**Boston University**
**Institutional Biosafety Committee (IBC)**
**July 19, 2022 Meeting Minutes**
**Location: Zoom and/or by phone**
**Start time: 12:00 PM End time: 2:59 PM**

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| Members Present: | R. Ingalls, B. Slack, E. Muhlberger (left 1:09 PM), E. Loechler (Joined 12:08 PM), R. Morales, T. Winters, C. Thurman, S. Niemi (left 2:42 PM), J. Keeney, R. Timmerman, V. Britton (joined 12:08 PM, left 12:55 PM), J. Barton (left 12:56 PM, joined again 2:11 PM), S. Ghosh |
| Guests Present: | A. Griffiths, P. Richmond, N. Dey, M. Fitzgerald, G. Madico, S. Benjamin, A. Ahmad, T. Strange, LT Watson, K Tuohey |
| Staff Present: | L. Campbell, C. McGoff |

**I. Review of May 17, 2022 IBC Meeting Minutes**
No concerns were voiced.
Motion: Approve
For: 11; Against: 0; Abstain: 0; Absent: 2

**II. Member Training Session:** Dr. Anthony Griffiths provided members with an overview of the establishment of aerobiology at BSL-3 level in the NEIDL. The goal of the research is to measure the efficacy of ultraviolet light in the inactivation of aerosolized virus.

**III. New Business:**

A. SQAP Report: Problems updating shipping training records to RIMS from BioRAFT will be resolved soon.

B. Review of Research Occupational Health Program (ROHP) & Environmental Health and Safety (EHS) Incident Report: There were no incidents to report to the committee.

**IV. Protocol Review**

**1. Bhz – New Application**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 2548 | | Inactivation of SARS-CoV-2 using ultraviolet light | 3 | NA | BUMC |

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| Primary Reviewer: Elke Muhlberger | Secondary Reviewer: Shannon Benjamin |
| Applicable NIH Guidelines: N/A | |

Meeting Comments: This new protocol investigates new devices for inactivation of airborne viruses, particularly in facilitating transmission of SARS-CoV-2 viruses. They will evaluate efficacy of ultraviolet light-based inactivation on aerosolized viruses. A specially designed self-contained BSL3 unit will used for the purpose inside the aerobiology facility in the NEIDL. PI was invited to give a presentation on the apparatus and to describe the procedural details of the proposed work. This was presented before the review of the protocol when individual steps of their experiments, including transfer of biological samples, creation of aerosol using nebulizer, movement of the aerosol through the machine, exposure to UV light, methods of collection of treated aerosol samples, decontamination of the equipment and quantitation of the remaining viruses in the aerosol were all described in great detail. Liquid and solid waste handling will be performed using validated NEIDL-specific SOPs and 5% microchem plus will be used as a general disinfectant. The committee recommended that some of details of the experiments should also be added in the revised application. The following will be communicated to the PI:

- While the PI has previous experience with aerobiology experience and BSL3, the PI has not gone through BSL3 training at the NEIDL. Please indicate which other staff will be assisting Honko with experiments and list them on the protocol.
- Please remove as this room is SA only
- Correct typo (“After use of the Class II cabinet, …” It should be “class III”)

