I. Review of June 2018 Meeting Minutes
Motion: Approve
For: 12
Against: 0
Abstain: 0

II. New Business

A. Safety Committees Report:
   Approved Applications/Amendments (S. Ghosh)
   Since the June IBC meeting, 1 new protocol, 5 three-year renewals, 10 amendments and 7 annual renewals have been approved.

B. Research Occupational Health Program Report
   On 06/26/2018, a 4th year PhD student was bit by an ABSL1 transgenic mouse while wearing one pair of nitrile gloves and a lab coat. Due to poor grip while scuffing the mouse it was able to turn and bite his finger. He was evaluated and treated by ROHP. The researcher was working under an IBC protocol that involves adenovirus but this particular mouse did not contain any virus or hazardous agents at the time of the incident. The incident was reported to BPHC.

C. Environmental Health & Safety Report
   For the 6/26/2018 incident there was no root cause identified. It was noted that the student has a lot of experience handling mice and has been sufficiently trained. The following steps have been taken to prevent recurrence: the student will ensure he has a secure scruff when handling mice. A member questioned if the incident was reportable to NIH OSP, whether Ube3A protein is a human modified protein and if so, whether it could induce an immune response, and
whether the gene expresses in salvia. N. Dey indicated that he would investigate further and report back to the IBC.

The committee was informed that the USDA is on site today conducting an announced inspection related to permitting for the prion research conducted in the Harris lab.

III. Protocol Review:

A. New Applications

1. Biohazard (Bhz)
   Principal Investigator (PI):
   Biological Use Authorization (BUA) Tracking ID #: 2323
   Title: Mechanical stretch-induced inflammation in human lung tissue
   Primary Reviewer: Rosina Georgiadis
   Secondary Reviewer: Robert Timmerman
   Biosafety Level: BSL-2
   Animal Biosafety Level: N/A
   Campus: CRC
   Applicable NIH Guidelines: N/A
   Protocol Expires: New Application
   Layman’s Description: Our lab will obtain human lung tissue samples from Massachusetts General Hospital and human airway smooth muscle cells in culture from Beth Israel Hospital. We are interested in how these samples behave when they are exposed mechanical stretch similar to what these tissues and cells are exposed to in the lung during normal breathing.

   Meeting Comments:
   The PI seeks to understand the mechanism of lung inflammation in patients who are under mechanical ventilation. They place primary human lung tissues under stretched conditions and test what molecular changes are associated with such stretching. Additionally, cultured smooth muscle cells obtained from de-identified biopsy samples of normal and asthmatic patients will also be tested to address the same questions. Tissues or isolated cells, labeled with fluorescent markers, will be stretched in biosafety cabinets using tissue or cell stretchers and visualized by fluorescent and confocal microscopy to visualize mitochondria and measure ATP production rates and other measurements (direct glucose uptake) as an indicator of local inflammation. Specimens will be bleached before being discarded. Reviewers discussed whether the tissue sample transport containers are adequate. EHS will work with the PI to address appropriate transport and ensure appropriate containers are being used. Members discussed what microscope would be utilized and noted that the PI will use a microscope in her lab and in one of the Core Facilities. Members questioned whether the Core Facility had an approved IBC protocol given the recent departure of the Director and whether the material is being inactivated, and what PPE is being used at the microscope. It was noted that the Core Facility needs an approved protocol for any work being conducted in the Core, inactivation is not indicated in the protocol and PPE included lab coats, gloves, goggles and surgical masks.

   Changes/Clarifications Required:
   Personnel Information: The PI and Associate PI should be listed as personnel and all associated questions answered. Please include Mr. Bou Jawde as personnel. Personnel shipping materials under this protocol must complete shipping training.
Research Laboratory Facility Information: Remove the ABSL1 reference for the Engineering Research Building room 344 given there is no animal work occurring under this protocol.

PPE and SE: Q2- A biosafety cabinet (BSC) is required. All appropriate boxes should be checked.
Q5- Update BSC certification information.
Q7A- Specify that fresh bleach will be used.
Q11: Change the language in this section to indicate that transportation boxes are leak-proof and shatter-proof in addition to the use of a leak proof zip lock bag. Describe the nature of boxes used for transporting materials from Beth Israel Hospital.
Q12: (Labeling of biohazards) is answered NO. All containers and equipment containing biohazards should be so labeled.

