



Boston University
Institutional Biosafety Committee (IBC)
September 21, 2021 Public Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:00 PM End time: 1:22 PM

Members Present: C. Abraham, B. Slack, I. Afasizheva, E. Muhlberger, R. Davey, R. Morales, T. Winters, C. Thurman, J. Keeney, R. Timmerman, J. Barton, S. Ghosh
Guests Present: K. Mellouk, R. Corley, P. Richmond, K. Tuohey, S. Muchohi, A. Ahmad, J. Davis, T. Killeen, M. Fitzgerald, C. Idiokitas, J. Wood, V. Carlo-Carson, C. Williams, L. Selmi, J. Penner-Hahn, LT Watson, B. Braun
Staff Present: S. Ghosh, L. Campbell, C. McGoff

I. Welcoming Remarks

II. Review of August 17, 2021 IBC Meeting Minutes

No comments or questions were voiced.

Motion: Approve

For: 12; Abstain: 0; Absent: 0

III. New Business

A. Presentations

1. BSL-3 and BSL-4 Research at the National Emerging Infectious Disease Laboratories (NEIDL)

The Director of the NEIDL provided an update on the BSL3 and BSL4 work being done at the NEIDL. The presentation included: the mission of the NEIDL, current research activities, the viral and bacterial pathogens included in this research, statistics on faculty and staff members, total lab space, and current funding. It was stated that currently there are 19 unique protocols related to SARS-CoV-2 with the potential for work SARS-CoV-1 in the near future. He also shared planned work for the upcoming year including the use of iPS cells and organoids, testing new therapeutics, and developing vaccines.

2. Annual Environmental Health and Safety (EHS) Research Safety Report to IBC

The Senior Safety Specialist from Research Safety, Environmental Health and Safety (EHS), provided their Annual Report, reporting on data from July 1, 2020 - June 30, 2021 including information on the following: type and total number of inspections occurring on both campuses, the number of deficiencies and deficiency rate per inspection, high frequency deficiencies, laboratory safety training data, and training system updates. The presentation provided a detailed report on guidelines EHS instituted for working with SARS-CoV-2 and additional inspections they provided to the laboratories engaged in this research. EHS also clarified that their process on how their office handles issues of noncompliance following lab inspections.

B. ROHP and EHS Incident Report:

- 8-31-21: An asymptomatic PhD student working in a BSL1 lab, tested positive for SARS-CoV-2 and again on 9/2/21, but negative on 9/3/21. Researcher worked closely with Healthway and was cleared to return to work after remaining asymptomatic. He was deemed to have tested positive due to amplicon exposure. Additional PPE use, enhanced cleaning protocol, and reminders to prevent future contamination was recommended. This incident was reported to the BPHC. EHS worked with the lab to decontaminate the space and equipment. Samples were collected and sent out for Covid-19 testing. Awaiting the results of the testing. The decontamination procedure will be repeated if samples test positive for SARS-CoV-2 again.

- 9-7-21: an animal care technician reported to the ROHP that he had punctured his left thumb while attempting to open the lock on a non-human primate cage. ROHP and Animal care staff consulted on this incident, and determined that there was very low risk for Herpes B exposure. However, because no exposure could be ruled out, ROHP implemented Herpes B protocol and did baseline testing today for Herpes B. ROHP recommended treatment, medical counseling and follow-up. This incident was reported to the BPHC.

EHS attributed the root cause of the exposure to broken and defective equipment. The broken lock key was replaced to prevent reoccurrence. The animal care technician followed proper exposure control plan. PPE use and ROHP response actions were all appropriate.

