



**Boston University**  
**Institutional Biosafety Committee (IBC)**  
**September 20, 2022 Meeting Minutes**  
**Location: Zoom and/or by phone**  
**Start time: 12:05 PM End time: 2:50 PM**

**Members Present:** R. Ingalls, B. Slack, I. Afasizheva, P. Liu, W. Lu, V. Gouon-Evans, E. Loechler (arrived 12:54 PM), R. Morales (left 2:34 PM), C. Thurman, S. Niemi, J. Keeney, R. Timmerman, V. Britton, J. Barton, S. Ghosh

**Guests Present:** S. Muchohi, R. Corley, P. Richmond, K. Tuohey, N. Dey, M. Fitzgerald, T. Killeen, LT Watson, C. Bennett, D. Siwik, V. Carlo-Carson, T. Cafarella, K. Slater, K. Crucioli

**Staff Present:** L. Campbell, C. McGoff

**I. Introduction to the Public Meeting**

The Chair of the IBC welcomed attendees; members and guests, were introduced.

**II. Review of August 16, 2022 IBC Meeting Minutes**

No concerns were voiced.

Motion: Approve

For: 14; Against: 0; Abstain: 0; Absent: 1

**III. Presentation:**

**A. Biological research at BSL-3/ABSL-3 (Select and Non-Select Agent) and BSL-4/ABSL-4 laboratories**

Dr. Ron Corley, Director of the NEIDL, provided guests with background on the NEIDL's mission, laboratory space statistics, training in the BSL3 and BSL4 programs, funding, as well as current and future NEIDL research projects. It was also announced that the NEIDL will have a new Director in December 2022.

**B. Environmental Health and Safety (EHS) Annual Report**

EHS Program Manager and Biosafety Officer, N. Dey provided the EHS annual report. Information included: the total number and type of laboratory safety inspections on both BU campuses, deficiencies and deficiency rate per inspection on both campuses, lab safety training data, and the total number of Biological Use Authorizations (BUAs) performed for new and existing laboratories on both campuses.

**IV. New Business:**

**A. Review of Research Occupational Health Program (ROHP) & Environmental Health and Safety (EHS)**

Incident Report

There were no incidents to report to the committee.

**V. Protocol Review**

**1. Bhz – New Application**

BUA	(PI)	Title	BSL	ABSL	Campus
2569		Soft robotic device for cardiac surgery	2	NA	CRC
Primary Reviewer: Inna Afasizheva			Secondary Reviewer: Ron Morales		
Applicable NIH Guidelines: N/A					
This protocol was WITHDRAWN from the review and discussion because the committee felt that the only biological materials to be used in the protocol was porcine lung, which is not considered as a biohazardous material.					

**2. rDNA/Bhz – New Application**

BUA	(PI)	Title	BSL	ABSL	Campus
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1709		Project 1: Rapid prototyping and fabrication of thermoplastic-based Microfluidics chips and Electronics systems to enable biosensor assays. Project 2: Rationality designing and building genetic systems to act as optimal, characterized cell-free or bacterial cell-based biosensors	2	N/A	CRC
Primary Reviewer: Rob Davey			Secondary Reviewer: Jim Keeney		
Applicable NIH Guidelines: Section III-F Experiments Exempt From NIH Guidelines					
<p>Meeting Comments: The work is described as two projects. The first is fabrication of a microfluidic device which has no biological or recombinant components. The second project is to incorporate recombinant proteins produced from E. coli, which is of relevance to the committee. The recombinant work involves using molecular biology techniques to join a fluorescent protein from Aequorea Victoria (jellyfish) to a photo-reactive colored protein from Synechocystis, that can sense environmental changes within the device. PCR followed by conventional cloning techniques will be used to assemble the constructs and express them. These will be analyzed in a flow cytometer where it is assumed the bacteria will be sorted. In this submission they are updating personnel, lab space, and some procedures. Personnel additions are three graduate students that will be trained by the PI. Lab space changes involve replacement of room on the 4<sup>th</sup> floor with that on the 6<sup>th</sup> floor of the building which will contain the work to one floor of the building so that stairs or elevators will no longer be needed to go between lab spaces. Materials are treated with fresh 10% bleach at end of work destroying the bacteria. Main risks are exposure of personnel to the recombinant bacteria. Since this is E.coli and is expressing a fluorescent protein, which is known to be benign, it is likely to be of low health risk and is appropriately performed in a BSL1 lab. The PI has indicated that synthetically derived DNA will be used. This appears to be a misinterpretation of what was meant by synthetic DNA. The work involves recombinant DNA work only. Overall, the work is of low hazard and should pose minimal risk to personnel. The following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• Please uncheck the Synthetically derived nucleic acid molecules box in Section IX since the protocol does not indicate ordering synthetic DNA for cloning purposes.</li></ul> <p>BUA Site Assessment: No significant issues were noted.</p>					
Motion: Conditional Approval (Administrative Review)		For: 14	Recuse: 0	Against: 0	Abstain: 0
		Absent: 1			

