Boston University
Institutional Biosafety Committee (IBC)
March 22, 2022 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:03 PM End time: 2:07 PM

Members Present:	C. Abraham, R. Ingalls, E. Muhlberger, R. Davey, T. Winters, R. Morales, C. Thurman, S. Niemi, J. Keeney, R. Timmerman (joined 12:05 PM), V. Britton, J. Barton, P. Liu (joined 12:23 PM), E. Loechler (joined 13:58 PM), S. Ghosh
Guests Present:	T. Killeen, M. Fitzgerald, P. Richmond, S. Benjamin, J. Wood
Stuff Present:	S. Ghosh, L. Campbell, C. McGoff

I. Introduction

S. Ghosh informed members that as of March 31, 2022, C. Abraham is stepping down as IBC chair as she is retiring from the Boston University. As of April 1, 2022, R. Ingalls will begin serving as the new IBC chair and B. Slack will serve as the IBC vice chair.

II. Review of February 15, 2022 IBC Meeting Minutes

No comments or questions were voiced.
Motion: Approve
For: 13; Against: 0; Abstain: 0; Absent: 2

III. New Business:

A. SQAP Report:

i. S. Ghosh gave a brief presentation on the steps that IBC follow to validate or determine the biosafety containment level for working with a particular pathogen listed in an IBC protocol.; the roles of the PI, IBC, and the Laboratory Acquired Infection (LAI) subcommittee was explained.
ii. Members were informed that there will be a new way of reporting ROHP and EHS incidents; this new reporting will begin at the next IBC meeting.

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

ROHP Report:

- 2.9.22: Amplicon exposure with NEIDL support staff
- 2.21.22: Asymptomatic PhD student positive for SARS-CoV-2 most likely due to Amplicon Exposure
- 2.24.22: Fully vaccinated scientist at the NEIDL tested positive for SARS-CoV-2 and was due to amplicon exposure.

EHS Report:

EHS and the NEIDL are following up on the three incidents reported on by ROHP. No other comments or questions were voiced.

IV. Protocol Review

1. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2356		Testing medical countermeasures against high consequence pathogens in non-human primates	4	4	BUMC
Primary Reviewer: Rob Davey		Secondary Reviewer: Steve Niemi Guillermo Madico			
Applicable NIH Guidelines: N/A					
Meeting Comments: The goal of this protocol is to test therapies against BSL4 pathogens that include Ebola and Marburg viruses. The work is funded by NIH and other government agencies for bringing treatments to the clinic.					

The work covers use of Non-Human Primates to be tested for vaccine or drug efficacy. The animals are vaccinated first and then challenged with the virus in the A/BSL4. Risks include handling sharps, animal bites, animal escapes and blood contact as well as the normal issues of handling pathogens in the BSL4, as needed for determination of virus load in blood and tissues. Since the animals can have Herpes B infection, there is also risk in handling before virus challenge in the ABSL4. Mitigation strategies in place include extensive training of all staff for BSL4 *in vitro* work and ABSL4 animal work. This includes general lab staff as well as a group of dedicated animal veterinary technicians and vets. Training documentation was extensive and provided a good indication of staff competency. Some staff changes were indicated, removing people that have left BU. Sharps are handled with great care with warnings provided to supporting staff when sharps are being used, use of a needle block and disposal in a sharps container. Animals are secured in single caging that provides clear sight of the animal so that staff can concentrate on one at a time. The cage can be used to constrain the animal. Animals are either catheterized for sample collection or sedated while being worked with. This prevents inadvertent interaction with an animal. Procedures for cage cleaning, changing and working with animals are clearly stated. These are based on approved SOPs which evaluate risk mitigation. Animal escape is described that isolates, calms and then captures the animal, returning to caging. Where possible, material is chemically inactivated by a validated protocol so that it can be removed from the BSL4 space. This helps to decrease contact time and therefore risk to personnel in handling infected material. TRIzol and formalin are two common inactivating methods. In general, 5% Microchem Plus, a well-documented disinfectant against many pathogens, is used for clean-up and decontamination. This maintains its potency for more than a year. Overall, there is an appropriate balance of risk and mitigation that meets concerns for this protocol. The following will be communicated to the PI:

- Please remove from the personnel list as she no longer works in your group.