- Please state that 70% ethanol is not used for virus inactivation but for cleaning purposes.
- The committee recommended a brief description of the workflow of the procedure in a way that someone, who is not familiar with aerosol chambers, be able to follow and understand the underlying biosafety measures. Most of the information is already there, but it would be helpful to restructure it a bit. For example: "The virus sample to be aerosolized will be transported into the ante chamber in a beta cannister and transferred into the class III cabinet through the beta port. In the class III cabinet, the virus-containing solution will be placed into the base of the nebulizer (How? Open tube? Or will virus solution be pipetted in a container in the nebulizer?)". Examples also include "Maximum volume will not exceed XXX ml. Maximum virus concentration will not exceed XXX PFU/ml," etc.
- "Interrogate Virus Stocks to determine characteristics", remove language that refers to the use of the inactivation SOP for materials removal, as SOP 0535 does not cover removal from the suite.
- In Section 3, please clarify which highlight safety features/procedures such as HEPA filter on the air compressor line, 2 in line HEPA filters on the vacuum line, gull wing being secured (locked) w/ subsequent pressure decay testing, VHP fumigation at the conclusion of the study.
- Please confirm if the gel sampler will be used as an alternative to having the AGI present in the class III. Add language to the description that describes the AGI being dipped in epoxy which mitigates the risk of broken glass.
- When describing disassembly of the biaera unit please clarify that the internal fan will run when the class III BSC is being fumigated to ensure internal components are decontaminated.
- Select "centrifugation" and "plating" in the Laboratory Procedures table in the PPE section.
- Please remove all references in the disinfectant section that refers to "approved minimum contact time" to "overnight per SOP (#)".
- Add "70% EtOH" to the disinfectant section.
- Update all BSC certification expiration dates for all BSCs.
- For the material transportation section, while describing materials being removed from the class III BSC, please state that the beta canister key required to open the canister, will be attached to the inside of the BSC in the suite designated for use. This will ensure that the beta canister is only open in the BSL3 within the BSC.

BUA Site Assessment: All cabinets are certified. All listed spaces are approved for proposed work and planned use of PPE are appropriate. It was noted that this type of cabinet is considered as a self-contained BSL-3 laboratory; however, to use this cabinet for any select agent, it will have to be done in BSL-4 suite and have to be registered.

*PI of this protocol left the meeting before deliberation and voting.*

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| Motion: Conditional Approval (Primary, Secondary Reviewer and Bob will re-review) | For: 12 | Recuse: 0 | Against: 0 | Abstain: 1 | Absent: 0 |

**2. rDNA/Bhz – Annual Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 1888 | | Host Response to Filovirus and Henipavirus Infections | 4 | NA | BUMC |

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| Primary Reviewer: Rob Davey | Secondary Reviewer: Guillermo Madico |
| Applicable NIH Guidelines: Sections III-D-1-c, III-D-1-a | |
| Meeting Comments: The aim of this project is to study how cells react to filovirus and Henipavirus infection and which cellular pathways involved in the antiviral defense are blocked or activated by filoviruses. In this annual review the only change is to update the BSC certification dates. The protocol remains well written from the aspects of personnel training and detailed description of the work being performed. Disinfectant used is 5% Microchem Plus, which is approved for this class of viruses. All work is performed in BSC within BSL4 laboratory by personnel wearing BSL4 suits. All centrifugation steps are performed using buckets and rotors equipped with sealed covers. | |

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| Recombinant virus work is focused on viruses with reporter genes such as GFP or luciferase, which do not create additional risks. Their work on swapping portions of the virus genome from one filovirus to another, is not expected to alter pathogenesis and is balanced by being performed in the BSL4. This was previously reviewed the DURC subcommittee and was determined to be a non-DURC matter. A NEIDL eFSAP registration to include Henipaviruses recombinant DNA work objective will be submitted. All biosafety cabinets are duly certified and safety training for all members are current.<br>Committee voted not to require any annual renewal submission for this protocol.<br><br>*PI recused herself from voting.* |

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| Motion: Approve | For: 10 | Recuse: 1 | Against: 0 | Abstain: 0 | Absent: 2 |

**3. rDNA/Bhz – Three Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
|---|---|---|---|---|---|
| 1792 | | Structures and Functions of RNA Editing TUTases | 2 | NA | BUMC |

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| Primary Reviewer: Elke Muhlberger | Secondary Reviewer: Jim Keeney |
| Applicable NIH Guidelines: III-D-1-a, III-D-2-a; Appendix B-II-C | |
| Meeting Comments: The goal of this protocol is to understand the RNA metabolism of unicellular parasite Trypanosoma that causes sleeping sickness. This parasite possess special RNA editing mechanism that add uridine residues in the RNA molecules they synthesize. PI is interested in investing the detail mechanism of terminal uridyl transferase (TUTase) enzyme of this parasite. They will purify the TUTase from mitochondrial fractions and also will do site directed mutagenesis on genes coding for TUTase. To get a better understanding of the mechanism of the TUTase enzyme, they will them in the parasite and follow up how RNA editing is modified. The biosafety concerns are centered around the use of two trypanosoma strains they use in their work. However, none of these two strains infects humans or cause disease, one infects only insects and the other one infects small mammals only such as mice. All surfaces exposed to trypanosoma will be disinfected with 70% ethanol and supernatants from the culture will be treated with bleach at a final concentration of 10% for 30 minutes before sink disposal. The following will be communicated to the PI:<br>• Please include the additional personnel working on the protocol in the personnel list.<br>• Since Room is also being used in this protocol, add the room in the facility information section.<br><br>BUA Site Assessment: One personnel needs to be added. Room is to be added. | |