Biosafety Training: At least one member should have updated shipping training. All other training requirements are complete for all members.

BUA Site Assessment: Approved.

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

2. rDNA/Bhz
PI: BUA Tracking ID: 2331
Title: Transfer of materials for storage at BUMC
Primary Reviewer: Elke Muhlberger
Secondary Reviewer: James Keeney
Additional Reviewer: Debbie Stearns-Kurosawa and Nadia Yun/Guillermo Madico
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Campus: BUMC/NEIDL
Applicable NIH Guidelines: Section III-D-1-a; Section III-D-2-a.
Protocol Expires: New Application

Layman’s Description: Materials from Texas Biomedical Research Institute will be transferred to BUMC NEIDL and stored in a locked freezer (plasmids, CRISPR lentivirus library, 2 siRNA libraries and cell lines). Fixed cells in plates will be transferred and stored in a cold room.

Meeting Comments:
The PI is a new faculty member at the NEIDL. The protocol contains the list of reagents to be transferred to BU, including hundreds of plasmid constructs, a lentiviral construct library that encodes several different CRISPR constructs, two siRNA libraries and a number of human cancer cell lines. The PI also plans to transfer inactivated biological samples, mainly formalin treated HeLa cells previously infected with ebola virus. This protocol is only for storage of these materials. Members questioned how materials are transported and the primary reviewer indicated that they didn’t have any concerns about transport, that standard shipping carriers are used. It was noted that an inactivation certificate (for the inactivated materials) must be provided per BU Policy and that it is the PI’s responsibility to maintain the inactivation certificate. It was also noted that RIMS does not display documents that are uploaded in this section and that these should show up in the pdf and this is a RIMS issues that should be addressed.

Changes/Clarifications Required:
Research Laboratory Facility Information: Add NEIDL rooms 406, 412B, and 412E and provide associated information.
PPE and SE: Q8- Add the phrase ‘Fresh’ to the '10% bleach' to indicate bleach is freshly prepared.
Q11- Indicate that primary shipping boxes are leak and shatter-proof.
Hazardous Biological Agent: Add lentivirus vectors.
Inactivated Biological Samples (Section I): The source institution sending the inactivated biological samples, infected or associated with RG3/RG4 agents, must submit a certificate (for example, a letter signed by the authorized institutional official) for the shipment attesting that the samples have been processed using institutionally approved methods for inactivating and removing samples from the BSL-3 or BSL-4 laboratory. The certificate of inactivation must be uploaded with the Application for review and approval by the IBC Chair and EHS prior to transfer.

Biosafety Training: All members are current with all training requirements.
BUA Site Assessment: Approved.
Motion: Conditional Approval (Administrative Review).
For: 16
Against: 0
Abstain: 0

B. Three-Year Renewal Applications

3. rDNA/Bhz
PI: BUA Tracking ID: 1620
Title: Single Neuron Mechanisms of Sensory-Motor Learning
Primary Reviewer: Robin Ingalls
Secondary Reviewer: Rao Varada
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Campus: CRC
Applicable NIH Guidelines: Section III-D-4
Experiments involving whole animals. Recombinant DNA, or DNA or RNA molecules derived therefrom (from any source except > 2/3rds of eukaryotic viral genome) transferred to any non-human vertebrate or any invertebrate organism (III-D-4)
Protocol Expires: 08/24/2018
Layman's Description: We study the neural basis of vocal learning in songbirds, and this research subject is advancing the understanding of many fundamental processes of brain development, learning and memory. We use virus to manipulate neurons in key songbird brain regions to produce a protein that is fluorescent only when the cells are active. A microscope video camera can record this change in fluorescence to attain a readout of the activity of many cells over time. The attenuated viruses used in this work have become standard tools in thousands of labs around the country, and since these viruses are non-replicating, there is no public health risk.

Meeting Comments:
The objective of this protocol is to understand the intricate neural circuit dynamics of sensory motor learning by studying the anatomical and functional changes in the brain that accompany the song learning process in zebra finches, canaries and bengalese finches. They will manipulate the expression of molecules known to modulate neuronal functions by injecting viral vectors that express individual modulators or express fluorescent proteins
which can be monitored by microscopic video camera. Viral vectors are injected stereotactically in specific regions of the brain of the birds. The protocol involves elaborate animal surgery and monitoring procedures. Viral vectors used in the study will be purchased through UPENN or UNC viral vector core facilities. The protocol also involves use of small amounts of neuro-stimulants. It was noted that reviewers received a revised protocol where all work with toxins was removed and that the use of a BSC was added. The PI has IACUC approval for this work. Members questioned if the birds carry any human pathogens and it was noted that zebrafish are bred and that canaries are purchased, and that there is the potential that the birds may carry human pathogens, which is why proper PPE including a face shield and mask are important.