### 3. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2397		Host and viral determinants regulating Flaviviridae pathogenesis and immunogenicity	2	2	BUMC
Primary Reviewer: Barbara Slack			Secondary Reviewer: Colleen Thurman		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-D-3-a, III-E-1; Appendix-B-II-D, Appendix G-II-B					
Meeting Comments: This protocol investigates infectious cycle of several RG2 viruses including Zika, Dengue, vaccine strain of yellow fever virus, west Nile virus (WNV) and seasonal coronaviruses. They have described quite well the general lab practices and all additional safety measures for working with these viruses including double gloves. They clarified that they will alert pregnant or expected to be pregnant lab members the hazards of handling Zika or Dengue viruses and will ensure that those individuals not work with those agents. They will use human and mosquito cell lines. The viruses will be generated by transfecting recombinant DNA into cell lines and will check frequently the absence of any mutations from the original constructs. DNA RNA analysis by RT-PCR and protein analysis by western blotting and immunofluorescence will also be done. They also use replication incompetent adenovirus, AAV and lentivirus vectors for expressing cellular and viral proteins, fluorescent reporters and Cas 9 nuclease and guide RNA for CRISPR technology work. They will also use replicons for some of these viruses to study their genome replication. Live mosquito work will be done in insectary in the NEIDL. The protocol also includes multiple animal model studies with the viruses mentioned above. In some experiments animals will also be injected with recombinant viral vectors					

prior to infection with wild type of virus to understand the role a particular cellular or viral protein. Detail of the animal work in the NEIDL and all safety measures are described in great detail. It was noted that according to BMBL 6<sup>th</sup> edition, work with WNV may be done in BSL2 containment. The following will be communicated to the PI:

- Section I.1- please leave box for amendments blank
- Section III.3- ROHP date is missing (Zhu)
- Section VII.3- In Lab procedures section, please specify use of bleach at final concentration of 10% for decontamination of liquid waste. (Note- this is correctly specified in section VIII.7)
- Section VII. 3. C. 2. Mice Work 2.1 General laboratory practices and 2.3.1 Experimental injections into mice
- Recommend broadening housing statement to NEIDL ABSL2 vivarium housing since all suites in floor vivarium may be used ( ).
- 3. C. 2.3.6 Blood and tissue collection (recommend broadening language to allow for multiple methods of blood collection to be discussed in the IACUC protocol as long as hazards are covered (e.g. sharps handling and disposal). Recommend broader wording “pentobarbital euthanasia solution” since Fatal Plus is Schedule II while other formulations are Schedule III, and you may wish to purchase and track an alternative product (e.g. Beuthanasia, Euthanasia III, Euthasol).
- Section VIII.5. BSC certification needs updating.
- Section A.- Several rodent and mosquito cell lines are listed as NHP. Only Vero cells should be listed here. These non-primate, non-human lines (all BSL1) do not need to be included in the table at all.
- Section A. Two IACUC numbers are provided for AAV and Yellow Fever injections in mice. Approvals for some other viruses are listed as pending. It is not clear if applications have been filed for AdV and lentivirus injections in mice. Please update.

