This meeting is open to the public.


Guests Present: T. Killeen, M. Auerbach (by phone), N. Dey, J. Davis

Staff Present: S. Ghosh, C. McGoff, J. Hutchinson (by phone)

Confidentiality: Members are required to maintain the confidentiality of all non-public information entrusted to them. Members may not disclose any confidential information except as authorized by an appropriate institutional officer or as required by law. They may not use any confidential information except to carry out their obligations as committee members. No information may be used by committee members for their own benefit.

Conflict of Interest: The NIH Guidelines state that no IBC member may “be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.” The Chair must be notified of the conflict and the member must recuse themselves from the review and vote on the protocol.

I. Review of December 2018 Meeting Minutes

Motion: Approve

For: 14
Against: 0
Abstain: 1

II. New Business

A. Safety Committees Program (SCP) Report

Approved Applications/Amendments

Since the December 2018 IBC meeting 1 new protocol, 3 three-year renewals, 10 amendments and 14 annual renewals have been approved.

Reportable Event

The committee was informed that the 11/27/18 incident involving a laboratory technician who cut her finger with a scalpel that was used to dissect tissues from a non-transgenic mouse injected with rDNA was reported to the NIH Office of Science Policy. NIH responded that the actions taken in response to this incident appeared appropriate and no further information is required at this time.

Meeting Schedule

Members were informed that the February and April IBC meeting dates coincide with school vacations and the SCP will poll members to determine if either meeting needs to be rescheduled.

B. Research Occupational Health Program (ROHP) Report

No report.

C. Environmental Health & Safety (EHS) Report

No report.
III. Protocol Review:

A. New Application Review

1. rDNA /Biohazard (Bhz)

<table>
<thead>
<tr>
<th>BUA</th>
<th>(PI)</th>
<th>Title</th>
<th>BSL</th>
<th>ABSL</th>
<th>Campus</th>
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</thead>
<tbody>
<tr>
<td>2355</td>
<td></td>
<td>Material transfer to NEIDL/BUMC</td>
<td>2</td>
<td>N/A</td>
<td>BUMC/ NEIDL</td>
</tr>
</tbody>
</table>

Primary Reviewer: Elke Muhlberger
Secondary Reviewer: Ron Morales & Carmela Abraham

Applicable NIH Guidelines: Section III-D-1-a and III-D-2-a
Protocol Expires: New Application

**Meeting Comments:**
The PI is a new faculty member at Boston University (BU). The purpose of this protocol is to obtain approval from the IBC to transfer research reagents from his former lab to BU. No experiments are being proposed at this time and an amendment will be submitted before experimental work begins. Members discussed the materials being proposed for transfer and the appropriateness of the space listed for storage. It was noted that the PI had indicated to SCP staff prior to submission that he is not planning to transfer any risk group 3 agents however, references to RG3 agents and plasmid clones remain in his application. The committee indicated that these materials must be removed from this protocol prior to approval. EHS staff noted the BUA Site Assessment identified additional rooms (not currently listed in the application) will also be used. Members stated that these rooms must be added if used. Members discussed that some of the agents (such as enterovirus EVD-68, Coxackievirus B3, and equine encephalitis virus) will need to be reviewed by the Laboratory Acquired Infection subcommittee.

**Changes/Clarifications Required:**
Research Laboratory Facility Information: Only room 502 is listed in Section IV. The protocol later states that material will be stored in room 511 and possibly the liquid nitrogen dewer in room 506, reconcile and add these two rooms to the list.
Research Project Description: Q2 Remove the reference to Yellow fever virus (YFV) vaccine strain as previously requested. Venezuelan Equine Encephalitis virus (which is a BSL3 select agent virus) must be removed from the scientific objective statement of this BSL2 protocol.
The list of materials to be transferred to BU lists a full-length clone for a YFV vaccine strain and a wild type Asibi strain. Remove these two materials from the list. Transfer of a full-length molecular clone of Yellow fever virus vaccine strain 17D would require validation of attenuation by PCR or similar method and IBC approval of the validation before it may be received in a BSL2 lab. Further, possession of a YFV Asibi strain would require BSL3 containment and an approved protocol. Prior to approval of this protocol, these plasmid reagents must be removed.
Hazardous Biological Agent (Section A): Add lentiviruses to the Hazardous Biological Agents list (BSL2). Remove nonpathogenic bacteria and purified proteins from the Hazardous Biological Agents list. Replace “Sedai virus” with “Sendai virus”.
Recombinant DNA (Section H): In the Applicable NIH Guidelines section it is written that section III-E-1 is applicable because “no more than two-thirds of the genome of any eukaryotic virus” will be used, whereas in response to the Eukaryotic experiments questions it is written that greater than 2/3 of the viral genome is present in the vector. Please reconcile.
Agent specific training may be required for the use of EVD-68, Coxsackievirus B3 or other highly pathogenic viruses.