**Changes/Clarifications Required:**

*Personnel Information:* Update the personnel table indicating the appropriate titles and their corresponding descriptive roles. If Dr. Otchy is the PI (rather than Co-PI), this should be indicated.

*Research Project Description:* Q3- Elaborate on the description of viral vectors that are being used for expression of individual proteins, including adenoviral vectors.

*PPE and SE:* Q4- Check face shield, safety glasses and shoe covers.

*Materials Used in Research:* The ‘Select Biological Toxin’ box appears to have been checked in error.

*Biosafety Training:* All members are current with all training requirements.

*BUA Site Assessment:* Approved.

*Motion:* Conditional Approval (Administrative Review).

*For:* 16

*Against:* 0

*Abstain:* 0

4. **rDNA/Bhz**

   **PI:**

   **BUA Tracking ID #:** 1643

   **Title:** Mechanisms of Autoimmune Disease

   **Primary Reviewer:** Debbie Stearns-Kurosawa

   **Secondary Reviewer:** Erin Sawyer

   **Biosafety Level:** BSL-2

   **Animal Biosafety Level:** ABSL-2

   **Campus:** BUMC

   **Applicable NIH Guidelines:** Section III-D-1-a, Section III-E-1; Appendix C-II

   **Protocol Expires:** 08/07/2018

   **Layman’s Description:** Our studies evaluate ways to interfere with T cells causing autoimmune diseases with an emphasis on type 1 diabetes and scleroderma. We study pathways and molecules that are important for the generation, function and survival of T cells that destroy the insulin-producing cells in the pancreas. These insights are then used to test whether blocking these novel pathways (for example with antibodies) in diabetic mice leads to therapeutic benefit. These studies will further our understanding of the mechanisms of autoimmune diseases and may result in the development of innovative therapies.

   **Meeting Comments:**

   This protocol investigates how the immune system’s ability to recognize self versus foreign antigens is regulated. In a normal individual, protective cellular response is activated upon identification of foreign antigens but self-antigens are tolerated with high precision.
Autoimmune diseases generally result from the breakdown of these control mechanisms. The goal of this protocol is to develop better strategies for controlling autoreactive T-cells in autoimmune diseases such as scleroderma or type 1 diabetes. They will isolate memory T-cells from mouse models of type 1 diabetes as well as from other specific knockout and transgenic mice and test differentiation and memory cell function of those isolated T-cells. In some experiments, retroviral vectors will be used to manipulate expression of specific genes in these T-cells. Some of these manipulated T-cells will be injected into other mice to test the effect of their in vitro genetic manipulations in live animals. In other experiments, they will use human patients and healthy volunteer blood to isolate human memory T-cells, which will be genetically manipulated and used to create humanized mice. EHS confirmed that the PI’s request to change NEIDL 502M to 513M is appropriate as the ELISPOT equipment to be used in the protocol has moved to NEIDL 513M. EHS is working with the lab on an exposure control plan.

**Changes/Clarifications Required:**

- **Research Project Description:** Q3- Merge the Annual Renewal statement in the last paragraph of the Laboratory Procedure Section with the main body of the lab procedure as this application is no longer an annual renewal.
- **PPE and SE:** Q5- Update BSC certification date.
- **Materials Used in Research:** Please contact Dr. Carol Sulis, Hospital Epidemiologist (617-414-5037 or csulis@bu.edu) to discuss how patient blood samples are being collected safely and transported to the lab. Please indicate the date of this communication at the bottom of this page.
- **Recombinant DNA (Section H):** Please update Applicable NIH Guidelines section (Q19) to indicate Applicable NIH Guidelines: Section III-D-1-a, Section III-E-1; Appendix C-II.

