Boston University
Institutional Biosafety Committee (IBC)
August 16, 2022 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:02 PM End time: 2:18 PM

Members Present:	R. Ingalls, B. Slack, I. Afasizheva, P. Liu, W. Lu, V. Gouon-Evans, T. Winters, R. Morales, C. Thurman, S. Niemi, J. Keeney, R. Timmerman, V. Britton, J. Barton (left 2:10 PM), S. Ghosh
Guests Present:	N. Dey, M. Fitzgerald, S. Benjamin, J. Wood
Staff Present:	L. Campbell, C. McGoff

I. Chair's Report:
Dr. Wining Lu and Dr. Valerie Gouon-Evans, were introduced as new IBC members. The Chair reported that S. Benjamin is leaving Boston University and thanked her for the contributions she made to the IBC, EHS and the NEIDL. The chair also briefly summarized the mission of the IBC and the role of the reviewers.

II. Review of July 19, 2022 IBC Meeting Minutes (R. Ingalls)
No concerns were voiced.
Motion: Approve
For: 13; Against: 0; Abstain: 2; Absent: 0

III. New Business:

A. Proposal of Designated Member Review of Teaching lab protocol's use of rDNA
Members were informed that a PI has recently contacted IBC staff requesting an urgent review of a protocol involving the use of rDNA and a separate material for a BU course starting in September. Due to the urgency of the submission and the date of the next scheduled IBC meeting, the Chair asked members to vote on a motion to allow the protocol to be reviewed by DMR as soon as possible for part of the protocol (non-rDNA material) and that an amendment be submitted for review at the full convened meeting for the rDNA material.
Motion: Approve: allow proposed teaching lab protocol to be reviewed by DMR.
For: 15; Against: 0; Abstain: 0; Absent: 0

B. SQAP Report: The IBC Noncompliance policy will be discussed at the next IBC meeting.

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

IV. Protocol Review

1. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2446	[redacted]	SARS-CoV-2 research. Diagnostic development and evaluation, antiviral testing, and host response evaluation	3	N/A	BUMC
Primary Reviewer: Robin Ingalls		Secondary Reviewer: Sajal Ghosh Additional Reviewer: Shannon Benjamin			
Applicable NIH Guidelines: Section III-D-1-a					
Meeting Comments: The original protocol investigates efficacy of small molecules as antivirals for SARS-CoV-2 infections, develop new diagnostics and to identify suitable cell lines to in which SARS-CoV-2 variants can be grown for further analysis. Protocol also recently started to work on characterization of monkeypox viruses from recent outbreaks. The current amendment is only to receive various cell lines from collaborators in NIH that are recombinantly modified to express hACE2 receptor and TMPRSS2 protease so that their role in the infection of SARS-CoV2 can be studied. There were no concerns with this amendment.					
Motion: Approve	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

2. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2560	[redacted]	Inflammation in Skeletal Muscle Injury Repair	2	2	BUMC
Primary Reviewer: Inna Afasizheva		Secondary Reviewer: Steve Niemi			
Applicable NIH Guidelines: N/A					

Meeting Comments: The goal of this new protocol is to study specific roles of different cell types in the skeletal muscle injury repair. The involvement of specific cell types in regulation of inflammation will be assessed by depleting selective cell types during skeletal muscle injury repair. PI proposes using diphtheria toxin (DT) in mouse model which selectively expresses DT receptor on specific cell types. Wild type mice are not sensitive to DT due to the lack of DT receptor expression. DT is included in the BU high hazard chemicals list. Briefly, to make working solution whole toxin will be diluted in PBS at concentration 2.5 ng/µl. Animal will be injected with DT at concentration 25 ng per gram of body weight. Injury of skeletal muscle will be applied in 24 hours. Tissue samples will be collected in different time points and used for immunological, biochemical, and molecular biology analysis. The risks of use of DT and safe handling practices are well described. Committee was informed that DT is likely metabolized to inconsequential peptides and amino acids or excreted intact in even smaller amounts. If excreted intact, the amount of DT already diluted in feces or urine will be further diluted by soiled bedding. Either way, the use of DT in this protocol does not require the ABSL-2 animal and animal waste handling precautions described in the protocol and they should be replaced with ABSL-1. Medical Director also assured that ROHP is available to provide them with Tdap vaccination. The following will be communicated to the PI:

- Please complete the title of each personnel in the protocol
- Indicate if Sachi is experienced in the procedures to be used in this protocol and include information about her experience, and when and where they were received.
- Autoclaving of the sharp containers is not recommended in BUMC. The sharp container may be disposed of directly in the red biohazard bod. If it must done differently, please provide explanation and include the protocol.
- Please provide BU IACUC number (approved or pending).
- Check box for “Animal Inoculations”
- Check the box for Safety Glasses for when injecting mice and handling those mice and cages post-injection.
- N-95, back fastening gowns and double gloves are not needed for animal-related activities.
- Change highest animal biosafety level for this protocol to ABSL-1 as DT is not a biologic and should not qualify for ABSL-2 precautions.