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| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 1 | Absent: 2 |

**4. rDNA/Bhz – Three Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
|---|---|---|---|---|---|
| 2392 | | Circuit structure and dynamics in prefrontal-limbic networks | 2 | 2 | BUMC |

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| Primary Reviewer: Barbara Slack | Secondary Reviewer: Colleen Thurman |
| Applicable NIH Guidelines: III-D-1, III-D-4, III-E-1, Appendix B-V, Appendix G-II-B, Appendix Q-1 | |
| Meeting Comments: This protocol investigates how prefrontal cortex (PFC) integrates sensory, motor and emotional information to guide action. This study combines in vitro electrophysiological techniques with tract-tracing, following survival surgery that infuses anatomical tracers to label pathways in monkeys. They investigate fixed brain sections under the microscope to determine if PFC-Anterior Cortex projection neurons and axon terminals have distinct excitatory, inhibitory, and neuromodulatory interactions. They also aim to translate their findings to mouse models of disease and in human tissues, through collaborative work with other labs. The project involves experiments using rhesus monkeys, mouse brain, and fixed human brain. All work with monkeys is carried out in collaboration with BU PIs. Survival surgery on NHPs will be performed to inject microliter quantities of anatomical tracers or AAV viral vectors to label neural pathways using various fluorescent proteins or opsins. Vectors are obtained from the UNC Vector core or Addgene. Harvesting and perfusing will be carried out in a fume hood. All instruments will be | |

decontaminated with bleach, and other materials collected as biohazardous waste. All waste, instruments decontaminated with 70% EtOH or 10% bleach afterward. Small amounts of tetrodotoxin will be used (below select agent allowable limit). Some fresh frozen brain will also be used for biochemical experiments. The electron microscopic work involves use of organic solvents, and some high hazard chemicals but those will be used according to the EHS approved SOPs. They do have approved IACUC protocol for their NHP work as well as for the work with mouse brain. Fixed human brain tissue is obtained from other BU collaborator. Solid waste from live monkeys collected and labeled for incineration at LASC. BUA site assessment has not been completed yet, but committee asked EHS to remind the PI to use cut-resistant gloves for their microtome use for unfixed tissues. The following will be communicated to the PI:

- Section III. Update Chang's rDNA/IBC policy training. Ensure BioRAFT training and ROHP clearances are current for all personnel.
- Is there an updated IACUC protocol number for the mouse work ( )? Should be Luebke approved through Jun 2023.
- Lab Procedures- Will homogenization of fresh frozen NHP brain tissue after thawing be carried out in a fume hood? It seems as though this procedure could generate aerosols. (Homogenizers with gaskets is not checked, and no BSC is listed.)
- Lab Procedures section states that osmium tetroxide will be neutralized using sodium sulfide/sulfite, sodium hydroxide, or oil (meaning corn oil?). It appears that the safest method is to neutralize in twice the volume of oil and the committee recommend that. Please modify or clarify.
- Section VIII. 4. Back fastening gowns are normally not used in ABSL2 NHP space except for surgery. Please add sleeve covers to "Other".
- Recombinant DNA/Animal Experiments: IACUC approved until 1/26/2025

BUA Site Assessment: This was not completed at the time of the meeting.

| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |
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**5. rDNA/Bhz – Three-Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
|---|---|---|---|---|---|
| 2135 | | Bridging genetic variation with behavior: molecular and functional mechanisms of quantitative trait gene regulation of the stimulant and addictive properties of methamphetamine in mice<br><br>Genetic basis of binge eating and its motivational components in a reduced complexity cross<br><br>A reduced complexity cross in balb/c substrains to identify the genetic basis of oxycodone dependence phenotypes | 2 | 1 | BUMC |

| Primary Reviewer: Rob Davey | Secondary Reviewer: Steve Niemi |
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Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a, III-E-1, III-E-3, III-F (exempt experiment); Appendix C-VI.

