Boston University
Institutional Biosafety Committee (IBC)
June 15, 2021 Meeting Agenda
Location: Zoom and/or by phone
Start time: 12:04 PM End time: 2:21 PM

Members Present:	C. Abraham, I. Afasizheva, B. Slack, R. Davey, X. Brown (Joined 12:10 PM), P. Liu, R. Morales, T. Winters, R. Varada, C. Thurman, J. Keeney (Joined 12:07 PM), R. Timmerman (joined 12:14 PM), V. Britton (Joined 12:05 PM), J. Barton
Guests Present:	J. Davis, A. Ahmad, P. Richmond, N. Yun, K. Tuohey, J. Wood, M. Fitzgerald
Staff Present:	S. Ghosh, C. McGoff, J. Hutchinson. L. Campbell

I. A. Review of May 18, 2021 IBC Meeting Minutes

No comments or questions were voiced.
Motion: Approve
For: 13; Abstain: 0; Absent: 1

B. Modification of May 2020 IBC Meeting Minutes

Because of the concerns from the guest speaker for the May 2020 IBC meeting that too much proprietary information has been put on the IBC meeting minutes, the sensitive information has been removed from minutes. This revised version will replace the version posted on the IBC website.

II. New Business

A. Safety & Quality Assurance Program (SQAP) Report:

Update on BMBL 6th Edition: J. Hutchinson informed the committee that the biosafety practice manual Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC and NIH, has been recently updated (6th Edition). American Biological Safety Association (ABSA) has published a summary of all the changes made in the 6th edition. The link for this update was provided to all member along with the IBC meeting agenda.
On a separate note, Ms. Hutchinson announced that she is leaving the Boston University and this was her last attendance in the IBC meeting. Members thanked her for her service and wished her the best in her future endeavors.

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

ROHP Report:

1. Asymptomatic researchers testing positive for SARS-CoV-2

An Undergraduate Student Researcher on the BUMC tested positive on 5/19/21. He was fully vaccinated, asymptomatic and had no known exposure. CT values were N1 ND; N2 39 and RP 30. There was no SARS-CoV-2 work in that lab since last August. Another Post-doctoral researcher in that same lab was also tested positive on 5/24/21 with CT values N1 ND; N2 39. This individual was also fully vaccinated, asymptomatic and had no known exposure. Both deemed to be the result of probable amplicon or plasmid contamination.
The undergraduate researcher mentioned above was tested positive again on 6/10/21. CT values this time were N1 ND; N2 3; and RP 29. He was again asymptomatic with no known exposure. All these researchers' follow-up PCR tests were negative. Additional assays were negative too.

Another Post-doctoral researcher in the NEIDL was tested positive on 5/20/21, although he was fully vaccinated, asymptomatic, and had no known exposure. CT values were N1 ND, N2 39, RP 26. This research does not work with SARS-CoV-2. This was deemed to be amplicon or plasmid contamination. Additional assays were negative.

2. 6-11-21: Contractor with unknown needle puncture to finger

A contracted worker for a biohazard waste removal company reported that he sustained a needle stick while trying to empty a biohazard container. He was provided counseling by the ROHP and advised to follow up with a local emergency room for evaluation and management of an unknown needle stick injury. ROHP did request a list of potential hazards around the location of the biohazard container. There was no way to know exactly which room the container originated from or how long the sharp was in the container. ROHP followed up with the contractor by phone on 6/14/21. The contractor is in a medical surveillance program and will follow up with his employer.

EHS Report:

Further follow up on this sharp injury incident by the EHS revealed that when this contract worker found that there were more sharp containers to be picked up than he thought he would need to, he tried to empty out sharps from one container to another half-empty container. He sustained the injury while trying to recap this re-packed sharp container. The root cause of this incident was not being conscientious and not following the guidelines. This individual has since then taken the BioRAFT sharp handling training again and confirmed that moving forward he will strictly follow the guidelines.

Biologic Reports were sent to BPHC.

III. Protocol Review

1. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2342		Identification of inhibitors of high containment virus infection	4	N/A	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Nadya Yun

Applicable NIH Guidelines: Section III-D-1-c

Meeting Comments: This protocol evaluates efficacy of small molecules in blocking infection of high consequence pathogens in high throughput screening system in BSL4 containment. If the small molecule blocks an infection, it becomes a candidate for therapeutic development. In this amendment, they want to characterize escape mutants from such drug screening test and further characterize those mutants to get a better understanding of the mechanism of interaction of the drug with viral components. Since the PI checked 'yes' to two Dual Use Research of Concern (DURC) questions in the IBC application, the protocol was reviewed in a separate DURC subcommittee meeting. The subcommittee determined that the protocol did not meet DURC because:

- The compounds being tested are not used clinically or agriculturally for treatment of the viruses;
- Escape mutants have lower natural fitness, and so there is no reasonable expectation that mutations will enhance the transmissibility of the virus;
- The viruses included in the protocol already have a broad host range, so a change in host range is not anticipated

No other concerns was noted.