BUA Site Assessment: EHS recommends use of protective glasses during cell sorting. No other concerns noted. ROHP clarified that they provide reproductive counseling to the lab members.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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#### 4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2396		B cell activating factor in non-infectious complications of common variable immunodeficiency	2	NA	BUMC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Ed Loechler		
Applicable NIH Guidelines: Section III-D-1-a, Section III-D-2-a, Section III-E-1					
<p>Meeting Comments: This protocol investigates the underlying molecular defects in Common variable immunodeficiency (CVID), which is the most common symptomatic primary immunodeficiency. This work will study the cytokine B cell activating factor (BAFF) and its relationship with the B cell maturation arrest that defines CVID in order to understand why these complications occur. Blood will be collected from CVID patients in the BMC clinic and cells and plasma will be separated out in PI's lab. PI will also save any biopsy samples that are collected from the patients for future studies if required. All human samples are collected through approved IRB protocols. Research work includes flow cytometry, cell culture, and enzyme-linked immunosorbent assays to measure the production of (BAFF) and identify the cells producing this cytokine. We will also perform RNA sequencing on naive B cells sorted from the stored PBMCs and stimulated with BAFF in cell culture. All work with human samples is done in a biosafety cabinet. The work also involves use of lentiviral vectors to establish iPS cells and CRISPR/Cas9 work to knockout specific genes of interest. The following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• Remove previous PI Comments.</li><li>• Biosafety Cabinet certification date needs update.</li><li>• Bleach concentration should be indicated as final concentration.</li></ul>					

- Please state the source of patients with CVID.
- Please describe briefly what research work will be done with the lung, lymph node, gastrointestinal, and spleen biopsies.

BUA Site Assessment: The biosafety cabinet is duly certified. Chemical safety training for two personnel is due. Lab indicated they are not working with lung biopsies or are storing them at this time. Some equipment needs biohazard sticker.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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#### 5. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2406		Probing physical tumor microenvironment	2	2	CRC
Primary Reviewer: Weining Lu			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-II-D, Appendix G-II-B					
<p>Meeting Comments: This study aims to characterize and model the physical abnormalities of the tumor microenvironment, such as elevated stiffness and mechanical stresses. The primary objectives of this project are to develop techniques to measure the mechanical stresses in vivo and longitudinally and to develop model systems where they can mimic modulation of mechanical stresses in tumors and their surrounding normal tissue. The project will implant/embed biocompatible fluorescent hydrogels as sensors in breast and colorectal cancers in vitro model, live animal work and ex-vivo work on mouse and human lung slices. Therapeutic interventions on those model studies will also be done. Additionally, acute lung injury and acute respiratory distress syndrome will be induced in mouse models and tumor samples will be collected for future histological analysis. They will also collect tissue for protein and RNA analysis by western blot and qPCR. The team will also use lentiviral transduction to conjugate fluorophores to the cancer cells of interest and plan to use lentiviral shRNA transduction to knock down genes of interest. The following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• Please add title of all personnel listed in the personnel list.</li><li>• Please clarify if _____ will work on BU CRC or at MGH. His ROHP status is inactive.</li><li>• Add room _____, _____ and the room where biohazardous materials are stored, to the protocol.</li><li>• Address the additional questions at the bottom of the “DUAL USE RESEARCH OF CONCERN,” section.</li><li>• In Section VII, “RESEARCH PROJECT DESCRIPTION,” the PI indicated: “All liquid waste must be disinfected with freshly prepared 10% bleach for at least 20 minutes before flushing down the drain”. But in Section VIII.7A, “PERSONAL PROTECTIVE EQUIPMENT AND SAFETY EQUIPMENT” #7A Liquid Wastes, the PI changed the time to 30 minutes before disposal down the sink after the liquid waste was disinfected with 10% bleach. Please be consistent.</li><li>• Note that : Procedure 5 ends with the statement, “LPS is not excreted in animal shedding”, which is inaccurate. These are mice with conventional gut microflora, including many gram-negative bacteria naturally containing LPS that is released when those bacteria are degraded and excreted. IBC recommends revision of this statement.</li><li>• Check pipetting infectious liquid.</li><li>• Move Lipopolysaccharide (LPS) from the Hazardous Biological Agent list (Section A) to High Hazard Chemical (HHC) list (Section F) and discuss the preparation of stock solution and safe handling aspect.</li><li>• Please include a brief statement for the purpose of use of the three HHC in the protocol.</li><li>• As stated in the lab procedure section, lentiviral transduction will be used to conjugate a fluorophore to the cancer cells of interest and will also use lentiviral shRNA transduction to knock down genes of interest. Provide a brief statement of the lentivirus work (source, replication competency, which generation vector,</li></ul>					