Meeting Comments: S. Ghosh read primary reviewer's comments. The goal of this protocol is to assess how genetic factors contribute to addictive properties of various substances such as methamphetamine and oxycodone. Their initial focus is on suspected RNA-binding proteins, transcriptional repressors and cytochrome proteins. .
Human neuroblastoma and kidney cell lines will be used in which they will modulate expression of proteins o their interest. Animal work will involve use of AAV vectors to alter expression of RNA binding protein levels in different tissues, including the brain. Main risk factors are AAV system during production and introduction into animals. The

group include research fellow who is highly experienced in work with AAV vector who will also train other members of the group. Work is performed in a BSC, and disinfectants used are 10% bleach for treatment of material that has contacted virus and for general cleanup, 70% ethanol. The work with animals is well detailed and needles are deposited into a sharps container. Committee discussed that animals treated with AAV vector may be maintained in ABSL1 facility. Overall the protocol appears to have only limited risks. The following will be communicated to the PI:

- The BSC certification date needs to be updated.
- All human cell lines are considered as BSL2 agent in Boston University. Please mark the highest biosafety level for the protocol as BSL2.
- In the hazardous biological agent table, mark all human cell lines as BSL2.
- Section VIII. Q6 Sharps is checked as "no". This should be "yes" as needles are described several times and a sharps container is used for disposal.
- Section VIII. Q8, please state contact time for disinfectant.

BUA Site Assessment: Some members need to update their training record. No other concerns were noted.

| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |
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**6. rDNA/Bhz – Three Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
|---|---|---|---|---|---|
| 1805 | | Molecular Mechanisms Regulating the Alternative Lengthening of Telomeres Pathway<br><br>Functional Characterization of the telomeric long non-coding RNA, TERR | 2 | 2 | BUMC |

| Primary Reviewer: Barbara Slack | Secondary Reviewer: Colleen Thurman |
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Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-D-3, III-E-1

Meeting Comments: The goal of our research is to understand how telomeres are maintained and how defects in telomere maintenance contribute to cancer progression. The study will use as models human osteosarcoma cell lines, and human osteosarcoma tumor samples. The cells will be transduced using lipid reagents, calcium phosphate, or replication incompetent lentiviral, adenoviral, or retroviral vectors, and analyzed using conventional biochemical techniques. In some experiments, cells will be transduced using a CRISPR/Cas9 system that utilizes catalytically dead Cas9, and third generation lentiviral vectors. The sgRNAs and Cas9 variants will be introduced on separate vectors, with the goal of increasing or repressing transcription of the telomere cap component TERRA, or knocking out genes involved in telomere maintenance. SCID mice will be injected with human tumor samples or cell lines to make xenografts. Mice will be treated with inhibitors that reduce survival signaling in tumor cells to determine if it leads to tumor regression. The protocol includes an active IACUC number and an exempt IRB approval number. The following will be communicated to the PI:

- Please ensure that rDNA/IBC policy training is updated for and (PI) and Chem Safety for . Also needs update of her ROHP clearance.
- VII.3. Please clarify if any of the tumor cell lines are manipulated before being used for making xenograft.
- VIII. 1. Animal handling/cage changing, Animal inoculations should be checked
- VIII. 4. Is this PPE accurate for animal work? Most ABSL2 mouse work is completed in a BSC, so back fastening gown, N95, and eye protection, including head cover, may not apply.
- VIII. 5. BSC certification needs update.
- VIII. 6. Please state that sharps boxes will be closed when ¾ full.
- VIII.6. Please clarify when are razor blades used for animal work? According to the IACUC protocol surgical implant of tumors is performed using scissors.

- VIII. 8. Please describe instances where 10% bleach must be used for disinfection and where 70% ethanol is appropriate as a primary disinfectant.
- IX. A. 4. IACUC approval number is out of date. The is approved through 6/9/2025.