BUA Site Assessment: Freezers for storing toxins should have biohazard sticker. Toxin stock needs to be made in fume hood.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

3. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2562	[redacted]	Discovery and development of therapies and consumer products derived from the human microbiome	2	2	Holobiome BUMC
Primary Reviewer: Robin Ingalls		Secondary Reviewer: Colleen Thurman			
Applicable NIH Guidelines: N/A					

Meeting Comments: The goal of this study is to build maps of how human microbiome influences our biolgy and to use this knowledge to develop drugs and functional foods. To do this the lab first optimize cultivation protocols to isolate diverse bacteria from human fecal samples and then screen them against human disease targets of interest.

Fecal samples are either purchased from commercial laboratories or obtained through collaboration with academic or clinical labs. They do culture human cell lines fro in vitro assays and receive animal tissues for analysis, although not clear how such tissues are used. To reduce the risk associated in handling fecal samples which at times may contain pathogenic bacteria, they are always handled under BSL2 conditions in a biosafety cabinet or in a sealed anaerobic chamber and all staff wear lab coat, gloves, goggles and appropriate shoes and pants. The surfaces that come in contact with these samples are disinfected with either 70% ethanol or 10% bleach. The following will be communicated to the PI:

- Please add a sentence to the detailed description section that all personnel are experienced in handling these GI pathogens and that they have received appropriate training on the risks of infections. Although it is noted in the personnel table but this will be helpful for ROHP to know that lab staff do not require any additional pathogen specific training
- Please clarify the use of animal tissues and where do they come from.
- If there are no live animals handled in this protocol the PI can uncheck the ABSL2 box under item 'Materials Used in Research". and check N/A in its place.
- It is stated in the laboratory procedure section that "…all staff are trained to handle such specimens, and we regularly clean any environment that comes in contact with these samples with 70% Ethanol or 10% Bleach." Is bleach the primary disinfectant? The 70% ethanol alone may be inadequate for disinfection of these samples.
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
709	[redacted]	Neuroimmunomodulation Within The Eye	2	1	BUMC

Primary Reviewer: Barbara Slack | Secondary Reviewer: Colleen Thurman

Applicable NIH Guidelines: Section III-D-2-a. Section III-D-4-b.

Meeting Comments: The goal of this study is to determine if alpha-MSH (melanocyte stimulating hormone) is an effective treatment for eye inflammation. They propagate cDNA plasmid encoding alpha-MSH in E. coli K12 bacteria. They Inject mice with pertussis toxin and Freund's adjuvant to induce uveitis and then test the ability of alpha-MSH plasmid injected into the eye to alleviate inflammation. They collect human primary peripheral white blood cells in BMC ophthalmology clinic or Mass Eye and Ear clinic and then fix and stain for alpha-MSH receptors and analyze by flow cytometry to determine if alpha-MSH receptor polymorphisms are associated with susceptibility to uveitis. This is a very well organized and thoroughly described protocol with the description of all safety procedures. The following will be communicated to the PI:

- Please note that ROHP clearance for Yee is overdue.
- Section VII.3-Lab Procedures states: "Any storage vials, uncapped needles still attached to their syringes will be discarded as biohazardous waste into either designated double red bagged bio-waste containers...or into sharps containers". Please clarify that uncapped needles attached to syringes will be discarded into sharps containers.
- Section VIII.1- please check 'animal handling..."
- Section H: Please update IACUC approval number listed under rDNA table (number [redacted] (formerly [redacted]) approved through 10/16/2022).