PPE use and safe handling, why 2<sup>nd</sup> generation vector is used). We recommend use of 3<sup>rd</sup> generation vector. second-generation lentiviral packaging plasmid as indicated in Section H (Recombinant DNA).

- If no lentiviral work is being done for the protocol, consider removing that section or clarify
- IBC recommends that PI should get an IRB exempt status

BUA Site Assessment: One member of the PI's group work in the lab to grow the *S. pneumoniae* and bring to the PI's lab following approved transport protocol. Rooms and needs to be added. Some safety training needs update.

Motion: Conditional Approval (Primary and Secondary Reviewer review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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## 6. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2145		rDNA Protocols for Molecular Cloning in Pediatric Infectious Diseases; COVID-19 studies	2+	NA	BUMC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Bob Timmerman		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendix B-II-A					
<p>Meeting Comments: The protocol has two distinct aims with common thread of rDNA and rDNA-related work in both. In the first the goal is to make genetic mutation in three bacteria <i>Streptococcus pneumoniae</i>, <i>Haemophilus influenzae</i> and <i>Staphylococcus aureus</i> to identify targetable genes for Otitis Media infection. The mutated bacteria will then be used in a chinchilla model of otitis media in a separate IBC protocol. There are no major changes in the part of the protocol. The other project is part of the original validation of COVID-19 vaccine together with the GCRU of Boston University in collaboration with Pfizer. Blood and serum samples are collected from those clinical studies by the GCRU stuff and Immune response against is tested in order to define optimal vaccine dose. PI also developed a biorepository facility for known COVID patients which include left over nasopharyngeal swabs as well as blood and serum from patients that were involved in the COVID study. It was clarified by the BSO that the lab does not use any sharps and blood are collected by the GCRU stuff. Following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• Please summarize the layman’s description to broadly describe what type of work is being done in the protocol. No need to describe goals of separate IRB protocols individually.</li><li>• Two personnel that are also working in project need to be added to the protocol.</li><li>• Loc Truong must complete rDNA/IBC policy training.</li><li>• Site Assessment noted that room        also needs to be added to the protocol.</li><li>• A protective filter must be added to the vacuum line in the biosafety cabinet that is used for SARS-CoV-2 work.</li></ul> <p>BUA Site Assessment: Some rooms need to be added (#        ). Biosafety cabinet and fume hood are duly certified. Lab using N95 respirator while handling COVID-19 positive or suspected positive cases. Two more personnel need to be added to the protocol. One person needs to update rDNA training.</p>					
Motion: Conditional Approval (Administrative Review)			For: 14	Recuse: 0	Against: 0
			Abstain: 0	Absent: 1	