BUA Site Assessment: This was not completed at the time of the meeting.

| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |
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**7. rDNA/Bhz – Three-Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 1563 | | Biosynthesis of alkaloids and functional characterization | 1 | NA | CRC |

| Primary Reviewer: Inna Afasizheva | Secondary Reviewer: Jim Keeney |
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Applicable NIH Guidelines: Section III-D-2-a and Section III-F-8, Appendix C-II

Meeting Comments: The goal of this protocol is to investigate the role of alkaloids on cellular stress. The PI's group focuses on the biosynthesis of alkaloids in their own laboratory and examine their protective effects on a worm model involving *C. elegans.* Worms are used as a model of oxidative stress, heat or cold-shock activated stress. Experiments involve sub-cloning in *E.coli* based vectors, overexpression of the genes involved in alkaloid biosysthesis in *E. coli* and purification of the recombinant proteins. DNA visualization method is based ethidium bromide use. PI included detailed protocol for safe use of ethidium bromide in the lab. *C. elegans* will be activated by two generations and synchronized in the agar (NGM) media. Larva-stage worms will be transferred to the liquid S complete medium into 96 well plates and subjected to experiment with stress and compounds of interest. CRISPR/Cas9 technology will be used in editing the *E. coli* genome. The following will be communicated to the PI:

- Update PI title in the personnel list.
- Exclude inactive lab members from the IBC protocol or update ROHP clearance for all of them.
- Student Aiwen Wen needs complete rDNA training.
- Live animals are marked. Update highest Animal Biosafety Level to ABSL-1.
- Update *C. elegans* protocol by including source of worms, growth condition (incubator, room …) and methods of their disposal after completion of the experiment.
- Add brief statement on additional protection for pregnant lab members from exposure to ethidium bromide.

BUA Site Assessment: PI's lab has special incubator maintained at 20°C for the culture of worms. Worms are purchased from commercial sources. The lab does have a biosafety cabinet, but it is not used for their *C. elegans* work. The lab indicated they usually autoclave used cultures before disposal and they maintain record of proper functionality of the autoclave.

| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |
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**8. Bhz – Three Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 231 | | Exposure Science and Environmental and Occupational Epidemiological Research Studies Requiring the Collection Handling Storage Analysis and Shipping of Biological Samples | 2 | NA | BUMC |

| Primary Reviewer: Tom Winters | Secondary Reviewers: Valeda Britton |
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Applicable NIH Guidelines: N/A

Meeting Comments: The projects of this IBC protocol are diverse in purpose, but all fall under the fields of environmental epidemiology and exposure science. This group collects blood, urine, saliva, vaginal swabs, breast milk samples in multiple settings and among groups including families of construction workers, Metropolitan Boston area, home, office, auto environments, breast feeding women, sugarcane workers in Nicaragua, elderly caregivers,

gymnasts, women planning to conceive, pregnant women, and brick makers in Nicaragua. Many biologic markers including endocrine-disrupting chemicals, stress chemicals, polybrominated diphenyl ethers (PBDE), Tris(1,3-dichloro-2 propyl)phosphate (TDCPP), tetrachloroethylene (TCE) in metals are analyzed. Dust samples are collected in multiple settings and N95 respirators are used in these settings. Most collections of specimens are done at Boston University Medical Center but lab work is done at the Brown University and CDC. They are attempting to correlate medical illnesses with occupational and environmental exposure. Methods used for storage, transport and analyses of materials appear appropriate. Biosafety issues in the protocol include drawing blood samples, obtaining breast milk samples, sputum samples in multiple settings. For the safety purposes they practice bloodborne pathogen standards for all of their work. Disinfection and handling of liquid waste appears appropriate. Solid wastes are discarded in double red bags. The following will be communicated to the PI:

- Please update training and especially, shipping training for and and other members of your group. It appears that is not listed in the training list and is not up to date on shipping. Please remove names from the list who are no longer in the lab.
- Update ROHP clearance for all members as appropriate
- Update biosafety cabinet certification date. Listed certification date of 2019 has expired.
- Make sure IRB approvals are up-to-date.
- Note that BUA inspection must be completed for the approval of this protocol.