BUA Site Assessment: PI's lab was inspected last time on 12/7/2021 and biosafety cabinets were recertified on 12/13/2021. One personnel (needs to be removed from the personnel list as she has left the lab.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent:1

2. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2116		Gene regulation by non-coding RNA and chromatin modifications	2	N/A	BUMC

Primary Reviewer: Sajal Ghosh	Secondary Reviewers: Jim Keeney

Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, Section III-E-1, Section III-F-5, III-F-8

Meeting Comments: This protocol investigate new mechanisms for modification of chromatin structure by microRNAs and chromatin modifying enzymes such as histone methyl transferase DOT1. These modifications play crucial role in the regulation of gene expression. They do their studies in *Caenorhabditis elegans* (*C. elegans*) and then validates them in mammalian cell culture. They compare gene expression in wild type *C. elegans* with their mutant versions that are either unable to produce specific miRNA or lack histone methyl transferase DOT1 expression to evaluate the role of these factors in the control of gene expression during different biological processes. They will compare the results in human cell lines. They also have created DOT1 knock out cell lines for this purpose using CRISPR/Cas9 technology.

PI provided a brief but succinct description of the biology *C. elegans,* how they are grown, viewed live under microscope, harvested from bulk culture for nucleic acid and protein extraction including disinfection and disposal. They are grown on agar plates containing nonpathogenic *E. coli* OP50 strain (with no resistance to antibiotics). *C. elegans* grow only in low temperature (16 to 20°C) and do not survive at 37°C. They are thus not harmful to humans. Agar plates are discarded in red biohazard bag and wash liquids are bleached and discarded in the sink. PI has listed individual sets of experiments which include a) basic culture methods; b) molecular biology methods including real-time qPCR, deep sequencing, Western blotting, IP, CHIP, Run-On transcription using BrUTP; c) high power microscopy and d) generation of transgenic nematodes. Creation of transgenic animals require extensive rDNA work but actual introduction of plasmids into nematodes are done by an offsite company. All cell culture work will be done in

biosafety cabinet. PI acknowledges that their tissue culture room is under renovation. Old BSC is being replaced with new ones. Cell culture work is on hold until new BSC arrives and certified. In a revision submitted just few days ago, three undergraduate students have been added. Their safety trainings looks complete and PI indicated that their ROHP clearances are being processed. No concerns were noted. BUA Site Assessment: The lab is in good standing with all safety issues and documentations. Currently, the tissue culture work is on hold pending renovation of the lab and it seems purchase of a new BSC.					
Motion: Approve	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

3. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
619		Does fibronectin bridge the gap from nanoscale mechanotransduction to mesoscale mechanobiology? Dissecting the role of mechanical tension in extracellular matrix fibronectin function	2	N/A	CRC

Primary Reviewer: Pinghua Liu			Secondary Reviewer: Bob Timmerman		
Applicable NIH Guidelines: N/A					
Meeting Comments: This protocol investigates the role of Fibronectin (Fn) of the Extracellular matrix (ECM). The ECM is believed to help regulating wound healing and development. Two goals are studied in this project; 1) the pattern of adhesion receptors on the surface of Fn fibers in the presence or absence of Fn fiber stretch; 2) Fn matrix production in endothelial and epithelial cells cultured on substrates of varying rigidity. In these studies human cell lines including primary human umbilical vein endothelial cells and human epithelial cells, both purchased from PromoCell, will be cultured in Biosafety cabinet. Fibronectin will be added to those cultures to determine how they affect interaction with other adhesion molecules on the cell culture surfaces. Since the fibronectin from commercial sources often have contaminations, they will purify their own fibronectin for their studies. The laboratory procedures and safety concerns are adequately explained. There are members leaving and new members joining the lab. No concerns were noted. BUA Site Assessment: The lab well equipped to perform the proposed experiments. Biosafety cabinet certification is scheduled.					
Motion: Approve	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1777		Regulation of Cholinergic Neuronal Cell Function and APP processing in Alzheimer's Disease	2	N/A	BUMC