IV. Protocol Review

1. rDNA/Bhz – Three Year Renewal

| BUA | (PI) | Title | BSL | ABSL | Campus |
|--|------|--|---------------------------------|------|--------|
| 1670 | | Synthetic biology and automated culture platforms for cellular systems | 2 | N/A | CRC |
| Primary Reviewer: Rob Davey | | | Secondary Reviewer: Ron Morales | | |
| Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a | | | | | |
| <p>Meeting Comments: The lab is studying the function and evolution of cellular systems using synthetic biology approach where they are introducing new biomolecules into bacteria and human cells to study gene regulation. Recombinant proteins are produced from synthetic DNA. Potential hazards include culturing in shakers, plating, centrifugation, vortexing of cultures, freeze drying of nucleic acids, and generation of recombinant DNA and their handling. They are also working with several pathogenic bacteria where they will be analyzing their antibiotic resistance properties. In this renewal they added <i>N. gonorrhoeae</i>, pathogenic <i>Escherichia coli</i> and <i>Staphylococcus aureus</i> strains. Committee discussed that these agents are already known to cause laboratory acquired infection or are associated with gastrointestinal illness as well as pneumonia and more often skin lesions and as such, additional care should be practiced while working with these agents. Medical Director (ROHP) confirmed that the lab workers have been trained regarding health risk issues and records are on file at ROHP. Good training description is provided for the entire extensive personnel list. Culture flasks with caps and appropriate aerosol containment is used. Further, 10% bleach and 2% Wescodyne will be used for disinfection. Following will be communicated to the PI:</p> <ul style="list-style-type: none"> PI and Hanrong need to update their annual safety trainings (LST, BSL1/2, BBP, Chem safety and rDNA/IBC policy training. The main risk is aerosolization, ingestion (<i>E. coli</i>), skin contact on open wounds (<i>S. aureus</i> and <i>N. gonorrhoeae</i>) and eye contact for <i>N. gonorrhoeae</i>. Please add the following statement in the laboratory procedure section: In the event of an incident with an antibiotic resistant bacteria, this information will be communicated to the ROHP or other medical personnel that might treat the lab workers. Also add the following statement that workers will check for open wounds on themselves and avoid working with <i>S. aureus</i> and <i>N. gonorrhoeae</i> samples until they are healed. "Clean Harbors" is no longer the hazardous waste vendor at BU. Please omit all direct citation of "clean Harbors" and just indicate the waste will be collected by the hazardous waste vendor. Change Safety glasses to Safety goggles as they are appropriate for handling <i>N. gonorrhea</i> due to conjunctivitis risk. It is indicated that only small amounts of the bacteria will be grown. Specify the approximate volume of that "small" amount. Add "freshly made" to the 10% bleach and indicate contact time for bleach and wescodyne. <p>BUA site Assessment: The laboratory has appropriate exposure control plan. Some members ROHP clearance need to be updated and they are already in contact with the ROHP office. Few members need to renew their safety trainings</p> | | | | | |

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| and one departed member (Diviya) need to be removed from the personnel list. Their biosafety cabinets are duly certified. | | | | | |
| Motion: Conditional Approval (Administrative Review) | For: 12 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 0 |

2. Bhz – Three Year Renewal

| BUA | (PI) | Title | BSL | ABSL | Campus |
|--|-----------|---|---------------------------------|-----------|--------|
| 1043 | | Reactive Oxygen Species in Patients with Heart Failure; Modification of Cardiovascular Proteins by Metabolic Disease: Metabolic Predictors for Diastolic Hear Failure | 2 | N/A | BUMC |
| Primary Reviewer: Carmela Abraham | | | Secondary Reviewers: Jim Keeney | | |
| Applicable NIH Guidelines: N/A | | | | | |
| <p>Meeting Comments: The project is to identify molecules in the blood that can be used as biological markers in heart failure patients as well as in patients displaying symptoms of metabolic diseases associated with heart failure as some of these markers may be used to assist diagnosis and treatment and improve prognosis. Blood and urine are collected from patients for this longitudinal study. Also, an echocardiogram will be performed. Blood markers are analyzed by commercial ELISA kits or radioimmunoassays. All analyses are performed at BUSM. PI provided clarifications on how samples will be collected from study participants and brought to the lab. Following will be communicated to the PI:</p> <ul style="list-style-type: none"> VIII. 7. Liquid waste needs to be treated with 10% bleach FINAL concentration for 30 minutes. No need to wait for 60 minutes. Please update accordingly. VIII. 4. Uncheck animal procedures if no animals used. IX. Table: Please check Radiation and X-Ray for the use of radioimmunoassays. Complete Section G and provide approval number. <p>BUA Site Assessment: The lab has exposure control plan. One of the lab member is working with ROHP to update medical clearance. One member need to update BSL1/2 training. The lab have eye wash and safety shower validated.</p> | | | | | |
| 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 |
|---|------|---|-------------------------------------|------|--------|
| 1545 | | Oxidative Stress in Myocardial Remodeling and Failure | 2 | 2 | BUMC |
| Primary Reviewer: Barbara Slack | | | Secondary Reviewer: Colleen Thurman | | |
| Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-E-1; Appendix B-II-D | | | | | |
| <p>Meeting Comments: This protocol investigates how oxidative stress cause heart damage and how the oxidative stress response signaling pathway is altered in heart failure. Cardiac myocytes isolated from rats are exposed to various molecular partners of specific signaling pathways by the use of adenoviral vectors to understand the role of individual member proteins in the process. Standard molecular biology experiments including the DNA synthesis assays using tritiated thymidine incorporation, will be performed to evaluate the responses. They also use transgenic mice for Cre-Lox mediated conditional expression of certain signaling pathway member. Safe handling of tamoxifen in the animal study is nicely described. Following will be communicated to the PI:</p> <ul style="list-style-type: none"> Some BioRAFT trainings need update (Colucci- BSL1/2, rDNA/IBC policy; Luptak – rDNA/IBC policy) Some ROHP clearances need updating (Chambers, Colucci, Luptak) Section VIII.1- please check animal handling Section VIII.3- check face mask (re: COVID protocols) | | | | | |

- Section VIII.4- check head and shoe covers, double gloves and surgical mask (to conform with the text in Procedures section describing tamoxifen injection).