BUA Site Assessment: This was not completed at the time of the meeting.

| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |
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**9. Bhz – Three-Year Renewal**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 944 | | Rapid Antibiotic Susceptibility Testing by Surface Enhanced Raman Spectroscopy | 2 | NA | CRC |

| Primary Reviewer: Inna Afasizheva | Secondary Reviewer: Bob Timmerman |
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Applicable NIH Guidelines: N/A

Meeting Comments: The goal of this project is to develop a portable, affordable, easy-to-use technique to determine antibiotic susceptibility testing (AST) including minimal inhibitory concentrations (MIC) during short time period. The study is based on the discovery that when susceptible strain of *Staphylococcus aureus* or *Escherichia coli* is exposed to an antibiotic, the intensity of specific biomarkers in its surface-enhanced Raman scattering (SERS) spectra drops significantly in as little as two hours. The overall goal of this study to create portable technique based on laser scattering signals for the detection of bacterial human pathogens on the minutes time scale. The protocol has long history and multiple funding sources during last 14 years. Bacteria enrichment protocol, which does not involve large volumes and performed in BSC, is standard. Collection of BSL-2 bacterial strains is well cataloged in the Biohazard table in the protocol. Committee discussed if any the of listed agents is a concern for laboratory acquired infection (LAI). Medical Director confirmed that Neisseria gonorrhea falls in that category but it is already included in BU LAI list and agent information sheet on this is already available to researchers. Additionally, ROHP already provided in-person safety training to lab members on these agents. The following will be communicated to the PI:

- Ranjith Premasiri is included twice into the personnel table with two different descriptive roles. Please reconcile.
- Please state that for liquid waste bleach will be added at final concentration of 10%.
- Committee recommends a that instead of disposing liquid culture wastes in the red biohazard bag, the liquid wastes could be inactivated by mixing with bleach to a final concentration of 10%, letting stand for a set period of time, typically 30 minutes and disposing down the drain.
- For disposing of agar plates, committee recommends tape-shut the plates and dump in the red biohazard bage. Do not dip them in bleach solution.
- Update BSC certification date.

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| BUA Site Assessment: Some members need to update training record and ROHP clearance and they have been informed of those requirement. Biosafety cabinet is duly certified. | | | | | |
| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 3 |

**10. Bhz – New Application**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 2557 | | Cellular Therapeutics and Systems Immunology Lab (CTSI) | 2 | 2 | BUMC |

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| Primary Reviewer: Robin Ingalls | Secondary Reviewer: Steve Niemi |

Applicable NIH Guidelines: N/A

Meeting Comments: This is a BSL2/ABSL2 protocol covering a collaboration between PI's lab and investigators at BCH and MGH that involves development of a non-human primate (NHP) model for graft-versus-host disease (GVHD). This is a highly clinically relevant work. Rhesus macaques will be housed at BUMC animal facility and transferred to/from MGH for transplant work. At BU, the work is largely focused on harvesting blood and tissue (primarily bone marrow, LNs; possibly skin or GI biopsies, and CSF) for immunologic studies. The biohazards involve the NHP samples themselves which can be infected with herpes B virus as well as other potential infectious agents that could afflict humans, as well as the risk of manipulating a large primate. All animals will be anesthetized before sample collection, although not specifically stated in the application. The protocol provides sufficient detail for the IBC to understand how catheters are placed, bone marrow is obtained, skin and LN biopsies are done, etc. Standard PPE will be utilized including face shield, mask, etc. There is no plan for long-term storage of samples and there does not appear to be any bench studies done on the samples after they are obtained except possibly centrifugation. Committee also discussed whether for non-BU protocol members, their safety training received in their parent institutions can be accepted in lieu of BioRAFT training. Absence of BioRAFT training record does not necessarily mean that they do not have appropriate safety training. Veterinary clinician member of the protocol clarified that activated hydrogen peroxide containing disinfectant "Peroxigurard" is indeed used as a regular disinfectant in the animal house. The following will be communicated to the PI:

- Please modify Layman's Description as follows:
  Please remove what is written here in Q1 and place it at the beginning of Q3, "Describe laboratory procedures…"
  Replace the Layman's Description with the following:
  Hematopoietic stem cell transplantation (HCT) is a life-saving therapy offered to many individuals with cancer. This project will support collaborative work between the PIs lab and investigators at Boston Children's Hospital and Massachusetts General Hospital to develop an animal model that more closely resembles human disease. Our broad goal is to understand graft vs host disease and other complications related to transplantation in order to save human lives.
- Please delete the following sentence from that section to be moved: "I can perform these when available but if there is someone there who would be willing to jump in on these we would welcome that".
- Please clarify if any manipulation of the samples will be done. The PI checked centrifugation as a lab procedure perhaps for the blood samples?
- Please add the following sentences at the end of Q3: All animals will be anesthetized prior to sampling. All research staff collecting samples will be trained in the specific procedures.
- Section on Overview and Grant Funding, "Is your grant administered through:" – should check "Boston University - Medical Campus (ORA)" instead of "Other".

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| BUA Site Assessment: Exposure Control Plan needs to be adopted and uploaded in BioRAFT. ROHP clearance is not available for several members. Training record for some of the listed members could not be verified in BioRAFT. No biosafety cabinet will be used. | | | | | |
| Motion: Conditional Approval (Administrative Review) | For: 10 | Recuse: 1 | Against: 0 | Abstain: 0 | Absent: 2 |

**11. rDNA/Bhz – New Application**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 2457 | | DAMP Cloud-based Research Laboratory Service Platform | 1 | NA | CRC |

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| Primary Reviewer: Robin Ingalls | Secondary Reviewer: Ron Morales |
| Applicable NIH Guidelines: Section III-F Exempt Experiments | |

Meeting Comments: This is a new IBC application to establish a core facility to provide cloning, DNA extraction, plasmid preps, and such to investigators both in and outside of the BU community. As the details of the laboratory procedures will vary depending on the individual client's needs, the PI's protocol can only provide broad descriptions of the planned studies but this is similar to other IBC protocols from core facilities on campus that IBC have reviewed. Lab manipulations will include plating lab strain E coli for transfection of plasmids, nucleic acid isolation involving magnetic beads, use of commercial Qiagen kits, PCR, cloning, and agarose gel electrophoresis. The committee determined that this is a BSL1 protocol. It was noted that the work will be performed in a BSL2 designated lab space. It was discussed that even though the work for this protocol may not require BSL2 containment, the basic safety principles of a BSL2 facility must be followed. The following will be communicated to the PI:

- The PI needs to complete the Chemical Safety training module.
- Several members of the lab have not completed their medical clearances (ROHP).
- Please clarify that the experimental procedures will be executed by only the lab staff members identified in the protocol.
- Are laboratories requesting the service expected to have an approved IBC protocol? If yes, how will the lab check for that?
- Will requesting labs be expected to send sample materials? If yes, please provide description of how the lab will receiving them.
- In the Materials Used in Research section, the protocol should be marked as BSL1 with rDNA.
- Since Biosafety cabinet will not be used in protocol, the make/model/serial numbers of the cabinet should be removed.
- Since the *E. coli* strains to be used for transformation work is not a biohazard material, the response question of storage and transportation of biohazardous materials need to be removed with the statement that no biohazardous materials are used in this protocol.
- Please ensure that there are personnel with shipping training for sending materials to clients.

BUA Site Assessment: This was not completed at the time of the meeting.

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| Motion: Conditional Approval (Administrative Review) | For: 11 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 2 |

**12. rDNA/Bhz – New Application**

| BUA | (PI) | Title | BSL | ABSL | Campus |
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| 2559 | | Profiling of cancer cell lines, patient derived tissue and cfDNA | 2 | NA | BUMC |

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| Primary Reviewer: Sajal Ghosh | Secondary Reviewer: Bob Timmerman |
| Applicable NIH Guidelines: Section III-F | |