**Biosafety Training:** All members are current with all training requirements.

**BUA Site Assessment:** Approved.

**Motion:** Conditional Approval (Administrative Review).

- **For:** 16
- **Against:** 0
- **Abstain:** 0

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5. **Bhz**  
**PI:**  
**BUA Tracking ID:** 635

**Title:** Biospecimen Archive Research Core  
**Primary Reviewer:** Barbara Slack  
**Secondary Reviewer:** Robert Timmerman  
**Biosafety Level:** BSL- 2  
**Animal Biosafety Level:** N/A  
**Campus:** BUMC  
**Applicable NIH Guidelines:** N/A  
**Protocol Expires:** 08/06/2018

**Layman’s Description:** The mission of the Biospecimen Archive Research Core is to collect high quality samples of normal and diseased human material with appropriate clinical annotation and make these materials, known as biospecimens, available to qualified researchers while ensuring the informed consent, safety and anonymity of all providers.

**Meeting Comments:**

The Biospecimen Archive Research Core (BARC) is a core facility that provides biological tissue samples obtained from Boston Medical Center patients who have given informed
consent for experimental use of their normal or abnormal specimens removed during medical procedures at the hospital. Only tissues destined to be discarded are collected and stored for scientific studies. Tissue samples are typically frozen fresh in liquid nitrogen or are embedded in paraffin blocks. Lab personnel wear gloves, lab coat and safety glasses while working with these materials and use universal precautions. Some samples are processed using electron microscopy following standard staining techniques using heavy metal. The protocol provides a detailed description of individual bench protocols that are typically used in the core. In order for samples to be released from the repository, recipient investigator’s research plans are reviewed by the BARC oversight committee to ensure the research plan is consistent with the informed consent of the tissue donor. It was noted that the reference to use of NHP tissue should be removed if this use is not occurring. Members questioned if frozen tissues were being used, it was noted that they are and that they will be dissected with a cryostat.

Changes/Clarifications Required:
Overview and Grant Funding Information: Remove text from the summarize changes box. This is only for amendments and annual renewals.
Personnel Information: The PI should be added to the personnel table and complete associated questions and required training. B. Thomas must also complete Laboratory Safety training.
Research Project Description: Q3- Provide additional detail on the use of Osmium Tetroxide (OsO₄), along with information on its disposal.
PPE and SE: Q5 - Update BSC certification date.
Materials used in Research: Check the High Hazard Chemical Box and complete section F for OsO₄.
Contact Dr. Sulis to discuss the safe handling and transport of clinical samples to the Core.
Other Potentially Infection Material: Section (B): Provide an IRB protocol number and expiration date.
Biosafety Training: PI needs to complete BSL1/2, BBP and rDNA/IBC Policy training. B. Thomas needs to complete Lab Safety Training.
BUA Site Assessment: Approved.
Motion: Conditional Approval (Administrative Review).
For: 16
Against: 0
Abstain: 0

6. rDNA/Bhz
   PI: BUA Tracking ID: 1612
   Title: Proteinuria causes progressive kidney disease by impairing autophagy
   Primary Reviewer: Carmela Abraham
   Secondary Reviewer: Rao Varada
   Biosafety Level: BSL- 2
   Animal Biosafety Level: ABSL-1
   Campus: BUMC
   Applicable NIH Guidelines: Section III-D-1-a, Section III-E-1; Appendix B-II, and G-II-B
   Protocol Expires: 08/10/2018
   Layman’s Description: Proteinuria is associated with progressive chronic kidney disease which affects more that 20 million Americans. End stage renal failure can occur when large amounts of the protein albumin are exposed to the proximal tubular epithelial cells of the kidney. Exploring the presently unknown pathophysiologic processes in proteinuric kidney disease can lead to the development of new therapeutic tools to prevent or slow the progression to chronic kidney failure.
**Meeting Comments:**
The PI is investigating how excessive amounts of albumin interfere with the normal function of kidney epithelial cells leading to progressive chronic kidney disease including proteinuria. The PI hypothesizes that albumin impairs autophagy in proximal tubular epithelial cells in the kidney, which is a critical cellular function responsible for turnover of cellular macromolecules and organelles, including dysfunctional mitochondria. Using *in vitro* assays and *in vivo* animal model studies, the PI will test if artificial impairment of autophagy leads to the development of proteinuria. Conversely, they will also test if pharmacological upregulation of autophagy in a diabetic mouse model (that develops proteinuria) will lower the burden of proteinuria-induced damage in the kidney. The protocol involves a variety of *in vitro* assays on kidney cell lines, primary mouse kidney cells, and tubules. Lentiviral and adenoviral-vector mediated transfection and transduction will also be used. It was noted that the PI has valid IACUC approval, that R. Mulhurn is leaving and should be removed from the protocol, and that Dr. Schwartz should be removed from the shared rooms list.