PI recused himself from the voting.

Motion: Approve	For: 13	Recuse: 1	Against: 0	Abstain: 0	Absent: 0

2. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2286		Biomolecule Production Core - Propagating BSL4 pathogens	4	N/A	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Nadya Yun

Applicable NIH Guidelines: Section III-D-1-a, III-D-1-b, III-D-1-c

Meeting Comments: This protocol serves as a production core for RG4 and other high consequence agents and is responsible for safe and secure storage of viruses, preparing virus stocks and providing samples to other PI with approved research plan. In this amendment, PI is requesting to receive one of the agents that is already included in the protocol, from Texas Biomedical Research Institute (TBRI). The BSL4 BSO clarified that PI has followed all necessary protocols to receive the material from TBRI. Research experience of few lab members and lab sharing information were also updated in this amendment.

Motion: Approve	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

3. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1548		The VETSA Longitudinal Twin Study of Cognition and Aging (VETSA 4)	2	N/A	CRC

Primary Reviewer: Pinghua Liu	Secondary Reviewer: Tom Winters

Applicable NIH Guidelines: N/A

Meeting Comments: This project investigates how aging influences cognitive functions, such as memory, thinking processes, and intelligence. The protocol involves neuropsychological testing, interviews, measurement of standard vitals, vision testing, audiograms and simple motor tasks. From a laboratory sampling aspect, standard blood chemistries will be drawn from participants using an outside vendor, Examination Management Services, Inc (EMSI). EMSI will be responsible for sharps disposal, as well as securing and disposing of all biohazardous wastes. Blood samples will be centrifuged in the lab but all samples will remain in original containers that they are drawn in, and there will be no transferring of blood samples between different containers. Centrifuged samples will be stored in refrigerator for Fed-Ex pickup. Samples will always be shipped in accordance with DOT/IATA shipping regulations. PI acknowledged that although contact and handling time of the participant blood samples is minimal, lab personnel will adhere to engineering and PPE controls noted in the project guidelines and strictly follow OSHA blood borne pathogen guidelines for handing blood samples with unknown infectious disease status (such as HIV, Hepatitis B, Hepatitis C). Since an outside vendor is performing blood sample draws, there is little to no risk of needlestick injuries. There will be no apparent liquid or solid waste. All contaminated materials will be placed in biohazard bag and EMSI will secure and dispose of any biohazard waste generated during their procedure. No viable infectious agents will be stored within the laboratory. Any spill will be disinfected with 10% fresh bleach.

- Please complete/update the following trainings in BioRAFT as they are delinquent at this time:
  - : LST, BSL1/2, BBP, Chem Safety
  - : BSL1/2, BBP, rDNA/IBC Policy training
  - : BSL1/2, BBP, Shipping training

BUA Site Assessment: All required safety protocols are in place. EHS are working on updating the ROHP clearance of those that are expired.

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

4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2026		Osteocytes and the effects of PTH and Gs alpha	2	1	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Rao Varada

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

Meeting Comments: This protocol investigates the role of parathyroid hormone (PTH) and mechanical forces in bone homeostasis. They use osteocyte cell lines for their studies in which they manipulate PTH signaling by selective modulation of signaling molecules by lentiviral vector-mediated expression of specific siRNAs. They prepare the virus particles in house using third generation packaging system. They also use CRISPR/Cas9 technology to delete the PTH receptor genes. They clarified that the vector for their CRISPR/Cas9 work express both the guide RNA and Cas

nuclease in single plasmid and they do not expect any off-target effect. They also isolate osteoclast and osteoblast from human tissue obtained through approved IRB protocol and use them in their studies. They also perform some of their studies on transgenic mice that have altered PTH signaling and use X-ray to visualize bone modifications during their experiments.