Meeting Comments: This is a new protocol from a PI in the Computational Biomedicine. The goal of this protocol is to generate a library of genome nucleic acid sequence data as well as mRNA and protein profile data from wide variety of cancer patients and controls and then from a large number of commercially available cell lines. They receive

human tumor tissue and blood samples from ProteoGenex, a commercial vender as well as from Biospecimen Archive Research Core (BARC). Cell lines are purchased from ATCC. They use standard laboratory techniques such as DNA, RNA and protein isolation from tissues and cell lines. Isolated DNA and RNA will be subjected to the library construction steps using Illumina Nextera library preparation kit which include round of DNA/RNA purification, ligation and PCR amplification. They are actively developing and applying tools and technologies for multi-sample and longitudinal biopsies analysis, single cell sequencing, long range read phasing, etc. Availability of such a vast amount of digital information will help to understand tumor development, development of resistance to treatment and progression to metastasis. Tissues from commercial sources will be shipped directly to the PI, whereas samples from the BARC will be brought to the lab by lab personnel with experience in shipping. They clearly mentioned that all handling of tissues and cell lines will be done biosafety cabinet until TRIzol or other cell lysis agents are added to the cells. Disposable scalpels will be used for cutting tissues. BSL2-specific PPE (such as lab coat, nitrile gloves, cut-resistant gloves when needed, and safety glasses/goggles) will be worn all the time. Liquid waste will be treated with bleach at final 10% concentration for 30 before sink disposal and solid waste will be put in red biohazard box. PI is the only member in the protocol. This is a nicely written straight-forward protocol. The following will be communicated to the PI:

- Section VII.3. Who is transporting materials from BARC to the Lab
- Section VIII.5. BSC will be used. Provide details (make/model/serial number/certification date)
- Section VIII.6. Sharp will be used. It is indicated in laboratory procedure section that scalpel blade will be used. Described more on type of sharps and disposal methods.
- Section IX: Uncheck rDNA box as Ligation and PCR amplification is not considered as rDNA work.

BUA Site Assessment: The Lab needs to adopt Exposure Control Plan and upload in BioRAFT. Biosafety cabinet is duly certified. EHS will provide spill kit and biohazard sign stickers.

| Motion: Conditional Approval (Administrative Review) | For: 11 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 2 |
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**13. rDNA/Bhz – Amendment**

| BUA | (PI) | Title | BSL | ABSL | Campus |
|---|---|---|---|---|---|
| 2460 | | Cerebrospinal Fluid Analysis in COVID-19 | 2+ | NA | BUMC |

| Primary Reviewer: Sajal Ghosh | Secondary Reviewer: Ron Morales |
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Applicable NIH Guidelines: Sections III-D-1-a and III-D-2-a

Meeting Comments: This protocol investigates the molecular basis of neurological complications typically found in COVID-19 patients such as altered mental status, stroke, seizure, muscle pain, etc. Their primary objective has been to demonstrate whether such changes are direct result of the presence of the virus in CSF or because of the surge of inflammatory cytokine in CSF. They have been testing presence of viral RNA, viral antibodies and measuring cytokines in CSF for their analysis. In the current amendment they are adding two experiments: 1) Gene expression and histopathological analysis of skeletal muscle tissues for SARS-CoV-2 infected hamster and 2) whether SARS-CoV-2-induced muscle atrophy can be inhibited by the overexpression of anti-atrophy gene in cell culture. They will receive inactivated SARS-CoV-2 infected hamster muscle tissue from a collaborator from New York University. The PI has attached the letter of verification of inactivation that he obtained from the collaborator. The inactivation procedures include 48 hrs incubation of muscle tissues with 10% formalin or dipping into TRIzol solution, both of which are proven method of SARS-CoV-2 inactivation. Inactivation was further validated by plaque assay test done with the extract of the treated and washed muscle tissue or by q-RT-PCR test for SARS-CoV-2 NSP14 gene expression. Both were negative for the presence of the virus. The rDNA work (which is new in this protocol) involves overexpression of plasmid that codes for an anti-atrophy gene in mouse and HeLa cells if it can inhibit anti-FAS antibody induced cell death. rDNA section has been completed appropriately. Cell culture work will be done in BSC and BSL-2 specific PPE will be worn while working with cell lines. Wastes will be treated with bleach to a final 10% concentration for 30 min before sink disposal.
No concerns were noted.

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| Motion: Approve | For: 11 | Recuse: 0 | Against: 0 | Abstain: 0 | Absent: 2 |