Primary Reviewer: Rob Davey			Secondary Reviewer: Jim Keeney		
Applicable NIH Guidelines: Section III-D-1-a					
Meeting Comments: This study will investigate how cell metabolism affects accumulation of amyloid precursor protein (APP), a protein involved in Alzheimer's disease, in neuronal cells. The work will test the role of proteases, signaling proteins, growth and morphogenesis factor receptors and lipid metabolism enzymes on accumulation of APP and APP derived peptides. Mouse or human cells will be made to express genes listed above using standard mammalian expression plasmids or treated with small molecule inhibitors of each enzyme target and then assayed for APP. Work is performed in a BSC with lab coat, safety glasses and disposable gloves. Certification date of the BSC is recent (Jan 2022). *E. coli* culture waste and other tissue culture liquid waste are treated with fresh 10% bleach. Treatment time is 30 minutes and is appropriate. The BSC used in the protocol has recently been certified. Only two lab personnel are listed on the protocol each with over 25 years of experience at BUSM. Overall, the work appears performed appropriately. The following will be communicated to the PI:					

- Please add room to the laboratory facility information section as the room is being used for the storage of biospecimens.

BUA Site Assessment: The lab well equipped to perform the proposed experiments. However, Room need to be added to the protocol as it is being used for the storage of biospecimens.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

5. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2360		Delineating mechanisms of breast cancer mediated immune suppression	2	2	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Colleen Thurman

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

Meeting Comments: The focus of this protocol is to understand how cells surrounding a tumor cell helps the cancer avoid detection by the host immune system, particularly in the metastatic organs. The research will use murine models of cancer metastasis, including cancer associated fibroblasts, T cells, CAR T cells (T cells with chimeric antigen receptor) as well as viral vectors such as, lentivirus and Moloney murine leukemia virus. Virus work and cell culture work will be done in biosafety cabinet using BSL2-specific PPE. Cells transduced with viral vectors or exosomes are inoculated in to mouse to study the behavior of those cells in tumor microenvironment. The following will be communicated to the PI:

- The ROHP clearance for and need update.
- needs to complete BBP training in BioRAFT.
- VIII.1. Check Animal handling/cage changing.
- VIII.4. Are disposable scrubs used?
- VIII.4. Please clarify if surgical mask and goggles will be used for inoculations or the inoculations are done in a BSC?
- VIII.5. Please update biosafety cabinet certification date.
- Update IACUC protocol number and approval date in Section H (PROTO201800701 approved until 2/10/2025).

BUA Site Assessment: The lab is all set to perform the proposed work with appropriate engineering control and PPE use.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

6. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2367		Birefringence microscopy imaging of tissues	2	N/A	CRC

Primary Reviewer: Elke Muhlberger	Secondary Reviewer: Ron Morales

Applicable NIH Guidelines: N/A

Meeting Comments: This laboratory is developing specialized microscope, which they can use to image specific tissues based on birefringence to observe the integrity of neuronal structures as related to conditions such as neuropathies, age-related dementia and ALS. They use two different type of samples; a) tissues from human cadavers provided by collaborators (fixed before coming to the BU lab, and b) brain tissues from non-human primates. Although some samples from the second group come as unfixed, the protocol provides detail of how those samples are transported to the lab and all the safety procedures they follow to avoid exposure risks. Research Safety Director clarified that safety glasses are always recommended in BSL2 lab. However, for obvious reasons, they cannot be used

during the use of microscopes. The protocol was simple and straightforward. The following will be communicated to the PI:

- Please provide training experience of and or add who will provide training.
- needs to refresh his Chemical Safety and rDNA trainings
- , , and need to refresh their Chemical Safety Trainings.