- Section III-Personnel- ROHP clearances of few members are not current. Please update.
- Section VIII.5. BSC certification date- please update
- Section VIII - 4 PPE for animal containment - shoe covers are a requirement.
- Section G- states the use of Faxitron and Irradiator. These procedures should be included in the VII section (research project description).
- rDNA table: Does the entry (host-vector-donor information) under 'Animal Experiments" refer to transgenic mice already generated in the lab? Please clarify.
- IACUC protocol PROTO 201800333 (AN-15515) is approved through 10.2.2021. Please update the information.

BUA Site Assessment: The ROHP clearance for some members need update and is currently being followed up. Safety goggles need to be added as a required PPE for handling some of the chemicals used in the work.

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

5. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1632		Structural Biology of the Type IVb Protein Secretion System of Legionella pneumophila	2	N/A	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Bob Timmerman

Applicable NIH Guidelines: N/A

Meeting Comments: This protocol investigates the role of two specific proteins of the Legionella bacteria that cause respiratory illness. These proteins contribute to the disease by allowing the bacteria to survive inside the cells. The proteins are isolated directly from Legionella bacteria or put into expression plasmids and expressed in *E. coli* or insect cells. The main biosafety risk is aerosolization of the Legionella bacteria. The protocol is well written. The PI is well aware of these risk and describes well the approaches to mitigate the risks. They will grow 100 to 1000 mL of Legionella bacteria at a time. To prevent aerosol generation bacteria cultures will be done in plastic, non-breakable tissue culture flasks with caps. Centrifugation will be done in O-ring sealed lidded rotor. As a good provision when bacteria are lyzed to obtain the protein being studied, aerosols will be avoided by not using aerosol producing equipment like a sonicator. 10% bleach is used as disinfectant.

- Please indicate if caps for the culture flasks make an airtight seal or a filter style caps.
- Protocol indicates use of biosafety cabinet. Considering the volume being used, it is advisable to load and unload the rotor in a BSC or to have the rotor sit for 30 minutes before opening to reduce the risk of aerosol release. Please add comment in the procedure description.
- It is stated the 10% fresh bleach will be used as disinfectant. Please indicate contact time.

BUA Site Assessment: Containment and procedures described in the protocol are all appropriate. There are no pending issues with the lab. ROHP clearance for members are current.

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

6. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2236		Assessing Food Intake with the Automatic Ingestion Monitor	2	N/A	CRC

Primary Reviewer: Pinghua Liu	Secondary Reviewer: Valeda Britton

Applicable NIH Guidelines: N/A
Meeting Comments: The protocol tests the accuracy of a camera sensor attached to eye glasses for taking pictures of food being eaten by the wearer. The pictures will be used to estimate calorie intake and use the data in diet management. In contrast to traditional methods of assessing diet, this apparatus may eliminate the need for participants reporting. The protocol involves analysis of blood metabolites and urine analysis. The committee discussed whether urine should be handled in a BSL2 containment and whether the application should be considered as a BSL1 protocol. The EHS and the Medical Director indicated that according to OSHA, urine is not considered as a biohazardous material unless it is visibly contaminated with blood. However, Research Safety Director pointed out that Boston University has traditionally considered urine or any other human body fluid as 'Other Potentially Infectious Material' as they may still contain infectious bacteria or viruses. Senior Compliance Specially clarified that if any PI has previously responded 'Yes' to the question of whether clinical samples are being received from BMC clinic and specified the name of the Clinician Specialist's that they contacted, that name will always show up in the application. ● Please complete the Chemical Safety and rDNA/IBC policy training for the PI. ● Please clarify when double-labeled water is being used, do you need to dilute using regular water to certain concentration or it will be used as the pure form? BUA: The research work part of this protocol is on hold for now due to the COVID-19 pandemic. PI and a few other members need to update on their ROHP clearance and they already are working on it. PI also needs to update chemical safety training. The rDNA or shipping training is not required for this group.

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

7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1554		NIH R01 DK121998, Growth Hormone Regulation of Sex Differences in Liver Metabolism NIH R01 ES024421, Xenobiotic-responsive hepatic long non-coding RNAs	2	2	CRC