**Changes/Clarifications Required:**
Overview and Grant Funding Information: This is a 3-year resubmission. The correct submission type should be selected.
Personnel Information: PI (Dr. Havasi) needs to update BSL1/2 training.
Research Project Description: Q3- Description of common buffers, centrifuge times, etc., do not need to be stated.
In Procedures, include a sentence that the pPACK packaging system consists of three plasmids and the lentiviral vector system is non-replicating.
PPE and SE: Q1- Check Plating and colony counting.
Q4- Add shoe cover and head cover for the animal PPE.
Q5- Update BSC certification date (should be 8/31/18).
Q8- Indicate that bleach will be freshly prepared.
Hazardous Biological Agent (Section A): Please correct “ACC” to “ATCC”.
Recombinant DNA (Section H): Modify Applicable NIH Guidelines to Section III-D-1-a, Section III-E-1; Appendix B-II, and G-II-B

**Biosafety Training:** All members (except the PI) are current with all training requirements.
**BUA Site Assessment:** Approved.
**Motion:** Conditional Approval (Administrative Review).
For: 16
Against: 0
Abstain: 0

7. Bhz    PI:    BUA Tracking ID: 1614
Title: The mechanical basis of primary open angle glaucoma; Mechanism of aqueous outflow resistance in normal and glaucomatous eyes; Cellular physiology of the aqueous outflow pathway; Hydrodynamic and morphological studies of novel glaucoma devices; Lysosomal enzymes in outflow pathway physiology and pathophysiology; Can TSP1 serve as a biomarker of Steroid-induced Glaucoma?; Function of Glycocalyx in the Trabecular Outflow Pathway; The role of thrombospondin-1 in regulating IOP
Primary Reviewer: Robin Ingalls
Secondary Reviewer: Erin Sawyer
Biosafety Level: BSL- 2
Animal Biosafety Level: ABSL-2
Layman’s Description: Glaucoma is usually associated with elevated pressure inside the eye caused by increased outflow resistance. The goal of the studies in Dr. Gong’s lab is to understand the mechanisms that regulate the aqueous humor outflow resistance in normal eyes and how this resistance is increased in glaucoma. We also investigate the mechanisms of potential drugs, and novel micro-invasive surgical devices in the treatment of glaucoma.

Meeting Comments:
This protocol investigates the mechanisms that elevate pressure inside the eye as happens in glaucoma. Increased ocular pressure is believed to be the primary cause of open angle glaucoma, the most common form of glaucoma seen worldwide. The increase in ocular pressure most likely results from a blockade of the flow of aqueous humor in the eye. The PI investigates the mechanism of this aqueous humor outflow in eyes from bovine, mouse, sheep, monkey and human sources by variety of hydrodynamic and morphological studies of the enucleated eye samples. Outflow resistance reducing as well as facilitating agents will be tested in perfused eyeballs to study the effects of aqueous outflow physiology. The protocol will also use mouse models where higher eye pressure will be generated artificially by chemical agents resulting in impairment of the eye morphology, which will be visualized by confocal microscopy. Bovine and porcine eyes will be obtained from a local abattoir. Human eyes will be obtained from the National Disease Research Interchange and Duke University. Rhesus monkey eyes will be obtained from a University of Nebraska and University of Wisconsin monkey colony and sheep eyes will be from Argentina. Human eyes are tested for HIV and Hepatitis. It was noted that eyeballs should be considered infectious material. The secondary reviewer indicated they would submit their comments following the meeting. Members questioned whether nonhuman primate (NHP) eye balls are free from communicable diseases. It was noted that reports on individual NHPs are typically available, and that colonies are regularly tested for communicable diseases. Members discussed proper waste disposal and whether human and animal tissues should be disposed of in red biohazard boxes, as this waste may not be incinerated. EHS informed the Committee that labs should bring tissues to designated freezers for proper disposal (including the carcass freezer in the ASC). Members indicated that education around proper tissue disposal may be needed to ensure labs understand how to properly dispose of tissue waste and suggested posting clarification on the IBC website. EHS will follow-up with S. Monstur to confirm the proper waste disposal and report back at the next IBC meeting. It was noted that the PI should be advised that tissues (eyeballs) need to be separated for frozen storage in a designated carcass freezer.