## 7. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2405		Epigenetic gene repression in Pulmonary fibrosis	2	1	BUMC
Primary Reviewer: Valerie Gouon-Evans			Secondary Reviewer: Colleen Thurman		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, Appendices B-II, G-II-B, I-I-B-1					
Meeting Comments: This protocol investigates the role of epigenetic modifications, which persistently alter the activation of genes, in the progression of lung fibrosis. Given that fibroblasts in the lungs are the main cells responsible for fibrosis development, they look at the epigenetic modifications that represses the transcription of					

genes essential to maintaining or returning lung fibroblasts to an anti-fibrotic or quiescent inactive state. They use gain and loss of function strategies to target the epigenetic regulators to investigate their mechanistic roles in switching fibroblasts between activated and quiescence states. The only biohazardous materials in the protocol is the use of primary human cells specifically patient-derived lung fibroblasts from ATCC or PromoCells. They transfect the primary human lung fibroblasts with recombinant DNA to over-express proteins that have been associated to fibroblast activation and fibrosis. Total protein from these transfected cells will be collected and used in several biochemical assays including Western Blotting and ELISA. Both human lung fibroblasts and recombinant DNA will be handled in a biological safety cabinet. They will also study lung fibrosis in mice model. In this bleomycin-induced mouse model of fibrosis, they will investigate the benefit of inhibiting histone methylation in halting fibrosis. IACUC approval is available for their work. Proper PPE are described (gloves, coats and safety glasses). The way they discard waste (liquid, material, solid) is well described and proper. All discarded materials are disposed in tape sealed bags and placed inside red biohazard waste boxes. Liquid bio-hazard wastes such as tissue culture fluid are treated with 10% bleach (freshly diluted) for 30 minutes or longer and then discarded in the sink. Solid biohazard wastes such as disposable culture dishes or flasks, pipettes, tips, etc. are discarded in the double bagged red biohazard waste boxes. When these boxes are about 75% full, both inner and outer bags are closed with adhesive tape off-site incineration by appropriate responsible BU authority (facilities and management). The following will be communicated to the PI:

- Please complete “State how many years experience, when and where” question for all members (just as is written for the PI. Addition of 4 students with no experience in handling rec DNA. They joined the lab and will be trained by other members of the lab.
- Bioraft training for rDNA/IBC Policy should be completed for \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_. Chem Safety training is due for \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_. \_\_\_\_\_.
- ROHP approval is missing for 3 students: \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_.
- Remove response from VIII. 10 and 11 for rDNA (they are not biohazardous) but replace them with information for human cell line.

BUA Site Assessment: Some members need update on training. Biosafety cabinet certification will expire soon. Spill kit must be in place. ROHP clarified that they can provide reproductive counselling.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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## 8. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2146		Reactivation of fetal hemoglobin as a treatment for sickle cell disease	2	NA	BUMC
Primary Reviewer: Sajal Ghosh			Secondary Reviewer: Inna Afasizheva		
Applicable NIH Guidelines: Section III-D-1-a, III-D-2-a, III-E-1; Appendix-B-II-D; Appendix G-II-B					
Meeting Comments: The goal of this protocol is to investigate the regulation of expression of fetal hemoglobin gene and hematopoiesis. with a long term goal to be able to induce expression of fetal hemoglobin in sickle cell anemia and thalassemia patients as a therapeutic approach. In this protocol, they treat either human umbilical cord blood-derived erythroid progenitor cell (HuDEP cell line) or primary hematopoietic progenitor cells with small molecules or protein growth factors, and analyze gene and protein expression, cell cycle progression, apoptosis, and phenotype. In some cases, these cell lines are transfected with genes responsible for fetal hemoglobin regulation through the use of lentiviral or adenoviral vectors. CD34+ hematopoietic progenitor cells will be purified from commercially purchased cord blood cells or from patients with sickle cell disease and beta-thalassemia and will be differentiated into erythroid cells. These cells will then be treated with small molecule compounds for specific time period and RNA and protein expression will be performed to determine fetal hemoglobin expression. Lentivirus and Adenovirus vectors will also be used for inducing expression of genes responsible for fetal hemoglobin gene expression. The objective and respective procedures and safety precautions used are well described. Cell transportation to core facilities are done in properly contained primary and secondary container. Culture wastes and unused virus preparations are					



treated with 10% bleach for 30 mins prior to sink disposal. Nicely written protocol. The following will be communicated to the PI:

- Update rDNA/IBC Policy Training for the PI and take fresh for .
- The protocol doesn't include animal work. Update descriptive role of by removing "animal experiments".
- If additional personnel are working in the protocol, please add them in the personnel list.
- EHS indicated that room is being used. Please add the room in section IV.
- Provide clear statement of how many years of experience and from where for both personnel.
- Update BSC certification date
- Also add 70% EtOH for surface decontamination.
- Update IRB protocol expiration date. Currently it says 9/28/2019.

BUA Site Assessment: Room needs to be added. One more person to be added. Both members need to update the rDNA/IBC policy training.

Motion: Conditional Approval (Administrative Review)	For: 15	Recuse: 0	Against: 0	Abstain: 0	Absent: 0
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## 9. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1663		1.Scleroderma-associated pulmonary arterial hypertension: The role of the oxidant state 2. Lymphatic Erg signaling in scleroderma fibrosis 3. The role of Fli1 in myeloid cells and its contribution to cardiac fibrosis	2	2	BUMC
Primary Reviewer: Barbara Slack			Secondary Reviewers: Steve Niemi		
Applicable NIH Guidelines: Sections III-D-1-a, III-D-2-a, III-E-1; Appendix G-II-B, B-II-D					
<p>Meeting Comments: The goal of this study is to study molecular mechanism of vasculopathy and fibrosis in Scleroderma and abnormal gene expression under these conditions. They use PBMCs from healthy donors or Scleroderma patients and analyze them by western blot and Q-PCR. They also work with fibroblasts from skin biopsies from healthy donors and Scleroderma patients as well as from foreskin cultures obtained from local hospitals. They also use adenovirus vectors to express various transcription factors to analyze their role in Scleroderma. They say they are not creating the virus in the lab but are packing them in the lab. The protocol indicates mice are irradiated, but it was not clear if this is a model for their study or is a treatment choice. The following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• Section I.2- please leave box for amendments blank</li><li>• Section III.1-Personnel- please provide training information for .</li><li>• Section III.2- some training dates need to be updated (no date for ?); ROHP clearance overdue for three members (listed as inactive).</li><li>• Section VII.3- please provide some details about the planned mouse experiments. (The protocol is designated as ABSL2, the lab procedures section mentions irradiation, but no further information is provided). Also, please confirm that packaging of adenoviral vectors in HEK293 cells will be done in the lab. (The protocol states that viruses are not 'created' in the lab though it does include a description of virus packaging; please clarify). If other transfection methods will also be implemented, please specify which reagents will be used.</li><li>• Section VIII.1- if mice will be used 'Animal Handling' should be checked.</li><li>• Section IX. If mice will be irradiated, 'Radiation and X-ray' should be checked.</li><li>• Section B. Please indicate the source of the patient skin and blood samples.</li><li>• Section H. Please provide IACUC approval number and date.</li></ul>					

- Based on the brief description of animal use (see Section IX.G. below), ABSL1 seems more appropriate than the selected ABSL2. Please clarify.
- Section IX.A.2.a. ("Does the Genus and species of biologic agent that you are proposing to conduct experiments with cause human disease?") - "No" is checked. Is this accurate? If so, then are BSL2 assignment and precautions required? If not accurate, please check "Yes".
- Section IX.G. provides the following brief description of planned animal experiments: "Mouse local irradiation of the head and neck region for analysis of radiation induced fibrosis. Protocol \_\_\_\_". Is irradiation used for induction, analysis, or both? Please clarify.

BUA Site Assessment: Room \_\_\_\_ is to be added. At least one person needs to take shipping training as they are shipping biological materials. PI's trainings are expired. Update of personnel list required. Lab indicates they are not doing Adenovirus work or are planning to. BSC is certified. Transportation container is not available.

