



Boston University
Institutional Biosafety Committee (IBC)
June 14, 2022 Meeting Minutes
Location: Zoom and/or by phone
Start time: 12:03 PM End time: 2:20 PM

Members Present: R. Ingalls, B. Slack, E. Muhlberger, X. Brown, E. Loechler (Joined 1:23 PM), R. Morales, C. Thurman, S. Niemi (joined 12:23 PM), T. Winters, J. Keeney, R. Timmerman, V. Britton, J. Barton, S. Ghosh
Guests Present: P. Richmond, A. Ahmad, N. Dey, T. Killeen
Staff Present: S. Ghosh, L. Campbell, C. McGoff

I. Review of May 17, 2022 IBC Meeting Minutes

No concerns were voiced.

Motion: Approve

For: 12; Against: 0; Abstain: 0; Absent: 2

II. Member Training Session: Members were provided with a presentation by the Chair on the history of Monkeypox, its biology, treatments, and how to safely work with this virus. It was noted that ROHP has added a training module on Monkeypox.

III. New Business:

A. SQAP Report

Members were reminded of how to retrieve and save attachments when reviewing IBC protocols.

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

There were no incidents to report to the committee.

IV. Protocol Review

1. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
609		Structure and Function of Histone Chaperones -The Structural Basis of Protein Biogenesis -Structural Biology of Apoptosomes and Related Signaling Complexes -Structural Biology of the Type IVb Protein Secretion System of Legionella pneumophila	1	N/A	BUMC
Primary Reviewer: Barbara Slack			Secondary Reviewer: Jim Keeney		
Applicable NIH Guidelines: Section III D-2 Appendix: B-I Containment BL-1					
Meeting Comments: The goal of this protocol is to study the three-dimensional structure of multiple biological macromolecules involved in different physiological processes that involve their movement through membrane structures. The protocol essentially involve cloning of those proteins in plasmids or in baculovirus expression system followed by transformation or transduction in <i>E. coli</i> or in infect cells. Large amount of proteins will be expressed and purified using standard biochemical techniques. Purified proteins will then be subjected to electron microscopic examination for structure intricacy. This was a simple and straight-forward application without any major concerns. The following will be communicated to the PI: ● Section IV. Please add for the use of Electron Microscope. ● Section VIII.2 (engineering controls)- Please check BSC (for purposes of sterility when doing Sf9 culture work). HEPA filter is not checked. If medium will be removed from insect cell (Sf9) cultures using house vacuum aspiration, then a HEPA filter should be used on the vacuum line.					

- Section IX. Please check N/A under Highest Animal Biosafety Level at the bottom of the page (Section IX).

BUA Site Assessment: All training and ROHP clearances are current. Biosafety cabinet is duly certified. The room needs to be added for the use of electron microscope.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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2. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
714		Mechanistic underpinnings of increased adipose tissue in HFpEF	2	N/A	BUMC
Primary Reviewer: Tom Winters			Secondary Reviewer: Valeda Britton		
Applicable NIH Guidelines: N/A					
Meeting Comments: The goal of this protocol is to identify molecules in the blood that can be used as biological markers for cardiomyopathy which can later be used as diagnostics and for treatment and improve prognosis. They are using biologic markers and echocardiograms done yearly to predict morbidities/mortalities in cardiomyopathy patients. Blood is drawn by the PI in the Outpatient Clinic and are brought to the PI's lab where they are centrifuged to isolate plasma and serum which are then stored in the PI's -80°C freezer. Human serum and plasma are tested by ELISA kits for specific biological markers, which include matrix metalloproteinases and their tissue inhibitors as well as many other related suspected molecules. Solid and liquid wastes are handled properly. Disinfection is done with 10% bleach and 70% ethanol. Transport is provided in shatterproof containers from the hospital to , the PI's lab. Biohazard in the protocol is patients blood and biosafety risks are associated with the use of sharps used in blood drawing. Universal blood borne pathogen standard work practice is invoked. The lab is appropriately designated as a BSL-2 lab. Protocol indicates that tissue from biopsy of skeletal muscle and adipose tissue will be used but no reference is made as to how those will be obtained and how will they be used in the protocol. The IRB approval is current. The following will be communicated to the PI: - Protocol indicates that tissue from biopsy of skeletal muscle and adipose tissue will be used but no reference is made as to how those will be obtained and how will they be used in the protocol. - Please indicate the source of unfixed skeletal muscle and adipose tissue biopsy samples. - Please adopt the exposure control plan and upload it in your lab's BioRAFT profile. BUA Site Assessment: They need to adopt exposure control plan and upload it into the lab BioRAFT profile. Training for both personnel are current, as is the ROHP clearance. Biosafety cabinet certification needs update. The room is not used for this protocol. Tissue samples are stored in freezer.					
Motion: Conditional Approval (Administrative Review)			For: 13	Recuse: 0	Against: 0
			Abstain: 0	Absent: 1	

3. Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2388		1) H-37773: MOM NEST Study: Safety, Efficacy, Pharmacokinetics, and Pharmacogenetics of Naltrexone in Pregnant Women with Opioid Use Disorder 2) NIDA Clinical Trial Network Protocol 0080: MOM Protocol - Randomized Trial of Buprenorphine for Pregnant Women with Opioid Use Disorder. 3) COVID-19 Perinatal Project (H-40096 and H-40270)	2+	N/A	BUMC

Primary Reviewer: Xin Brown		Secondary Reviewer: Tom Winters				
Applicable NIH Guidelines: N/A						
Meeting Comments: This study has three distinct goals which include a) To compare the safety and efficacy of two different medicines (naltrexone and buprenorphine) for pregnant woman with opioid use disorder; b) To compare the efficacy of two different formulations, taken orally everyday versus injection on a weekly basis; and c) To study mother-to-infant transmission of COVID-19. Infant development will also be evaluated at 24 months post-delivery. They will also be looking at placental tissue from COVID-19 positive women and from COVID-19 negative controls with CD26 and ACE-2 levels to help understand maternal-infant transmission. For all these studies, mother and infant saliva, hair, blood and urine samples will be collected in addition to placenta, core blood and breast milk samples. Most samples will be sent directly to other labs for processing and analysis. For the first two studies, the only manipulations in the lab are to collect plasma from blood after centrifugation and to cut out small pieces of placenta samples in a biosafety cabinet. For the COVID study, all tissues will be frozen at -80°C for at least two weeks or soaked in formalin overnight then placed in a sucrose/PBS solution at 4°C for at least 2 weeks before any testing will be conducted; serum and plasma will be collected from blood samples through centrifugation and heat inactivated under 60°C for 1 hour. Sample handling and processing including centrifugation, heat inactivation and sample aliquot procedures will be performed in the BSC. Clinical samples with potential for infection with SARS-CoV-2 will be handled at BSL-2/with BSL-3 practices. The COVID study will include placenta sampling with appropriate double bagging in a hard container for transport. Other samples will be collected at the BMC Inpatient Units and transported in leakproof and shatter proof hard transport cases. Outside transport will use BUMC shipping protocols with container. The following will be communicated to the PI: • has no lab safety training or ROHC clearance. She must complete all the required trainings in BioRAFT and secure medical clearance from the ROHP. • The response to the question “Does this project continues to be a non-DURC project.” Answer should be “yes”. Please modify appropriately. • Please update BSC certification date. This date should be less than one year old. • The statement for the liquid waste states “The only anticipated liquid waste would be excess blood after centrifuging and removing the plasma. All biological / hazardous waste will be placed in the biohazard boxes lined with 2 biohazard bags. When the box is full, plastic bags are tied up and box is taped shut and removed by custodial staff.” This is not appropriate for liquid waste disposal. Please state clearly how vials or centrifuge tubes containing small volume of remaining blood cells (liquid waste) or other related liquid waste materials will be disposed of? • State how the security of specimen storage rooms and are maintained? • In the hazardous agent list SARS-CoV-2 is listed as attenuated. How is it attenuated? Or is this a typo? • Please add all IRB application numbers that are relevant to this IBC protocol and provide their current expiration dates. BUA Site Assessment: The Exposure Control Plan is in place. ROHP clearance for three members need update. Heat inactivation of COVID samples at 60°C for one hour appears effective. The lab has multiple methods of facial protection for the COVID work. Each are effective and approved. According to BioRAFT, five members have current shipping training. All supplies for shipping are available to the PI. Solid wastes are incinerated at offsite location. Biosafety cabinet certification expired and needs update. Disposal method for small volume liquid wastes could not be confirmed.						
Motion: Conditional Approval (Administrative Review)		For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1