Primary Reviewer: Xin Brown	Secondary Reviewer: Colleen Thurman

Applicable NIH Guidelines: Section III-D-1-a, Section III-D-2-a, Section III-E-1; App G-II-B, B-II-A, B-II-D.
Meeting Comments: The overall purpose of this protocol is to better understand how liver metabolizes a wide variety of chemicals including drugs. The expression and function of liver enzymes, mainly cytochrome p450, will be studied in human and rodent cells and in tumors. The expression of genes will be altered in the cell lines and in tumors using viral vectors, plasmids and CRISPR/Cas9 technology. Viral vectors used include replication defective retrovirus, adenovirus, adeno-associated virus and lentivirus. The protocol provides detailed information on these viral vectors and on procedures that are being used, to ensure appropriate safety of the researchers. ● BSL1&2 and BBP training for Dr. and Dr. and ROHP clearance for and need to be updated. ● In the description of lab procedures, sometimes the solid waste is autoclaved first then disposed of, sometimes it is not autoclaved. For example for cultured cells in section VII.3 it is stated that "Sterile disposable pipettes and related cell culture items, such as used plates, that are used for cell seeding or suspensions are autoclaved with biohazards waste after being transferred either to red biohazard waste bags or appropriate sharps containers depending on waste type." Whereas for Retrovirus in section VII.3 it is stated "All syringes, needles and tissue culture materials, as well as all tissues and bedding derived from animals used in studies with replication-defective Adenovirus, will be transferred to red biohazard bags and containers and discarded." Please clarify under what circumstances the waste is autoclaved and the reasoning behind that. ● Biosafety cabinet certification needs to be updated. The current certificate date is 07/25/2018.

- Under liquid waste disposal, it was stated “liquid media is bleached prior to disposal”. Bleach final concentration and reaction time should be specified.
- Under solid waste disposal, it was stated “Biological waste is placed in a red bag and boxed”. It should be double bagged and boxed.
- Please update IACUC approval date for protocol PROTO201800698 (currently stated as 03/06/2019).

BUA Site Assessment: The lab has all the safety measures in place. Safety trainings are all current. Their biosafety cabinets are certified.

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

8. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1630		HIV transmission pathogenesis	2+	N/A	BUMC

Primary Reviewer: Rob Davey	Secondary Reviewer: Jim Keeney

Applicable NIH Guidelines: Section III-D-1-b, Section III-D-2-a, Section III-D-3-b, Section III-E-1; Appendix B-III-D, Appendix G-II-C

Meeting Comments: Goal of this protocol is to identify virus properties that confer transmission potential for HIV-1 and SARS-CoV-2. They will also characterize the role of immune factors, such as antibodies, that can prevent virus acquisition during potential exposure. Virus genes from clinical samples containing virus variants are isolated by PCR and then replaced into replication competent HIV vectors obtained from NIH HIV repository or are put into expression plasmids. Virus pseudotypes will be made using lentivirus or murine retrovirus based plasmid vectors (pLNCX, pLXSH) and the expression plasmids. For SARS-CoV-2 only expression plasmids are used. These are replication-defective and can only infect cells for one round. PBMCs isolated from human blood as well as common human stable cell lines will be used to perform virus replication and growth assays and for making pseudotyped viruses. The work will be done in BSL2 space in biosafety cabinets using BSL3 practices, which will involve Tyvek lab coats, goggles or face shield and face mask. They will use 1% wescodyne as disinfectant with 1 h contact time as well as 10% bleach. Cells used in cores are fixed which renders them non-infectious. Monoclonal antibodies or patient serum sample will be used for neutralization studies. Two of the DURC questions were checked in the application because the pseudotyped viruses that they are making, have a different host range compared to the original virus (HIV). However, this is a normal practice and the pseudotypes are replication-deficient and is thus not a DURC concern. Committee discussed whether the use of the phrase “using BSL3 practices” is appropriate and whether separate BSL3 training is necessary for members of this protocol. EHS clarified that “BSL2 with BSL3 practices” marked as the highest BSL for this protocol refers to the fact that the procedures will be done in BSL2 containment but additional PPE, as PI already mentioned, will be used during their work. However, the BioRAFT BSL3 training module provides in-depth information about BSL3 containment facility and work practices in that containment. Such elaborate training is not required for members of the protocols marked as BSL2 with BSL3 practices. It was noted that all such laboratories have specific SOPs posted in the laboratories. EHS further clarified that they review these SOPs at regular interval and updates them as needed. In response to a question about appropriate concentration of Wescodyne for disinfection, it was suggested that a 2% solution would be better than 1% solution. It was also discussed that the protocol does not involve any work in BMC clinical space and clinical samples they receive are all de-identifiable and are classified as Non-Human Subject Research.

- It is stated that “NL4-3 and Q23-17 backbones are capable of only a single round of replication” - but these are replication competent virus clones. Please clarify if you are using both replication competent clone as well as backbone constructs that lack certain portions of the original full-length clone.
- Committee suggested use of 2% Wescodyne in place of 1% for liquid disinfection. Please provide supporting evidence that 1% wescodyne is an approved concentration for HIV disinfection.
- Please indicate contact time for surface disinfection with bleach or Wescodyne.
- Please confirm that Wescodyne and bleach are not mixed together at any time for the purpose of disinfection.