**Biosafety Training:** All protocol personnel current with all required training

**BUA Site Assessment:** Approved

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

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

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### B. 3-Year Renewals

#### 2. rDNA/Bhz

<table>
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<tr>
<th>BUA</th>
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<th>BSL</th>
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<th>Campus</th>
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<tr>
<td>1737</td>
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<td>Hippocampal and Cortical Coding in Memory</td>
<td>2</td>
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<td>CRC</td>
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</tbody>
</table>

Primary Reviewer: Barbara Slack  
Secondary Reviewer: Erin Sawyer

**Applicable NIH Guidelines:** Section III-D-2-a, App. B-II-D, G-II-B  
**Protocol Expires:** 02/28/2019

**Meeting Comments:**  
The goal of this protocol is to delineate how a normal healthy brain develops memories and how behavioral adaptations impact stored memories. Researchers will artificially modulate expression of proteins that are either known to or suspected to affect memory development in specific regions of the brain. Adenovirus-associated viral vectors expressing those proteins under investigation will be injected in mouse brains in spatially and temporally selective locations. Effects of those expressions will be monitored by live imaging, electrophysiological measurements, and immunohistochemistry of brain slices from euthanized animals. The PI expects to gain insight on how behavioral and biological treatments could improve memory function.

**Changes/Clarifications Required:**  
**Overview and Grant Funding Information:** Remove text from the summarize changes box. This section is only for amendments and annual renewals. Also remove the checkmarks from the box above.  
**Research Laboratory Facility Information:** The Shared PI should be someone other than Dr. Hasselmo. Please revise.  
**Materials Used in Research:** Since AAV vectors are the only agents being used in animal work, the highest animal biosafety level for this protocol should be ABSL-1.

**Biosafety Training:** All protocol personnel current with all required training

**BUA Site Assessment:** Approved

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

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

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### 3. rDNA/Bhz
### iPS Cells: Novel Applications for Blood Bourne Disease

**Primary Reviewer:** Robin Ingalls  
**Secondary Reviewer:** Rao Varada  

**Applicable NIH Guidelines:** Section III-D-1-a; III-D-2-a, Appendix B-II-D, G-II-B  
**Protocol Expires:** 2/28/2018

**Meeting Comments:**
This protocol utilizes novel methods of making induced pluripotent stem (iPS) cells to study development of erythropoietic progenitor cells (blood cells). The long term goal is to be able to use these cells to develop cell-based therapies. As these cells can be generated from the patient’s own cells, there is no need to use embryonic stem cells as there would be no risk for rejection. They will use special approaches that they developed themselves to introduce cellular reprogramming genes Oct4, Klf4, Sox2 and cMyc via lentiviral vectors into both mouse and human blood cells. Pluripotency of these cells will be evaluated, which will then be allowed to differentiate into blood cells before being injected into an experimental mouse model. The PI is primarily interested in the development of megakaryocytes, which make platelets.

**Changes/Clarifications Required:**
- **Research Project Description:** Q3- The lab procedures section implies that the primary human blood cells are obtained from ATCC but in fact, they are derived from peripheral blood from human volunteers as described in “Other Potentially Infectious Materials”. Correct the statement in the research project description section appropriately.
- Be more specific and state which cells (iPS derived differentiated human or mouse cells or both) are being injected into the mouse for testing end stage differentiation.
- **PPE and SE:** Q1- Check animal handling and cage changing.
- **Other Potentially Infectious Material:** Clarify the patient population. If these are BMC patients, contact Hospital Epidemiologist Dr. Carol Sulis to clarify safe handling and transportation of patient samples to the research laboratory.
- Provide the current IRB expiration date.

**Biosafety Training:** All protocol personnel are current with all required training  

**BUA Site Assessment:** Approved  

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

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

### The Mechanism of Cancer Cell Growth, Metastasis and fetal globin gene

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<tr>
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<td>1702</td>
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<td>1049</td>
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<td>The Mechanism of Cancer Cell Growth, Metastasis and fetal globin gene</td>
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<td>2</td>
<td>BUMC</td>
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</table>
Meeting Comments:
This protocol has two specific aims. In one, the PI investigates the role of Sirt1 protein in cell migration and metastasis of prostate, breast, and lung cancers. Sirt1 is a histone deacetylase which is known to facilitate tumor development and its depletion by siRNA helps reverse the process. The PI investigates molecular players involved in the process and validates their findings in xenograft animal model studies. In the second aim, the PI investigates detail mechanisms of control of fetal hemoglobin gene expression. It has been demonstrated that some individuals who have sickle cell anemia may have better outcomes due to higher fetal hemoglobin expression. As fetal hemoglobin is not expressed in normal human adults and sickle cell patients have non-functional hemoglobin, artificial induction of fetal hemoglobin could be a novel therapeutic approach for sickle cell anemia. The PI investigates in this protocol if Sirt1 also plays a role in silencing fetal hemoglobin expression and if there are ways to abrogate such function. Several commercial human cancer cell lines and xenograft mouse models will be used in these projects.