Changes/Clarifications Required:
PPE and SE: Q1- Check animal handling and cage changing.
Q7B- Clarify that no liquid waste is being disposed of in red Biohazard boxes.

Biosafety Training: All members are current with all training requirements.

BUA Site Assessment: Approved.

Motion: Conditional Approval (Administrative Review).

For: 16
Against: 0
Abstain: 0
8. **rDNA/Bhz**  
**PI:** BUA Tracking ID: 1613  
**Title:** 1) Prevention and Treatment of Ischemic AKI  
2) Novel Phospho-proteomics Approach to Improve Acute Kidney Injury Diagnostics  
3) High Throughput Drug Repurposing for Antibiotic-Induced Acute Kidney Injury  
**Primary Reviewer:** Inna Afasizheva  
**Secondary Reviewer:** Rao Varada  
**Biosafety Level:** BSL-2  
**Animal Biosafety Level:** ABSL-1  
**Campus:** BUMC  
**Applicable NIH Guidelines:** Section III-D-1-a, Section III-D-2-a, Section III-E-1; Appendix B-II and G-II-B.  
**Protocol Expires:** 08/26/2018  

**Layman’s Description:** A reduction in blood flow to the kidney is a common cause of human kidney failure. The goal of our studies is to understand the role of nucleophosmin (NPM), a key Bax chaperone protein, as an early diagnostic marker of kidney injury (AKI) and a primary AKI mediator during ischemia. This might be a useful protein for preventing kidney injury in patients with acute ischemic kidney injury. We are also pursuing the signal pathways that mediate renal cell injury after nephrotoxin exposure using high throughput shRNA screening combined with traditional molecular and biologic approaches.

**Meeting Comments:**  
This project focuses on understanding the role of the nucleolar RNA-DNA binding phosphoprotein (NPM) as an early diagnostic marker of kidney injury and primary mediator of acute kidney injury during ischemia. The research is also advancing to the mechanistic studies of the signaling pathway that mediate renal cell injury after nephrotoxin (toxin produced in the kidney during the inflammation) exposure. The protocol will use immortalized renal epithelial cell lines from human, mouse or opossum as well as primary mouse kidney cells. These cells will either be stably transfected with plasmids that express different proteins involved in kidney function or transduced with adenoviral or retroviral vectors. Protein expressions will be monitored by fluorescent microscopy and also by western blot analysis. It was noted that it is unclear if the PI has valid IACUC approval for this work. EHS indicated that the BSC is certified and everything in the lab is in order. It was noted that the layman’s description and the project description need to be switched.

**Changes/Clarifications Required:**  
**Personnel Information:** Update rDNA/IBC Policy training for Dr. Borkan.  
**PPE and SE:** Q1- Check animal handling and cage changing.  
Q4- Check shoe covers and head covers.  
**Materials Used in Research:** The referenced IACUC protocol AN-15024 is an ABSL-1 protocol, but the highest animal biosafety level for this protocol as stated in this section is ABSL-2. Please reconcile.  
**Recombinant DNA (Section H):** Modify Applicable NIH Guidelines to Section III-D-1-a, Section III-D-2-a, Section III-E-1; Appendix B-II and G-II-B.

**Biosafety Training:** PI’s rDNA/IBC policy training needs update. All other training requirements are current.  
**BUA Site Assessment:** Approved.  
**Motion:** Conditional Approval (Administrative Review).  
**For:** 15  
**Against:** 0
**Layman’s Description:** We are looking for a simple way to study how a reformulation of hydroxy Urea using a new formulation vehicle from our laboratory can affect the delivery of the drug in Sickle cell blood from patient.

