-induced lung infection in humans, the PI will examine the expression of a specific long non-coding RNA in human specimens including Broncho-alveolar lavage fluid (BALF), blood, and human cells, to determine the match of its expression with clinical data.</p> <ul style="list-style-type: none">Clarify the methods to be used for the analysis of miRNA expression of human cells. If the methods are the same as those being used for mouse work, this should be stated. Otherwise, the methods should be described.<ul style="list-style-type: none">If the same methods will not be used, the primary reviewer indicated that she would like to review the resubmission.BSL1/2, BBP, and Chemical Safety training and ROHP clearance for the PI and Y. Jin need to be updated.Shipping training for responsible lab members needs to be updated.The BSC certification date needs to be updated.					
Motion: Conditional Approval (Administrative Review)			For: 15	Against: 0	Abstain: 0 Absent: 0

16. Bhz - Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
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1798		The energetic cost of immune function and consequences associated with white-nose syndrome on little brown myotis (<i>Myotis lucifugus</i>) in New England.	2	2	CRC	
Primary Reviewer: Carmela Abraham			Secondary Reviewer: Susanna Kurnick			
Applicable NIH Guidelines: N/A						
<p>Meeting comments: The goal of this research is to inform methods of surveillance and control strategies for fungal pathogens of bat species. This project will examine the relationship between basal metabolic rate (BMR) and complement protein activity, and the relationship between BMR and white blood cell counts in little brown myotis. It was noted that bite-resistant gloves are used for animal handling. In this amendment, the current PI is transferring the protocol to another professor in the Biology Department. Members discussed that if a bat dies, the carcass is typically sent to the State for testing.</p> <ul style="list-style-type: none">Clarify if bats are restrained during wing biopsies without anesthesia.Check centrifugation and animal handling in the PPE and Safety Equipment section (Section VIII.1).						
Motion: Conditional Approval (Administrative Review)			For: 15	Against: 0	Abstain: 0	Absent: 0

17. rDNA/Bhz - Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2113		Zika virus growth and characterization	2	N/A	BUMC
Primary Reviewer: Ron Morales			Secondary Reviewer: Carol Sulis		
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: In this amendment the PI proposes to obtain blood or serum samples from Zika or Dengue patients from the collaborating BD lab or purchase commercially from BEI. These samples will have tested positive for <i>Plasmodium vivax</i> or <i>Plasmodium falciparum</i> , which are causative agents for malaria. The goal is to determine that the diagnostic testing procedure the PI developed for Zika infection is not interfered by the presence of these malarial agents. It was noted that virus will not be cultured from these samples. The PIs current BSL-2 practices and procedures conform with the procedures to be followed for the proposed new agents. When needed, samples will be thawed and immediately used in the appropriate diagnostic assay; any remaining sample will be refrozen (if the appropriate amount remains) or discarded. It was noted that an Agent Information Sheet is available for these agents. <ul style="list-style-type: none">• Provide an update on Dr. Haydar’s training for virus handling; his ROHP clearance needs to be updated.					
Motion: Conditional Approval (Administrative Review)			For: 15	Against: 0	Abstain: 0
			Absent: 0		

18. Bhz - Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2172		Storage, Propagation and Distribution of BSL-2 Emerging Pathogens	2	2	BUMC
Primary Reviewer: Ron Morales			Secondary Reviewer: Tom Winters		
Applicable NIH Guidelines: N/A					
Meeting comments: The PI is requesting addition of four (4) BSL-2 human coronaviruses. These viruses generally cause mild self-limiting disease including the “common cold”. The PIs facility and procedures have been approved as BSL-2 and he follows BSL-2 practices and procedures for handling these agents. ROHP’s Medical Director clarified that the flu vaccination is recommended for the viruses being handled.					
Motion: Approve			For: 15	Against: 0	Abstain: 0 Absent: 0