- Biosafety level for human cell lines themselves are just BSL2. Please update.
- BSC certification is out of date (10/05/2019). Please update.

BUA Site Assessment: The lab has appropriate exposure control plan and other safety measures. Medical clearance for few members are being updated. Safety training is current of all members. Biosafety cabinet and fume hood are duly certified.

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

9. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2331		Transfer of materials for storage at BUMC	2	N/A	BUMC

Primary Reviewer: Inna Afasizheva	Secondary Reviewers: Jim Keeney

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

Meeting Comments: This protocol was submitted to seek permission for transfer of biohazardous and recombinant materials when PI moved to BU. This three-year renewal does not have any major changes other than some personnel turnover and addition of research facility information. PI now has several other approved IBC protocols that cover in detail his diverse research activities. No concerns were noted in maintaining this protocol as the authorization for storage of all his biohazardous materials.

BUA Site Assessment: Lab has all the safety plans in place. All training and ROHP clearances are current. All biosafety cabinets are duly certified.

Motion: Approve	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

10. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2303		Modulating Disease Microenvironments with Targeted Chemical Strategies	2	2	CRC

Primary Reviewer: Ed Loechler	Secondary Reviewer: Colleen Thurman

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-4-a

Meeting Comments: This new protocol proposes to investigate efficacy of chemical compounds as therapeutics against human diseases such as cancer and diabetes. The laboratory is developing novel chemical tools and drug delivery approaches based on advanced knowledge on interactions of macromolecules within the cell. A wide variety of human and murine cell lines are employed in which the cellular effects of their agents and formulations are evaluated by multiple approaches (for example, western blots, reporter assays, FACS, and immunofluorescence). These cell lines are representative of human, mouse and rat cells from distinct tissues. Both cultured cell lines, as well as primary cells in certain cases will be used. A mouse melanoma cell line will be used to create subcutaneous tumors in C57BL/6 mice to test anti-cancer formulations. Protocols will be performed using BSL2 procedures with appropriate PPE (gloves, coat, booties, face mask, sleeve covers, hair net, googles). Recombinant proteins will be expressed and purified from bacterial, human and insect cells and will be used in binding studies with agents synthesized in the lab. All cultured cell lines are handled in biosafety cabinets, using best practices and stored in incubators. Cell lines not in use are kept in cryostorage. A 10% bleach will be used for decontamination, though it is not mentioned that it should be freshly prepared. Committee was concerned that the application did not provide information on number of items mentioned in the protocol that made risk assessment difficult. It was not clear whether the agents are being synthesized in the lab or somewhere else. Reviewers and committee also noted that the phrase ‘therapeutic formulation’ needed clearification. The protocol further mentions that rDNA material will not be put into cells in culture yet many the cell lines have been marked as hosts in the recombinant DNA section. Committee could not evaluate whether the rDNA work and animal cell culture work was already being done in the lab before IBC approval. It was noted however, that PI mentioned that IACUC approval for their work is in place. Members noted that the PI may have misunderstood the regulatory requirements for the proposed work. Committee requested that this protocol be deferred until the next meeting following the PI’s response to the below information:

- Clarify if any work with rDNA and human cell lines are being done at present. If so, clarify why IBC application has not submitted earlier.
- Update rDNA/IBC policy training for , and .
- Clarify that the therapeutic formulation refers to the chemical compound library made by PI's lab.
- Clarify if any work with human primary materials are being done.
- Please reference your IACUC approval information in the laboratory procedure section (PROTO201800594 10/21/2019).
- Strain names for cell lines are not required. Please remove these words.
- It appears that only E. coli, Sf9, HiF and HEK cells will be used for transformation/transfection work. But A549, B16-F10, HEK-Blue, HeLa, HepG2, INS-1, KB, MCF7, MIN-6, NIH-3T3, Ramos, RAW264.7, TF-1, THP-1 cells will not be used for any rDNA work (example: transfection). If so, please remove these second set of cells from the rDNA eukaryotic experiments section.

BUA Site Assessment: The Lab needs to have exposure control plan and they are working on it. Several members need ROHP clearance. Safety training for some members are delinquent, which have been informed about. Their biosafety cabinet is certified right now but will expire soon. It was noted that recertification is scheduled for next week.