BUA Site Assessment: The lab is all set to perform the proposed work with appropriate engineering control and PPE use. PI is advised not to transport biological samples in BU Shuttle Buses.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

7. Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2364		Immunogenicity of herpes zoster subunit vaccine among ulcerative colitis patients treated with tofacitinib and other immunosuppressive regimens	2	N/A	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: N/A

Meeting Comments: The purpose of this study is to determine the immune response from the new Shingrix vaccine in Ulcerative Colitis (UC) patients those are on tofacitinib monoclonal antibody monotherapy in comparison to other UC therapies. Inflammatory bowel disease (IBD) is a chronic inflammatory state of the gastrointestinal tract. Patients with IBD are at increased risk for developing infections including shingles with the Herpes Zoster (HZ) virus. Since most IBD patients are treated with systemic immunosuppressants, an independent risk factor for HZ, the live attenuated HZ vaccine was not recommended. However, the release of the new inactivated HZ vaccine, Shingrix (GlaxoSmithKline, Brentford, UK), presents new opportunities for preventive care. The protocol investigates the efficacy of this treatment in IBD patients with multitude of ongoing treatment regimens. Blood draw form subjects will take place at BMC space during subject's standard care GI clinic visits. Cell-mediated immunity and humoral immunity to HZ will also be measured with commercial ELISA kits. The committee was informed that most of work in the lab was on hold during the COVID-19 pandemic. One member will complete the shipping training when they resume their work. The following will be communicated to the PI:

- Please change the submission type from "New project" to "3-year resubmittal". Also, change the word "amendment" to" 3-Year resubmittal" in the PI Comments section.
- Typo with 's Decriptive role – Should be investigator?
- When, where and for how long did get lab experience?
- Who is trained in shipping?
- must update the rDNA/IBC policy training. This is mandatory for all research work irrespective of actual rDNA work.
- Ensure appropriate PPE used for working with liquid nitrogen and freeze drying equipment.
- Question 6. Change "the" to "then."
- Indicate that the transport of blood from the GI clinic will be done in shatter proof containers.

BUA Site Assessment: The lab is all set to perform the proposed work with appropriate engineering control and PPE use. Lab indicated that their research work was on hold during the pandemic. One member will take the shipping training before they start the work.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent:1

8. rDNA/BHZ - New Application

BUA	(PI)	Title	BSL	ABSL	Campus

2540		Exploring the health promoting properties of *Parabacteroides distasonis*	2	2	BUMC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Colleen Thurman		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a					

Meeting Comments: This is a new application from an investigator in the Pathology department with the goal of understanding the ability of *Parabacteroides distasonis* (Pd) to promote human health. This organism is part of the normal colon flora and studies suggest that it can have anti-inflammatory properties. Biohazards include the Parabacteroides bacteria and human colon cancer cell lines which are all BSL2. The work will be divided between Tufts University and BUMC. Growth of the Parabacteroides will be done at Tufts along with preparation of lysates. At BUMC, the bacteria will be used to infect human colon cancer cell lines and mice. There will also be some manipulation of bacteria at BUMC. For the mouse experiments, either freeze dried non-viable bacteria will be fed via food or viable bacteria will be introduced via gavage. At the end of the mouse experiments, tissues and organs will be collected and fecal matter collected and stored. Additional studies involving introducing Pd genes into non-pathogenic E coli are listed in the rDNA table. The Laboratory Acquired Infection (LAI) review committee chair and the Medical director also evaluated the protocol for any LAI potential of these bacterial species and determined that these are anaerobic human gut microbiota of genus bacteroidales along with bacteroides and provotella. They are part of 55 gut species and they do not meet LAI consideration. The following will be communicated to the PI:

- The protocol states that a commercial shipper (or personal vehicle) may be used to move materials between BUMC and Tufts but no personnel are trained in shipping. Please have at least one lab personnel take the Shipping Training through EHS/BioRAFT.
- Typo: Paracteroides
- Please confirm that the sonication and French press of bacteria that will be performed at BUMC will be done in a BSC or similar closed environment.
- The protocol suggests some manipulation of mice will occur in the laboratory, please clarify.The protocol states that transgenic mice will be used but this is not mentioned in the detailed laboratory procedures section.
- A number of Parabacteroides species are listed in the biohazards table, but only Pd is described in the studies. Please clarify if these will all be manipulated as part of the protocol. If they will be used in the lab, please state so in the detailed laboratory procedures section (for example, refer to the table for a complete list of bacteria that will be used).
- Please clarify exactly what materials are being transported between BUMC and Tufts.
- In the PPE list, only safety goggles were checked for eye protection. Please confirm that safety goggles will be worn all the time by all lab personnel. Or if safety glasses will also be utilized in some situations, please also check this box.
- For animal work PPE, will back fastening gowns and disposable scrubs be used? This is no longer a requirement of standard ABSL2 work.
- Check animal handling and cage changing. Please make sure to mark this as the last item checked on this Section VIII before saving the page.
- The protocol states that all solid waste will be autoclaved before disposal. Are all solid waste will be autoclaved by the PIs lab before disposal? Or will it be disposed of in the red bag lined boxes? Culture plates, pipettes, tubes and other solid wastes that came in contact with bacterial may be disposed of directly in red biohazard boxes without autoclaving.
- Please add “fresh” to the 10% bleach disinfectant.
- IACUC approval is still pending, all in pre-review. Please include the following numbers in the “IACUC Approval Date” box.
    - IPROTO202200000009 Ani-TLR4 genes in bacteria
    - IPROTO202200000010 Mediterranean diet and microbiome
    - IPROTO2022000000007 Gut barrier and longevity

BUA Site Assessment: This is a new lab space that has been set up for the new PI. All safety measures have been implemented and no other concerns were noted. EHS will check further with the PI about their plan of autoclaving the solid wastes.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

9. BHZ - New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2538		Effects of exogenous testosterone therapy on communication in gender diverse speakers	2	N/A	CRC

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

Meeting Comments: The goal of the research is to understand how testosterone (T) therapy affects the voices of those who are gender diverse and assigned female at birth (GD-AFAB). This study will follow participants over the course of a year to understand how T therapy changes the physiological, acoustical, and perceptual features of their voice. The group will measure anatomical, physiological, and acoustic components. Changes in these measures in the perception of gender will also be determined. They will determine participant characteristics with changes in perception of gender. Self-collected saliva samples will be collected and stored frozen which will be further analyzed using commercial ELISA kits. Although it was not clear what will be measured in the ELISA test. The saliva collection method and their storage plan appears to be safe as the group stated that universal precautions for blood borne pathogen will be followed. The following will be communicated to the PI:

- Please update safety trainings (LST, BBP, Chemical safety and rDNA/IBC policy).
- Contact ROHP for medical clearance.
- State which room will be used for Saliva sample collection.
- Please state what will be measured in the commercial ELISA assays?
- Are both safety glasses and face shields will be used by researchers. If not, clarify under what circumstances either of them will be used.
- How the samples will be transported from room to ?
- Who are source of the material (in the Other Potentially Infectious Materials section) (meaning who are the participants? Provide IRB approval number and expiration date.

BUA Site Assessment: The lab well equipped to perform the proposed experiments. No concerns were noted.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

10. BHZ - New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2543		Evolutionary, ontogenetic, and environmental origins of human pathogen disgust sensitivity	2	N/A	CRC

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

Meeting Comments: This protocol investigates age-related changes in Pathogen Disgust Sensitivity (PDS) in children and adolescents. PDS is defined as an individual's sensitivity to pathogen-related stimuli, and functions to modulate what one touches, consumes, and with whom they interact. They propose that PDS is one of the core motivational triggers to initiate pathogen avoidance strategies. They want to investigate what factors influence variability in the PDS. They typically collect data on self-reported pathogen disgust sensitivity (PDS], direct blood samples, demographic data and anthropometric measurements. Blood samples will be analyzed for: IL - 6 and C reactive protein bracket (CRP) inflammatory markers. Collection of dried blood is not a risk to transmit blood-borne pathogens once dried for several hours and stored in the freezer, but collection with lancet use in finger requires BSL-

2 practices. The storage of samples will ultimately be in a -80° C freezer after returning from Honduras. PPE appears appropriate. Solid and liquid waste are handled appropriately. 10% bleach is used as a disinfectant. Primary and secondary containment of samples are provided. IRB approval is pending. No concerns were noted. BUA Site Assessment: The lab well equipped to perform the proposed experiments. No concerns were noted.					
Motion: Approve	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