**Meeting Comments:**
This protocol investigates new efficient ways to provide therapeutic drugs to affected tissues and cells. The study centers around a FDA approved sickle cell disease drug hydroxyurea (HU). This drug increases expression of a variant form of hemoglobin (called fetal hemoglobin), which does not allow formation of non-functional sickled hemoglobin, allowing less frequent blood transfusions in sickle cell anemic patients and helping them to breathe better. In their quest for a better delivery option for the HU drug compared to cumbersome transfusions, they are testing the efficacy of a nanoformulation of HU to determine if it could reach to desired cells more efficiently than the traditional HU chemical. In their experiments they are preparing the nanoformulated HU in house and treating blood cells from normal volunteer and sickle cell patients with either standard HU or the nanoformulated HU and measure enhancement of fetal hemoglobin expression. They are also carrying out similar testing in sickle cell disease mouse model. Members noted that it is unclear what the formulation of HU is and that additional details are needed for the purposes of risk assessment and to determine if procedures for safe handling are adequate. Members expressed concern about nanoparticles potentially being released into the air outside of the building if fume hood filtration is not adequate. The primary reviewer indicated that she believes the formulation is a lipid encapsulation and would not be of concern. She indicated that additional details are needed, including details on fume hood and BSC use.

**Changes/Clarifications Required:**

- **Research Project Description:** Q3 -
  a) Clarify what the Nano particle formulation of hydroxyurea (HU) is and describe in greater detail the components of powder Nano-formulated HU.
  b) The HU is a hazard when inhaled, ingested and on skin contact. Provide additional details on how the powdered nano-HU is handled when reconstituting into liquid. Is it being handled in a fume hood or in a special equipment with aerosol protection?
  c) Describe the PPE to be used when conducting this as a normal procedure and in the event of an accidental spill of powdered material.
  d) Describe in greater detail the purpose of using a sickle cell disease animal model in the context of the use of nano-HU. How will the mice be anesthetized for HU or nano-HU inoculation? Indicate whether mice will be inoculated intratracheally in a biological safety cabinet or chemical fume hood.
e) What are the challenges of using nano-HU in animals to make it ABSL-2 experiment? In section IX the highest animal biosafety level chosen is ABSL-1. Please clarify what the appropriate ABSL is and reconcile.

f) Clarify and describe if animals have been assigned a chemical containment level (CCL) for the administration of nano-HU they are given?

g) Provide additional information on who is providing and transporting the human blood samples. Who is responsible for transport? What BMC laboratory will be doing the IGE analysis?

PPE and SE:
Q1- Uncheck “plating, colony counting” unless working with cultured pathogens or rDNA-related cultures. Check off “animal handling” and “animal inoculation” on the table. Uncheck “Freeze drying, lyophilizing” this is not described in the procedures section.

Q3- Check only one “goggles”, “safety glasses”, “face shield”. If these are needed for separate procedures, describe in procedures section.

Q4- Check off the PPE that will be worn in the animal facility, specifically for the chemical containment room. Check “N95” and “shoe covers”.

Q5- Update the Biological safety cabinet certification.

Q7A and 7B- Provide additional details when handling and disposing of liquid and solid wastes with Nano-HU and liquid wastes mixed with biological and nano-HU.

Q10- Re-write to focus on how and where biohazards will be stored. Move procedures described in this section to procedures section.

Q11- Add language for the transport of human blood samples to include the use of a leak-proof, shatter-proof primary and secondary container.

Materials Used in Research: Contact Dr. Carol Sulis, Hospital Epidemiologist (617-414-5037 or csulis@bu.edu) to discuss how patient blood samples are being collected safely and transported to your lab.

Biosafety Training: All members are current with all training requirements.

BUA Site Assessment: Approved. Exposure control plan will be adopted. Chemical fume hood recertification has been requested.

Motion: Conditional Approval (Primary and Secondary Member Review).

For: 14
Against: 0
Abstain: 0

C. Amendments & Annual Renewals for Committee Review

None

IV. Approved Amendments & Annual Renewals

A. Amendments

1. BUA Tracking ID: 1487
   Title: CLASSIFICATION OF STUDIES: 1. Human Studies-IMPAACT/ACTG 2. Human Studies-NIH, industry and internally sponsored 3. IACUC/Animal Protocols *Specific titles are listed in Section VII.
   Biosafety Level: BSL-2
   Animal Biosafety Level: ABSL-2
   Method of Review: Expedited, Administrative Review
Modification: To add one personnel and to update clinical study (IRB) listings

2. BUA Tracking ID: 1728
Title: New strategies to control hemorrhagic fever virus infection
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To add two and delete three personnel

3. BUA Tracking ID: 1495
Title: Oncorequisite Genes in MYC-Mediated Transformation
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To add one and delete one personnel