4. rDNA/Bhz – Three Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
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662		The Role of E-cadherin N-glycans in Oral Cancer	2	2	BUMC
Primary Reviewer: Barbara Slack			Secondary Reviewers: Colleen Thurman		
Applicable NIH Guidelines: N/A					
Meeting Comments: This protocol investigates the relationship between Wnt/beta-catenin signaling and E-cadherin glycosylation state in the development of Oral Squamous Cell Carcinoma (OSCC). The model they use in their experiments include human OSCC cell line, mouse model of OSCC (either by adding a specific carcinogen in drinking water or by injecting human OSCC cell line). They will also investigate tumor formation in mice by orthotopic tongue injection of primary OSCC tumor tissues. They will investigate the molecular characteristics of these tumor cell under various experimental conditions (including the use of beta-catenin inhibitor) such as flow cytometry, RNA-seq or the ability to form spheres in culture. Use of retroviral vector (MMLV) is also indicated in the protocol but no specific use of the vector is mentioned. Protocol indicates that the animal work described in the protocol will be done in collaboration with another PI in BU who has appropriate IACUC approval. The committee noted that PI communicated to the IBC Program Manager that no rDNA work or any work with MMLV vector is being done in the protocol currently. The following will be communicated to the PI: • Section I.2-Box for amendments should be left blank. • Section I.2- need ROHP clearance. Few other members need to update their ROHP clearance. • Section VII.3- Please describe the procedures that will be used for safe handling and disposal of 4-nitroquinoline-1-oxide. • Section VII.3- Please update IACUC approval number. Manis Bais IACUC approval record is approved through 6/17/2023 and has a title “Oral Cancer Models”. • Section VIII.1- please check 'animal handling, cage changing.' • Section VIII.4.- Are respirator and face shields both used? If animal inoculations are done inside the BSC, you are not required to use N95. • Section IX. The lab procedures section mentions use of human primary OSCC tissues; if this is still part of the protocol (an IRB number is provided), 'Other Potentially Infectious Materials' should be checked, and the associated table needs to be filled out. • Uncheck ‘Recombinant DNA’ • Section IX. Check 'Live Animal Use' also be checked (since the protocol intends to treat mice with a carcinogen or inject them with human cancer cell lines). BUA Site Assessment: PI has not been available for the BUA inspection; this is scheduled for the next week.					
Motion: Conditional Approval (Administrative Review)			For: 13	Recuse: 0	Against: 0
			Abstain: 0	Absent: 1	

5. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
698		Analysis of human tumor xenograft models and frozen blood samples from stroke patients	2	N/A	BUMC
Primary Reviewer: Robin Ingalls			Secondary Reviewer: Bob Timmerman		
Applicable NIH Guidelines: N/A					
Meeting Comments: The broad goal of this protocol is to study the survival receptor, DEspr (dual endothelin-1 / signal peptide receptor), which is expressed on neutrophils, and its role in the pathogenesis of stroke and ARDS. Specifically, the protocol plans to examine blood samples from patients with intracranial hemorrhage (ICH) as well as severe COVID-19 pneumonia. The biohazards include blood samples which are manipulated in the laboratory, including pipetting, vortexing, and centrifugation of blood. Flow cytometry, cellular imaging and analytical cores are used on fixed samples. A BSC is available for use. Details are lacking in terms of where the samples are obtained from, and how exactly they are manipulated. Following will be communicated to the PI:					
General Comments:					

- The protocol has an unusually long “Brief Scientific Objective” and poorly organized description of what exactly the lab is working on now, in relation to individual research objectives set in the project scientific objective section. Please organize them and remove statements that are not being done.