BUA Site Assessment: All trainings are current. Biosafety cabinet is duly certified. New secondary container for transportation for transportation of biomaterials from BMC is being ordered.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

5. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
690	[redacted]	Molecular mechanisms of skin development, growth and regeneration	2	2	BUMC

Primary Reviewer: Inna Afasizheva | Secondary Reviewer: Steve Niemi

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

Meeting Comments: The goal of this study is to understand mechanisms of skin regeneration and tumorigenesis. Project involves collection to various tissues from variety of inbreed and compound transgenic animals (mice and naked mole rats), isolation of primary cells and immunohistochemical studies on them. In vitro studies include use of lentiviral vectors to manipulate gene expression in skin cells. All animal work is supported by approved IACUC protocols. PI proposes use of high hazard chemical DMBA to introduce DNA mutations into cells in cells lines and also in live animals. Protocol includes all information that may concern the IBC with extensive detail. The committee suggested the potential danger of DMBA to reproductive physiology particularly for women of child baring age should be made aware of the risks involved. The following will be communicated to the PI:

- Provide "Title" of [redacted] and [redacted] in the personnel information table.
- Since the protocol does not involve use of any infectious agent or select agents, change the response for infectious agents and select agents from "will not handle or work on this part of the project" to "Not applicable to this project" for [redacted] and [redacted] in the personnel table.
- Add the animal house facility room in section 4 where DMBA is added to the animals.
- Add a sentence in the laboratory procedure section to indicate that all members have been made aware of the risks associated with handling DMBA in relation to reproductive health, particular to the women researchers.

BUA Site Assessment: Specified lab members need updated blood borne pathogen training. Transport container for the DMBA needs to be updated. Biosafety cabinet is duly certified. No other concerns were noted for this lab.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

6. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
752	[redacted]	Design principles of novel neuromodulation therapies	2	2	CRC

Primary Reviewer: Sajal Ghosh | Secondary Reviewer: Colleen Thurman

Applicable NIH Guidelines: III-D-1-a, III-D-4-a, III-E-1; Appendix B-V, G-II-B, Q-1

Meeting Comments: The goal of this protocol is to design molecular tools to alter functions of specific brain cells to understand the role of those specific neuronal cells in normal brain and in the brain of individuals with neuronal diseases such as AD, dementia, Parkinson's disease, schizophrenia, or such. The hope is that such approach will used to develop advanced treatment plan for those diseases. One of their approach involve use of different rDNA molecules that will alter neural activities, such light-activated ion channels, ion pumps, transcription factors, signaling molecules and fluorescent proteins. They inject lentiviral vectors, AAV vectors, MuLV-based retroviral vectors expressing these factors into animals to know how those individual factors affect the function of a neuronal cell. At times these animals are treated with tetrodotoxin or with 6-hydroxydopamine (6-OHDA) to mimic specific disease phenotype. create Parkinson's disease model. Transgenic mice that conditionally express protein of interest via Cre-LoxP/tamoxifen, or that express calcium sensor GCaMP or where a-synuclein is overexpressed to simulate familial PD are also used. BrdU or EdU are also used at times to label newly developed neurons and LPS to stimulate systemic inflammation. Biohazard items in the protocol include human cells (HEK 293 cells, lentivirus vector, retroviral vector), they have provided detailed description on the origin and safety of viral vectors. Preparation stock solution and their

storage are described and are appropriate. PPE use in the lab and in the animal house looks appropriate. Use of sharp bins for collecting sharps and treatment of liquid waste with bleach is also appropriate. The committee noted that ROHP provides antidote for the 6-OHDA to the PI to store in the lab in case of an emergency. The following will be communicated to the PI:

- Update Personnel list – [redacted] has been listed twice.
- Provide "Experience, when and where" information for all members.
- rDNA training due for [redacted] and [redacted]
- BBP training Due for [redacted] and [redacted] and LST for [redacted]
  Waste should treated with bleach at a final concentration of 10% for 30 min before sink disposal. For surface disinfection it should be 'freshly prepared 10% bleach".
- VIII. 1. Check animal handling/cage changing.
- VIII. 5. Update BSC certification.
- IX. H 2. Update IACUC protocol numbers to new format. IACUC [redacted] approved 9/27/2021 approved until 9/26/2024.
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1539	[redacted]	Use of kidney specimens to identify endogenous antigens in membranous nephropathy Investigating the functional capacity of autoantibodies in primary membranous nephropathy	2	N/A	BMC