11. rDNA/BHZ - Amendment

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

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Inna Afasizheva
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-E-1	

Meeting Comments: The goal of this protocol is to perform *in vitro* studies of human iPS cells generated from people with Down's syndrome and the reprogramming of these cells into oligodendrocyte precursors and mature oligodendrocytes. Cell morphology, gene and protein expression measurements will be investigated in these cells. Three-dimensional organoid cultures will also be prepared. The work involves cell culture, cell and organoid fixation with 4% PFA, tissue freezing/sectioning/histology and immunohistochemistry. Procedures include protein and nucleic acid analysis using agarose gel analysis, western blotting and RNA collection for gene expression studies. This amendment is to reinstate the work with lentiviral vectors to express the shRNA against a particular human gene that is believed to be related to the development of Down's Syndrome. Also, research facility rooms were changed from the L building to the R building. PI inherited this protocol from her previous supervisor when he left BU. All existing rDNA work, including the viral vector work was removed at that time. So, this amendment is essentially reviving the previously reviewed and approved protocol that she inherited. She also will be storing several rDNA materials and human postmortem brain tissues that she obtained from her original mentor in BU. PI provided detail information about the source and generation of the lentiviral vector (3rd generation) and indicated that all members in the protocol have appropriate safety training for working with lentiviral vectors. The following will be communicated to the PI:

- Please modify descriptive role of members from "BSL2 only" to more exact roles.
- Please make sure that all lab members have ROHP clearance.
- Correct typo 'contracts' to 'constructs'.
- Please define HMGN1 at its first use.
- Check homogenization for RNA preparation.
- Provide current BSC certification date. It should be less than one year old.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

12. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
600		Development of Biomaterials for the Early Detection and Treatment of Disease	2	N/A	CRC

Primary Reviewer: Ed Loechler	Secondary Reviewer: Ron Morales
Applicable NIH Guidelines: N/A	

Meeting Comments: PI is developing molecular scaffolds to support the growth of animal and human cell types into sheets to use as tissue replacement constructs, such as for blood vessels. Additionally, various micro- and nano-particle based technologies are being developed for applications, such as ultrasound contrast agents, drug delivery vehicles, cell purification systems and agents that can modify chemical and protein behaviors. A collaborative project is also being pursued on the impact of perfluoroalkyl substances (PFAS) on women's health. Engineered cell sheet studies utilize human cells isolated from discarded placental tissue or from pluripotent stem cells. All cell lines are

cultured using standard BSL-2 practices by personnel wearing appropriate personal protective equipment (PPE). Biohazardous materials are stored and disposed of according to proper BSL-2 procedures. All non-cell culture related aerosol-producing manipulations are performed in a chemical fume hood. All cell culture aerosol-producing manipulations are performed in a biosafety cabinet. Cell and liquid waste is disinfected with 10% bleach (freshly prepared) prior to sink disposal. All solid and tissue culture waste is placed in double, red bagged, biological waste boxes and sealed when full. All sharps are placed into XL sharps boxes and sealed when full and are removed in accordance with BU EHS waste removal policy. Nanoparticle-related work is performed using appropriate PPE, and when appropriate, performed in a chemical fume hood. Iron-based nanoparticles are cleaned-up using a magnet. Liquid nanoparticle (NP) waste is accumulated, labeled, and treated as hazardous. Solid NP waste is placed into biohazard waste boxes and sealed when full. Both solid and liquid nanoparticle waste is removed by the BU Biological Waste Management Office. None of the proposed experiments seem to have significant hazards, and all are similar, with steps to minimize hazards being adequately described. Following will be communicated to the PI:

- Personnel Information (Section III.1) is not done consistently. Some participants are have no “Title” and descriptive role of some are listed as “Graduate student”. Please write only broad research activity in the descriptive role box.
- is listed twice.
- needs to refresh his Chemical Safety training.
- It was indicated that personnel that work with nanomaterials will use respirators. However, in Section VIII Personal Protective Equipment and Safety Equipment the surgical mask is checked and not the respirator. Please make the necessary correction.

BUA Site Assessment: The lab well equipped to perform the proposed experiments. No concerns were noted.

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