Specific Comments:

- Please check personnel list; listed as Sponsored Personnel but not in Personnel table.
 - Please update training for and ROHP clearances for all (only is current).
 - The brief description of the project (VII.2) is too long. Committee suggests delete the paragraph starting with “Our plan is as follows...” and move that to VII.3 (Laboratory Procedure section) which needs more detail (as below).
 - The Lab Procedure section does not provide sufficient detail as to what is being done. Suggest move the second paragraph from Q2 to start this section. Please delete the section that starts “Reference links...” and includes Q/A’s as this is not relevant to understanding the protocol. In bullet 3, please state where blood is being drawn. Is it taking place in the GCRU which is mentioned somewhere? The hospital? Or both?
 - The PI states blood will be processed; please clarify what this means (this is actually detailed in the wrong place, see below). Is any processing work being done in PI’s lab?
 - Q4 PPE is checked for animal containment but there is no animal work. Please remove. (To do this first check animal handling and cage changing in VIII.1. Then go to VIII.4 and uncheck all animal PPEs. Then go back to VIII.1 again and uncheck animal handling and cage changing and SAVE).
 - Please update BSC certification date.
 - In the answer to the sharps question it is stated that surgical instruments are used for harvesting tissues but there is no description of working with tissues, the protocol only describes blood work. Please remove if not relevant to the protocol.
- PPE question 11 asks how biohazardous materials are transported. The first sentence answers this question but the remaining information is irrelevant. Consider moving bullet 3 to the detailed project description (Section VII.3) since this information actually describes how the blood is being manipulated which should be included in Q3 (Section VII.3).
- In section B confirm if IRB is still active and approved (expired 6/4/22).

BUA Site Assessment: ECP needs to be adopted. needs ROHP clearance and two others need to update ROHP information. The personnel list is not current as one listed personnel has already left the lab. All training are current. Fume hood expired since January 2022 in room . Biosafety Cabinet is not used for their work; lab is not currently using animals on this protocol.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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6. Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
1818		ARCH Repository	2	N/A	BUMC
Primary Reviewer: Sajal Ghosh			Secondary Reviewer: Robin Ingalls		
Applicable NIH Guidelines: N/A					
Meeting Comments: This protocol acts as a central location of storage of variety of human samples from select group of HIV-infected patients those also have a history of alcohol consumption. The work is part of a NIH program Project called Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS (URBAN ARCH) Consortium					
Sample Repository. PI's lab will not perform any experiments but simply will provide the collected samples to various testing sites for individual research labs associated with this study. The overarching goal of this endeavor is to understand the consequences of alcohol on HIV disease and to mitigate its harmful effects. The biological specimens that will be received and stored include human plasma, serum, PBMCs, dried blood spots, fecal samples, hair, nasal secretions and saliva samples. The samples will come from different study cohorts by courier services and will be					

collected by The PI, his Admin Core staff, and the Biostatistics and Data Management (BDM) Core personnel and stored in a freezer at the Boston Medical Center. The staff are highly experienced in handling infectious human clinical materials and many of them have shipping training. Although they are not expected to general liquid or solid wastes, they have described liquid disinfection (10% bleach or bleach wipes) and red biohazard box disposal of solid wastes should there be any liquid spill or broken tube. All transfer from the courier drop-off area to the storage area will be done in leakproof primary container and leak and shatterproof secondary container. This is a simple straightforward protocol. The following will be communicated to the PI:

- Training update needed for the following members: _____ and _____ (LST), _____ and _____ (LST, BSL1/2, BBP, Chem Safety), Samet BSL1/2, BBP, Chem safety).
- Shipping training appear to have expired for _____ and _____.
- _____ needs to update ROHP clearance.
- There should be spill kit in the lab.