Primary Reviewer: Pinghua Liu	Secondary Reviewer: Sajal Ghosh

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

Meeting Comments: The objective of this study is to extend the study of identification of kidney proteins and auto-antibodies against kidney proteins involved in kidney disease like membranous nephropathy (MN). They use commercial antibodies or autoantibodies derived from patients serum to perform immunofluorescence studies on frozen or formalin fixed sections of human kidney or cultured cells engineered to express specific kidney proteins. Their work involves four distinct directions: a) use of FFPE or frozen tissue sections of kidney biopsies for IF studies, b) They elute glomerular IgG from human kidney biopsies from patients with MN and also clone plasmid constructs expressing kidney proteins which they transfect in HEK 293 cells and use the cell lysates to do western blotting with extracted IgG from patient kidney cells. Each of these steps has been described in detail including safety practices used for microtome, PPE use and waste disinfection and disposal. Biohazards include kidney biopsy tissues (for which they use universal precautions) and human cell line HEK293. Sharps are disposed of in separate sharp container which in turn goes into red biohazard bag along with other solid biohazard wastes and liquid waste is disinfected with bleach at a final concentration of 10%. Overall, this is a well-written protocol. The following will be communicated to the PI:

- Uncheck boxes in the "for amendments and annual renewals" section in the Overview and Grant Funding info page.
- [redacted] training is missing and [redacted] BSL1/2, BBP and rDNA training need update, as is Dr. [redacted] rDNA training.
- If more personnel are working in your project, please include them in the personnel list.
- In the 'Descriptive Role' Question please indicate briefly which person will the doing what part of the project.

- In the laboratory procedure section also, please indicate what is the source of kidney biopsy samples and other tissue sample.

BUA Site Assessment: PI clarified that he is the only person doing the cryotome work. Trainings are all current. PI indicated that one more personnel will be added to the protocol.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

8. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2410	[redacted]	Thin Filaments and Muscle Regulation	1	N/A	BUMC

Primary Reviewer: Tom Winters	Secondary Reviewer: Jim Keeney

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

Meeting Comments: This research group looks at the mutations related to thin filament troponin-tropomyosin perturbed muscle activity and relaxation which can lead to cardiomyopathies or skeletal muscle disorders. They study the interactions of actin bound myofibrillar regulatory proteins, tropomyosin and troponin at the atomic resolution level. Their research includes use of x-ray crystallography to define how mutations linked to the muscle control proteins perturb muscle activation and relaxation. This work is done at a BSL-1 level with no biological agents used. The proteins used for crystallographic studies are prepared from non-pathogenic *E. coli* transformed with individual muscle protein expression plasmids. They indicated that Bio RAFT training was completed for those using x-ray. Chemical and liquid wastes are segregated and accumulated in Satellite accumulation area followed by removal by the EHS. Solid and liquid wastes were handled appropriately. Disinfecting with 10% bleach was also appropriate. The PPE used is proper. Hearing protection was used during sonication. The following will be communicated to the PI:

- Please add room [redacted] for the use of Electron Microscope.
- N-95 respirator is not required for this work. Please uncheck.

BUA Site Assessment: All members are up-to-date with all required trainings. The N-95 respirator is not required for their work. No biosafety cabinet is required for their work either. The room [redacted] needs to be added to the protocol for the use of electron microscope.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

9. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
661	[redacted]	Biocompatibility of Dental Materials	2	N/A	BUMC

Primary Reviewer: Sajal Ghosh	Secondary Reviewers: Ron Morales

Applicable NIH Guidelines: N/A

Meeting Comments: The goal of this protocol is to test how ceramic versus titanium can the used as a base for dental implants. Normal human osteoblasts are isolated from waste bone harvested during extraction of wisdom teeth from healthy individuals in the clinic. Cells from these teeth are allowed to grow in specialized growth media in tissue culture plates. They are then harvested and seeded on to titanium or ceramic disks and tested for parameters for cell attachment, proliferation, differentiation and mineralization. They have appropriate IRB approval (exempt) for collection of tooth samples. It was noted that the laboratory procedure in the protocol is extremely long and contain copy of each of the SOPs present in the lab. Those are not necessary and must be eliminated. Otherwise the use of PPE, biosafety cabinet, transport of dental material from the clinic to lab, disposal of liquid and solid wastes are well described and appropriate for the type of work the lab does. Small amount of osmium tetroxide is used for histology experiments and its handling is detailed in one of the SOPs. Cellular imaging core and analytical instrument cores will be used. The following will be communicated to the PI:

- Copy of each SOPs in the lab are not required in the IBC application. Instead, describe succinctly what major laboratory steps are involved in the collection, harvesting and culturing of human osteoblasts. Describe briefly how those cultured cells will be attached to the titanium or ceramic disks to test superiority of one over the other for their usefulness as a base for dental implant. State briefly how wastes are disinfected and disposed of for the entire project and what PPE are worn during the work
- Make sure that BBP and Chem safety training for Dr. [redacted] is complete.
- ROHP clearances for all lab members must be updated.
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

10. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1804	[redacted]	Regulation of Gene Expression in the Immune System	2	N/A	CRC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Bob Timmerman

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

Meeting Comments: This protocol is designed to study multi-protein regulatory complexes that control expression of inflammatory genes. Human (Jurkat and HUVEC) and murine (RAW 264.7) cell lines, human primary macrophages isolated from whole blood obtained from commercial sources are used as models in their experiments. Plasmids encoding human and mouse transcription factors, reporters are propagated in E. coli K12 followed by transfection into cells using standard lipid reagents such as FUGENE. ChIP and reporter assays are performed for evaluation of protein/DNA interaction. Third generation lentiviral vectors, prepared in the lab using 293 cells are used to introduce shRNAs into cells to knock down specific genes. Mouse parainfluenza virus Sendai virus (non-pathogenic to humans) is also used to infect 293 cells to examine interferon beta activation. They purchase whole human blood from commercial sources for isolating macrophages. They also use CRISPR/Cas9 technology to knock out the several genes from human cultured cells. Guide RNA and Cas9 are expressed on the same vector are introduced into cells using lentiviral vectors. Off-target effects are not expected. They will also use catalytically inactive dCas9 to target specific genomic regions in order to purify selected chromatin fragments. Safety precautions described adequately. Wescodyne germicidal detergent or bleach will be used to disinfect bacterial and human culture liquid waste. However, the protocol does not specify final concentration and time of exposure of Wescodyne. The following will be communicated to the PI:

- Section I.2- Please leave box for amendments blank.
- Section III.2- Some safety training dates for [redacted] overdue.
- Section III.3- some ROHP clearance dates not indicated.
- Section VIII.2-Centrifugation with sealed rotors or sealed cups should be checked- protocol requires centrifugation of bacterial cultures and whole blood.
- Section VIII.5- certification date of BSC needs to be updated.
- Section VIII.7A- Please specify concentration of Wescodyne used to disinfect liquid waste; specify that when bleach is used to disinfect it will be added to a final concentration of 10%.
- No IRB listed, I assume this is not needed for whole blood from commercial sources.
- Section H.5- please answer question "will rDNA be provided to another PI?"
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

11. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
734	[redacted]	Neurogenetic Processes in the Fetal Neocortex	2	N/A	BUMC

Primary Reviewer: Pinghua Liu	Secondary Reviewer: Jim Keeney

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

Meeting Comments: This protocol investigates the effect of trisomy on chromosome 21 on the development and maturation of neuronal and glial cells. They generate iPS cell lines for their studies from people with Down Syndrome. They will culture iPS or CRISPR/Cas9-edited cells and then differentiate them into oligodendrocyte precursors, and then mature oligodendrocytes. Effect of epigenetic dysregulation on the development and maturation of oligodendrocytes will be studied on these cells. Three-dimensional organoid cultures will also be generated from these cultures on which they will and examine the development of neuronal and glial cells in multicellular, physiologically relevant environment. This protocol is well-written and it builds upon the prior experience from the PI laboratory. It was noted that PI also store some brain sample materials from her previous BU mentor but do not work on them at present. The following will be communicated to the PI:

- For [redacted] please reconcile the information on the personnel information page. Is she a graduate or undergraduate?
- If other members are working in the protocol, please list them.
- EHS indicated that additional room is being used. Please list them room in section IV.
- Define acronym iPS when used for the first time.
- It is mentioned in the laboratory procedure section that 4 iPS cell lines will be used. Please clarify whether these four are the ones listed on biohazards materials table. If not, please list the relevant ones.
- Please describe the work little more, especially what is being done with the other ATCC cell lines.