Motion: Conditional Approval (Administrative Review)	For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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#### 10. Bhz – Three-Year Renewal

For: BSL2 Three Year Renewal					
BUA	(PI)	Title	BSL	ABSL	Campus
2411		Flexible robots for diagnosis and therapy in the peripheral lung	2	NA	CRC
Primary Reviewer: Pinghua Liu			Secondary Reviewer: Valeda Britton		
Applicable NIH Guidelines:					
<p>Meeting Comments: This protocol will test their surgical robotic system for cancer surgical procedures using porcine lung as the material. The key data they are measuring is the force required to puncture through the lung tissue. The porcine lung tissue will be obtained from local slaughter house through sealed and insulated container. For the measurement, they will mount a needle to a disposable chuck. After that, all of the measurements are done remotely through a computer controlled automated system. Therefore, the safety concerns have all been carefully integrated into the experimental design. In addition, waste and sharp disposal have been well-described. Overall, this is a straight forward proposal and I do not have concerns. Committee discussed that if company supplier of the porcine lung is certifying that the lung is free of any infection, and if the PI can provide that documentation to the IBC, then the protocol does not have a BSL2 component and IBC approval will not be required. However, if the lab still want to perform the work in BSL2 containment, the lab must follow all BSL requirement. The following will be communicated to the PI:</p> <ul style="list-style-type: none"><li>• PI should update her safety trainings.</li><li>• Where is the research taking place ? Is it Comm Ave Rm ? Looks like this is where refrigerator is stored. Where is dissection taking place?</li><li>• Please complete all the questions in the DURC section (Section VI).</li><li>• How is Inston device cleaned, with what and for how long?</li><li>• Committee discussed that if company supplier of the porcine lung is certifying that the lung is free of any infection, and if the PI can provide that documentation to the IBC, then the protocol does not have a BSL2 component and IBC approval will not be required. However, if the lab still want to perform the work in BSL2 containment, the lab must follow all BSL requirement. Please clarify and respond.</li></ul> <p>BUA Site Assessment: ROHP stated it was their understanding that the lab will receive lung from a company and the company has in house representative from USDA who certifies that the organ is free of infection. Bleach is not available, only 70% ethanol is used. It is anticipated that there will be no liquid waste and the instrument will have minimal contact with the porcine lung. If they really want a BSL2 status for their lab, EHS will need to visit the lab and review BSL2 set up.</p>					
Motion: Conditional Approval (Administrative Review)			For: 14	Recuse: 0	Against: 0
			Abstain: 0	Absent: 1	



**11. rDNA/Bhz – Amendment**

BUA	(PI)	Title	BSL	ABSL	Campus		
2571		Use of cell culture to teach basic cell/molecular biology techniques and explore the mechanisms of neurodegenerative disease in undergraduate classes.	2	NA	CRC		
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Sajal Ghosh				
Applicable NIH Guidelines: Section III-D-1-a and III-D-2-a.							
Meeting Comments: This protocol supports teaching and hands-on laboratory work for undergraduate program in Neuroscience. The original application include treatment of culture of established human cell lines with distinct chemical compounds and testing their effect on cell behavior by standard molecular biological protocols such as western blotting and/or by microscopic observation. This amendment is to add rDNA work to a recently approved IBC protocol that covers use of human cell lines in a lab course on the CRC. The PI proposed to use commercially available plasmids from Clontech to express tagged constructs and constructs with point mutations in the genes listed in the rDNA table in CHO-K1 fibroblasts, HEK293 cells, HeLa cells, and H4 glioma cell lines. Cells will be transfected using commercial lipid reagents Lipofectamine or Polyethyleneimine. Students in the course will not construct the recombinant cell lines, rather they will handle them in culture and conduct studies on protein expression. No concerns were noted with this amendment.							
Motion: Approve			For: 14	Recuse: 0	Against: 0	Abstain: 0	Absent: 1