BUA Site Assessment: PI has not been available for the BUA inspection; this is scheduled for the next week.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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7. rDNA/Bhz – Amendment

BUA	(PI)	Title	BSL	ABSL	Campus
2406		Probing physical tumor microenvironment	2	2	CRC

Primary Reviewer: Robin Ingalls

Secondary Reviewer: Sajal Ghosh

Applicable NIH Guidelines: N/A

Meeting Comments: The goal of this protocol is to develop techniques to measure mechanical stress in tumor microenvironment and to test the biological consequences of those mechanical stresses on tumors. They implant biocompatible hydrogels with specific biophysical properties (that act as sensors and actuators), into the tumors. They also use biologicals that induce lung inflammation and determine how acute lung injury affect migration of cancer cells. In this amendment they are adding *Streptococcus pneumoniae* as another agent to induce lung injury to their animal work. Committee discussed how and where the bacterial will be grown and whether there will be any transfer of live bacterial culture from one location to the other. Further, it was also discussed that individual(s) working with the bacteria need(s) to have proper medical clearance form ROHP for working with *S. pneumoniae*. ROHP will also contact and offer vaccination against *S. pneumoniae*. The following will be communicated to the PI:

- Please clarify whether anyone other than _____ will also be working with *S. pneumoniae*. If so, indicate that in the personnel information section.
- Make sure that all individuals working with *S. pneumoniae* have proper medical clearance. Contact ROHP for this clearances.
- Provide a clear description of where exactly the bacteria will be grown and processed for inoculation into the animals.
- If it is to be grown in J. Mizgerd's lab, it must be carried to CRC in a personal vehicle putting the culture in sealed primary container and leak proof and shatterproof secondary container. This description must be included in detail in the laboratory procedure section. Transportation in public transport is prohibited.
- At least one member in the protocol should have current Shipping Training record.
- If you plan to grow the bacteria (*S. pneumoniae*) in own lab, your lab needs to be inspected and approved by the EHS for the initiation of any culture work with *S. pneumoniae*. Again, the detail plan must be clearly stated in the laboratory procedure section for the IBC approval.
- Move the detail animal work description with *S. pneumoniae* from the Hazardous Biological Agent list (Section A) to the Laboratory Procedure Section. Keep only a brief statement of animal work with *S. pneumoniae* in Section A.

Motion: Conditional Approval (Administrative Review)	For: 13	Recuse: 0	Against: 0	Abstain: 0	Absent: 1
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8. rDNA/Bhz – Three-Year Renewal