BUA Site Assessment: They have blood borne pathogen exposure control plan. They are working on updating ROHP clearance for some of the members. One member needs to update BBP training. Biosafety cabinet and fume hood are duly certified.

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| Motion: Conditional Approval (Administrative Review) | For: 12 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 0 |
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4. Bhz – Three Year Renewal

| BUA | (PI) | Title | BSL | ABSL | Campus |
|------|------|--|-----|------|--------|
| 2338 | | Effects of a Soft Robotic Exosuit on Exercise Capacity, Biomarkers of Neuroplasticity, and Motor Learning after Stroke | 2 | N/A | CRC |

Primary Reviewer: Inna Afasizheva

Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol evaluates if use of a soft robotic exoskeleton (exosuits) improves the ability to exercise at higher intensities during patients' rehabilitation after a stroke. Blood samples are collected from the study participants in the post-stroke exercise study before and after the exercise. De-identified saliva samples are also taken for genotyping before the exercise. Blood and saliva samples will be transported to another institute for analysis. Use of personal protective equipment appears appropriate. Blood-borne pathogen standard is invoked as they are handling blood, although the blood-borne pathogen training of the members are unclear. Transportation of blood and saliva is described in detail and appears appropriate. However, the nature of experiments that protocol members will perform in BU and in other institute are not clear. Following will be communicated to the PI:

- Provide response to the questions "State how many years of experience, when and where" for Anna Roto, Ridiane Denis and Yuri Kim.
- State clearly which part of the procedures will be done in BU lab and which part will be done in Spaulding Rehabilitation or other places.
- Provide description of laboratory procedures that Anna Roto will perform. The statement "Anna Roto will analyze samples as per the Spaulding lab's policies and procedures" is not very informative. Will she be doing any experiments in the other institute for this project?
- Please clarify if any of the genotyping experiments on de-identified samples will be done in BU. If so, provide the procedure, including the waste decontamination methods.
- Pipetting infectious liquid is indicated in the protocol but use of a biosafety cabinet is not mentioned. Please explain where processing of the biological samples (blood or saliva) will be done and what personal precautions will be used for the work with infectious materials.
- Clarify if any liquid or solid wastes will be generated out of this protocol in the BU lab and if so, how will they be disposed of.

BUA Site Assessment: Training is complete for all members. They are working with ROHP on updating medical clearance. They indicate that they will not have any direct contact with human materials. Required facilities and emergency management plans are in place.

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| Motion: Conditional Approval (Primary and Secondary Reviewer Review) | For: 12 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 0 |
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5. rDNA/Bhz – Three Year Renewal

| BUA | (PI) | Title | BSL | ABSL | Campus |
|------|------|---|-----|------|--------|
| 1537 | | Engineering T cells response for cancer adoptive immunotherapy using synthetic genetic and signaling networks | 2 | 2 | CRC |

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|---|-------------------------------------|-----------|------------|------------|-----------|
| Primary Reviewer: Elke Muhlberger | Secondary Reviewer: Colleen Thurman | | | | |
| Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1; Appendix B-II-D. | | | | | |
| <p>Meeting Comments: This protocol investigate ways in improving the efficiency of Cancer Immunotherapy. They particularly are engaged in the study of expression of tumor-specific chimeric antigen receptor expression on engineered T-cells which are supposed to find and kill cancer cells in the body. In their study they are trying to understand better the cytotoxic effect of immune system towards tumor cells so that currently known adverse effects of CAR-T cell therapy can be reduced or eliminated. They use lentiviral vectors to introduce genes of interest into the human or mouse T-cells in vitro and study their functional changes by various biological assays. They also introduce these engineered T-cells into the animals for validation. However, the animal work description lack details. They also use NIH-approved embryonic T-cell line to test how their approach of manipulation of gene expression works so that the approach may also be used in the study of developmental biology. The description of waste management, rDNA work and lab safety practices are well described. Following will be communicated to the PI:</p> <ul style="list-style-type: none"> • Except for the PI, training experience of lab personnel (when and where) are either missing or incomplete. Please update. • Please update all references of old IACUC protocol number (15-011) to the new number PROTO201800600. • Please clarify whether the animal work will be done in the PI's lab or in the animal facility. • In PPE and Safety Equipment table, check "Animal handling, cage changing". • Update BSC certification date. • It is indicated that sharps are not used, but animal injections are done in the protocol is done. This needs to be clarified. • Liquid waste handling is restricted to broth culture but should include cell culture supernatants and viral liquid waste as well. • NIH 3T3 cells should be removed from the list of hazardous material (mouse cell line is not biohazardous). • Please update the 15-011 IACUC number to the new format approval number (PROTO201800600) in Hazardous Biological Agent list for all agents going into animals. <p>BUA Site Assessment: Lab has blood borne exposure control plan in file. Updating ROHP clearance for all members are in progress. Trainings are all current. One member (Yong Liang) needs to be removed and one other member need to be added. Biosafety cabinets and fume hood are duly certified.</p> | | | | | |
| Motion: Conditional Approval (Administrative Review) | For: 12 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 0 |