4. BUA Tracking ID: 1461
Title: 1) Neural Substrates of Cognitive Decline in Aging 2) Neurobiological Consequences of Hypertension &Aging 3) Memory/Executive Function in Prefrontal & Temporal Lobe Cortex 4) Non-human Primate Model for Assessing Motor Recovery after Stroke 5) iPSC infusion as a treatment for ischemic stroke in the non-human primate
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To add two personnel

5. BUA Tracking ID: 2246
Title: Stem cells in lung development and disease
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review (in consultation with EHS)
Modification: To add use of sulfur dioxide

6. BUA Tracking ID: 1470
Title: Mechanisms of metastatic melanoma phenotype development
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Full Committee Review
Modification: To change PI

7. BUA Tracking ID: 2173
Title: Molecular Biology of Melanoma
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-1
Method of Review: Expedited, Administrative Review
Modification: To add two personnel

8. BUA Tracking ID: 935
Title: Lens-Amyloid: Biochemistry and Diagnostic Imaging Clinical validation of a laser eye scanner for AD Effects of Blast Neurotrauma on Alzheimers Disease Pathogenesis CTE and posttraumatic neurodegeneration: neuropathology and ex vivo imaging
Mechanisms of Repetitive Neurotrauma and Chronic Traumatic Encephalopathy (CTE):
Pathways to Diagnosis, Treatment, Protection, and Prevention Gadolinium Distribution in Rat Brain After Systemic Administration of Gadolinium-Based Contrast Agents Assessed by High-Resolution Metallomic Imaging Mass Spectrometry (MIMS)
RETROSPECTIVE HUMAN BRAIN STUDY: Regional Gadolinium Distribution and Concentration in Postmortem Human Brains from Subjects Exposed to GBCAs Evaluated by MIMS Brain Mapping Immunotherapeutic Targeting of Phosphorylated Tau Proteoforms for Prevention and Treatment of Chronic Traumatic Encephalopathy (CTE)
Targeting Tau Proteinopathy for Prevention and Treatment of Chronic Traumatic Encephalopathy (CTE) and Related Tau Protein Neurodegenerative Diseases The Eye as Window to Brain Injury: Noninvasive Retinal Imaging to Detect and Monitor Acute and Chronic Effects of Neurotrauma
Biosafety Level: BSL-2+
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To add one personnel

9. BUA Tracking ID: 892
Title: Molecular mechanisms of pulmonary inflammation
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To add one personnel

10. BUA Tracking ID: 1487
Title: CLASSIFICATION OF STUDIES: 1. Human Studies-IMPAACT/ACTG 2. Human Studies-NIH, industry and internally sponsored 3. IACUC/Animal Protocols *Specific titles are listed in Section VII.
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To delete two personnel

B. Annual Renewals

1. BUA Tracking ID: 785
Title: Molecular and Pharmacological studies of neurodegenerative diseases
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-1+
Method of Review: Expedited, Administrative Review
Modification: To add two personnel and two plasmids

2. BUA Tracking ID: 1792
Title: Structures and Functions of RNA Editing TUTases
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Method of Review: Expedited, Administrative Review
Modification: To delete one personnel

3. BUA Tracking ID: 1788
Title: Provide services related to the use of Flow Cytometer analyzer and cell sorting instruments
4. BUA Tracking ID: 1932
Title: Rel Homology Domain Signal Transduction Pathways in the Sea Anemone Nematostella vectensis
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: To delete one personnel

5. BUA Tracking ID: 1399
Title: Control of embryonic development by CK2: CK2 as a core Wnt/beta-catenin component Effect of CK2 Dysregulation on Heart Morphogenesis Cardiac proliferation: Role of Protein Kinase CK2
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: No changes

6. BUA Tracking ID: 2231
Title: Insulin regulation of cell nutrition Secretion from adipose cells Regulation of lipolysis Regulation of leptin production
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Method of Review: Expedited, Administrative Review
Modification: Genomic and biochemical studies of Piwi proteins and piRNA regulation mechanisms

7. BUA Tracking ID: 714
Title: MYOKINES AND THE CARDIAC SECRETOME IN PATIENTS WITH HEART FAILURE (previously called ROS in heart failure patients)
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Method of Review: Expedited, Administrative Review
Modification: No changes