BUA	(PI)	Title	BSL	ABSL	Campus
2391		Deep Brain Stimulation using engineering nanotransducers	2	2	CRC
Primary Reviewer: Ed Loechler			Secondary Reviewer: Colleen Thurman Additional Reviewer: Ron Morales		
Applicable NIH Guidelines: Section III D-4-a, E-3-1; Appendix B1, G-I & G-II-B, M-I					
Meeting Comments: The goal of this protocol is to develop an optoacoustic neuro-stimulation platform with nanotransducers that efficiently convert pulsed laser energy into acoustic waves to enable highly localized stimulation of neural tissue. This is a minimally invasive alternative to the widely performed method of deep brain stimulators that uses electrodes and stimulation units surgically implanted. These nanotransducers are made up of chemical functionalized carbon nanotubes (CNT) and semiconducting polymer nanoparticles (SPN) that target specific channels in the neuronal membrane upon exposure to a nanosecond pulsed laser. This protocol was written well which described the different arms of experiments conducted. The microbubble nanomaterial solutions to be used in <i>in vitro</i> and <i>in vivo</i> experiments will be prepared in PI's lab. The precursor materials will be obtained from a collaborating research lab at Purdue. Synthesis of the materials are done in the chemical fume hood. Personnel will don protective gloves and safety goggles. In-vitro neuron experiments will be performed with cultured embryonic neuron cells from embryonic rats obtained from the Charles River Lab. The cells will be transduced with commercially acquired AAV vectors that express fluorescent markers. The treated cells will then be exposed to a nanosecond pulsed laser and its response would be studied. The procedure will be performed in a BSC. Wastes will be treated with 10% bleach solution before disposal in biohazard boxes. <i>In vivo</i> neurostimulation experiments will be performed by the lab. Mice will be anesthetized and a cranial opening will be created at a specific region above the motor complex to deliver the SPN and CNT solutions. For the minimally invasive <i>in vivo</i> procedure, mice will be anesthetized and injected with the SPN and CNT solutions along with a mixture of microbubbles through the tail vein, followed by an ultrasound and tissue sample collection to confirm the solution delivery. Upon confirmation of solution delivery, the mice will be subjected to laser pulse treatment followed by evaluation of the neuronal response. Laser safety goggles will be worn along with other PPE mentioned above. All committee members were in agreement that AAV-injected mice may be maintained in ABSL-1 facility. EHS will further evaluate whether the carbon nanoparticle treated mice poses any biosafety risk, although it is believed that shedding of nanoparticles from mice injected intracranially or vial tail vein is not a common event. It was also understood that stereotactic injection in the brain cannot be done inside a BSC because of the vibration. However, because the nanoparticle formulation is in liquid form and only one or two microliter amount of the preparation will be injected, aerosolization is not a concern. The following will be communicated to the PI: • Please indicate the title of (the person identified to conduct animal experiments). • PI needs to complete her BSL1/2 training module. • The PI completed Section H Recombinant DNA for Animal Experiments. It was indicated there that C57BL/6 mice would be treated with AAV vector with fluorescent markers. Although the AAV use <i>in vitro</i> experiments are described, but the animal work with the AAV is not described. This needs to be described in the laboratory procedure section. • Please provide a brief commentary on the personnel exposure risk to nanoparticles from the injected animals and also clarify how should the animal carcass be disposed of. • What PPE are used in the event of a spill clean-up? Is a respirator worn to clean an accidental spill of powder materials used to create the nanomaterials outside the chemical fumehood? • Personnel should also don lab coats as part of their PPE. • Please indicate how liquid biological waste is treated and disposed of. • Will back fastening gown, disposable scrubs, N95 respirator, and goggles be used? Normally just a disposable lab coat or jumpsuit over either street clothes or scrubs, gloves +/- surgical mask or eye protection for benchtop work are enough for regular ABSL2 work.					

BUA	(PI)	Title	BSL	ABSL	Campus		
2553		Clinical support and Personnel Training for Boston University NHP colonies	2	2	BUMC		
Primary Reviewer: Barbara Slack			Secondary Reviewer: Steve Niemi				
Applicable NIH Guidelines: N/A							
Meeting Comments: The objective of this project is to provide adequate continuing care to non-human primates (NHPs) on the holding protocol and appropriate training to the veterinary services technicians and lab personnel as appropriate, on the Animal Science Center training protocols. This protocol covers collection of blood, bone marrow, saliva, urine, CSF, urine, fecal, and tissue samples from uninfected NHPs by veterinary personnel. Training is up-to-date, and PPE and other check-list sections are completed appropriately. However, the committee noted that the Lab Procedures section does not provide a narrative of safety measures to be taken when collecting these samples. Although the protocols provides associated IACUC protocol numbers where detail of the procedures are described, IBC recommended that reference to existing standard operating procedures (SOPs) with brief general description of the procedures would be helpful for evaluation of the risks associated with the procedures. It was noted that apart from tissue and blood/fluid collection from the NHPs, the project does not involve any additional safety risks. The following will be communicated to the PI: • Please refer specific SOP numbers of the procedure to be performed on the NHPs, including a broad statement of each SOPs or the title of those SOPs. • Committee suggested that training on radiological procedures also be included in the laboratory procedure and in the Radiation and X-Ray section (for example for detecting occult TB infection). • Section VIII.2 – Protocol indicates use of BSC/other containment as engineering control, but section VIII.5 says BSCs will not be used. Please clarify or correct for consistency. • Section VIII.12- Why no biohazard labels on equipment? BUA Site Assessment: Exposure Control Plan for the Animal Science Center needs to be uploaded into BioRAFT. needs to update NHP training. All general lab safety equipment are in place and duly certified. All wastes are disposed of appropriately in both the NEIDL and W-building facilities. <i>PI recused herself from voting.</i>							
Motion: Conditional Approval (Administrative Review)			For: 13	Recuse: 1	Against: 0	Abstain: 0	Absent: 0