Motion: Deferred	For: 10	Recuse: 0	Against: 4	Abstain: 0	Absent: 0

11. rDNA/Bhz – New Application

BUA	(PI)	Title	BSL	ABSL	Campus
2517		1) Novel Three-Dimensional Cancer-Bone Metastasis Model Systems. 2) Pathophysiological and molecular biological studies on periodontal diseases using Mammalian cell cultures	2	1	BUMC

Primary Reviewer: Barbara Slack	Secondary Reviewer: Rao Varada

Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a

Meeting Comments: This new protocol investigates molecular mechanisms of bone metastasis using a three-dimensional model that uses free-floating live neonatal mouse calvarial bone in the presence or absence of cancer cell lines in a roller-tube model system. They investigate the effect of specific culture conditions that mimic bone resorption or bone formation as well as chemotherapeutic agents and perform various biochemical and histological analysis. They also are cloning CXCL promoter DNA for site-directed mutagenesis followed by functional analysis. Their IACUC approval for their animal work is valid until November 2021.

- Lab safety and BSL1/2 training need to be updated for , and . ROHP clearance needed for all members of the protocol.
- To better assess the biosafety risk please provide more procedural description on how the neonatal pup calvaria bone is harvested.
- The lab procedures section states that " RAW cells were treated with 1µg pcDNA3 as control and/or 1 µg hTNFAIP1* plus inhibitor..." Are RAW being transfected with TNFAIP1 cDNA? If so, what transfection method will be used?
- In section A (Hazardous Agents)- *P. endodontalis* and *P. gingivalis* are listed. It is not clear how they will be used and handled and disposed of;
- The protocol mentions use of LPS (purified?) from *E. coli* and *P. gingivalis*. Please clarify if LPS is being purified from these bacteria in the lab or are being purchased commercially, and briefly describe handling and disposal of these organisms if relevant to the protocol.
- Section H. rDNA. Please update table to indicate that cDNAs encoding the CXCL1 promoter, and TNFAIP1 will be cloned and propagated. Remove cDNAs that are not applicable to this protocol.

• THP-1 (human monocyte) cells are listed in the rDNA table under host strains - they should also be listed in Section A. BUA site assessment: Biosafety cabinet is duly certified. It was noted that a few lab members need updates on their safety training. All are working on updating their medical clearance.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

12. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2099		BME Core Facility	2	N/A	CRC

Primary Reviewer: Inna Afasizheva	Secondary Reviewer: Ron Morales
Applicable NIH Guidelines: Section III-D-2-a	
Meeting Comments: The Biomedical Engineering (BME) core facility houses a number of instruments for research work. The core also include a shared mammalian tissue culture space. All PIs using the core facility must obtain their own IBC protocols and list the core facility as shared research space. All researchers working in the facility must wear appropriate PPEs, follow safety guidelines and instructions from the facility manager. In this amendment PI is adding another faculty as a Co-PI to the protocol. The new co-PI will use the facility space for two teaching lab courses. No concerns were noted with the additions.	

Motion: Approve	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 0

13. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2092		Analysis of small RNA processing during vertebrate embryogenesis	2	1	BUMC

Primary Reviewer: Carmela Abraham	Secondary Reviewer: Ron Morales
Applicable NIH Guidelines: Section III-D-1-a; III-D-2-a, Section III-E-1	
Meeting Comments: This proposal aims to understand the molecular machinery that controls RNA processing and decay during vertebrate development and also during viral infections. Research is done in zebra fish embryos and in human and mouse cell lines. The purpose of this amendment is to add the use of replication-defective adenovirus as a vector to overexpress GYS1 and GFP in mammalian cells. The research description and the recombinant DNA sections provide detail of how the effect of overexpression will be monitored. In addition, inactivated SARS-CoV-2 samples (infected cell extracts in Trizol) will be obtained from a collaborator in Texas Biomedical Research Institute. It was a nicely written protocol. Committee was informed that because inactivated biological samples can be safely handled in BSL1 containment, no special training for receiving samples is necessary. • The certification date of the biosafety cabinet has expired (02/26/19). Please provide recent recertification date. • Please remove mouse cell line C2C12 from the hazardous biological agent list as mouse lines are considered as hazardous agents. • Please provide the inactivation certificate of the samples for review prior to receipt of samples from the source. • The lab is reminded to continue to follow safety precautions for handling of inactivated COVID samples. This also include continued wearing of masks along with the normal PPE and lab cleaning.	

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