BUA Site assessment: All trainings are current. Update of personnel list is needed. Additional room is being used although it is not listed in the table. BSC is duly certified.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

12. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2141	[redacted]	Dissecting Long-Range Cortical Networks During Behavior	2	2	CRC

Primary Reviewer: Sajal Ghosh	Secondary Reviewer: Steve Niemi

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

Meeting Comments: This protocol investigates how communications among sensory, motor and cognitive function give rise to behavior of human. In this animal work heavy protocol the lab use live mouse model where animals first go through behavioral training for making whisker-guided decision (with rewards). These animal are then head-fixed on a restrainer and cranial window will be made to provide optical access to visualize and perturb neuronal activities. Electrophysiological recordings will also be made with additional implants. For in vivo labelling of neuronal structure and function, they will inject 3rd generation lentivirus vector, AAV vectors or glycoprotein-deleted rabies virus vector. These viral vectors will come premade, pre-aliquoted in appropriate amounts and titer from various Vector core facilities and will express genes related to behavioral functions. At times they will also do some gene modification on vectors before giving it to the core for making the virus stock. Biohazards in this protocol are human cell lines, 3rd generation lentivirus and glycoprotein deficient rabies virus vector. Tetrodotoxin will used at concentration well below allowable select agent toxin amount and tamoxifen for conditional induction of transgene. Personnel working with viral vectors are appropriately trained with safety precautions. Sur gical instruments, needles, glass micropipetts, razor blades and glass slides will all be disposed of in EHS- approved sharp container. Small volume unused viral vectors will be treated with bleach at a 10% final concentration of 30 min and seal tubes will be

discarded in red biohazard bag. Surgical instrument will be disinfected with 2% wescodyne for 30 min. The following will be communicated to the PI:

- Most of the members need to update their safety trainings and rDNA training in BioRAFT.
- Check the select biological toxin box in section IX and complete the section F for SA toxin details.
- Check animal handling and cage changing.
- Provide BSC information and certification date (required for the tissue culture work).
- Add human cell lines in the hazardous biological agent list.
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

13. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
783	[redacted]	Structure and Function of Bacterial Adhesion Pili	2	N/A	BUMC

Primary Reviewer: Robin Ingalls	Secondary Reviewer: Ron Morales

Applicable NIH Guidelines: N/A

Meeting Comments: This lab is interested in understanding of how bacteria adhere to cells in the environment with particular interest in delineating how they attach to urinary tract, respiratory tract or intestine. They study the adhesion pili of *E. coli* bacteria. Biohazards in this protocol include *E. coli*, *H. influenzae* and CaCo 2 human intestinal cell line. Bacteria are grown in agar plate or in small volume liquid culture and are added to the cells followed by electron microscopic visualization. They also isolate pili from bacterial culture using a gasketed homogenizer. The also use biosafety cabinet for aerosol generating procedures. The protocol is straightforward and addresses all the safety concerns appropriately. The following will be communicated to the PI:

- [redacted] needs to complete her medical clearance with ROHP
- Dr. [redacted] annual medical clearance needs to be renewed with ROHP
- If W-415 is not being used, please remove it from the Facility list.
- Please update the date for most recent BSC certification.
- If the homogenizer/blender is disassembled for the cleaning, please make sure that the apparatus is thoroughly disinfected prior to disassembling.

BUA Site Assessment: All trainings are current. Biosafety cabinet is duly certified. PI indicated that [redacted] is no longer in use. Lab is compliant with all safety and engineering requirements.

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

14. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1770	[redacted]	Identification and development of biomarkers for diagnosis, monitoring and treatment of Barrett's esophagus and esophageal cancer	2	N/A	BUMC

Primary Reviewer: Tom Winters	Secondary Reviewer: Bob Timmerman

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol performs genetic and genomic analyses of tumor tissues and blood of patients with head and neck cancer and esophageal cancer at various stages of disease to identify and develop biomarkers for development, progression, treatment and monitoring of the disease. Tissue samples are received from BU School of Medicine, the University of Rochester, and University of Pittsburgh. DNA and RNA are isolated from these tissue

samples and from relevant human cancer cell lines. The DNA sequencing work will be done at the Ontario Institute for Cancer Research. Shipping is done in secondary contained shatter-proofed containers. Liquid and solid waste are disposed of properly, disinfectant use is appropriate. The tissue will be frozen or fixed as is processed. The biosafety cabinet is certified. Personal protective equipment is appropriate. It was not clear what materials will be shipped and how? It was also not clear whether any other work will be done with large number of cell lines listed in the protocol other than extracting DNA or RNA. The following will be communicated to the PI:

- Please state briefly what will be shipped to other places and how will it be done.
- Large number of human cell lines are listed in the protocol. Please state what these lines are (lineage) and what they are being used for in this project.
- Note that BUA site assessment with the EHS must be completed for the approval of this protocol.

BUA Site Assessment: Not done yet.

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1