Changes/Clarifications Required:
Personnel Information: C. Wilson must complete rDNA/IBC training. Since Y. Liu is no longer in the lab, remove her name from the list.
Research Project Description: Q3- Include a sentence that all experiments with lentivirus vectors will be performed in a biosafety cabinet.
The 30 minutes of UV lighting (to destroy DNA) should be added to the BSC decontamination procedure stated, not just 70% EtOH before and after use.
Decontamination of hoods in W834 (a ABSL2 housing room) is done with Rescue, chlorine dioxide, or quatricide, not 70% ethanol. Please revise.
PPE and SE: Q4- PPE requirement have changed for the W834 ABSL2 housing room. Unless this project has specific requirements otherwise, PPE now consists of booties, lab coat/gown, hairnet, surgical mask, Tyvek sleeve covers and double gloves when manipulating animals, and double gloves. N95s and back-closing gowns are no longer standard requirements. Please update.
Q5-Please include detail of the BSC and update the certification date.
Recombinant DNA (Section H): Add the name of the retroviral vector (pSUPER) in the ‘Virus Packaging System’ box.

Biosafety Training: All protocol personnel are not current with all required training
BUA Site Assessment: Approved
Motion: Conditional Approval (Administrative Review)
For: 17
Against: 0
Abstain: 0

IV. Approved Expedited Amendments & Annual Renewals (Administrative Review)

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<tr>
<th>BUA ID</th>
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<tr>
<td>1470</td>
<td>Mechanisms of metastatic melanoma phenotype development</td>
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<td>To add one personnel</td>
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<tr>
<td>487</td>
<td>Initiation and regulation of RSV mRNA transcription and genome replication (NIH) Development of an in vitro assay for paramyxovirus polymerases (Alios BioPharma) A structure analysis of the intact virion and replicative complexes of human respiratory syncytial virus (MRC, UK) Treating respiratory syncytial virus infection by targeting the viral polymerase (The Hartwell Foundation) Development of a non-radioactive assay for the RSV polymerase (Merck) The B cell repertoire as a window into the nature and impact of the lung virome (NIH)</td>
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<td>N/A</td>
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<td>1409</td>
<td>Replication and Transcription of Filoviruses Early Host Immune Response in Protection against Filovirus Infection</td>
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<td>In vitro studies of the amyloidogenic natures of transthyretin and immunoglobulin light chain proteins</td>
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<td>The Role of Interferon Regulatory Factor 5 in the Pathogenesis of SLE</td>
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<td>650</td>
<td>Growth of laboratory-adapted, vaccine and wild-type negative strand RNA viruses (NSRVs), expression of virus proteins and generation of recombinant laboratory-adapted, vaccine and wild-type negative strand RNA viruses</td>
<td>2</td>
<td>2</td>
<td>To remove two personnel, change lab safety coordinator, and add a shared room</td>
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<tr>
<td>2012</td>
<td>1. Phase 2, Multi-Center Trial of Lorcaserin in the Treatment of Cocaine Use Disorder 2. Lacosamide effects on alcohol self administration and craving in heavy drinkers 3. The Effects of Exenatide, a GLP-1 Agonist, on Alcohol Self-Administration in Heavy Drinkers</td>
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<td>N/A</td>
<td>To remove two and add two personnel and extend approved clinical studies with another drug</td>
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<td>Virus - Host interactions during HIV-1 pathogenesis</td>
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<td>1729</td>
<td>Role of protein ubiquitination in angiogenesis</td>
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<tr>
<td>1340</td>
<td>Neuromodulation and Cortical Memory Function</td>
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### Annual Renewals

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<tr>
<td>645</td>
<td>A) Calcium Influx Factor B) Ion Channels and calcium regulation C) Store-operated calcium entry and PLA2g6 in health and disease</td>
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<td>2</td>
<td>To add two and remove three personnel, and update contact information and funding source</td>
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<td>1367</td>
<td>L2pB1 cell and its natural antibody in health and disease</td>
<td>2</td>
<td>2</td>
<td>To remove one personnel, update funding source, and remove animal handling</td>
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<td>602</td>
<td>Plasma Amyloid-Beta Peptides, Depression and Alzheimer's Disease in the Homebound Elderly: Name Longitudinal Study of a Subset</td>
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<td>1</td>
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<tr>
<td>1248</td>
<td>The pVHL/Jade-1/beta-catenin axis in renal cancer; Polycystin, Jade-1 and beta-catenin in cystic kidney disease; Transcription factors in renal disease and renal development</td>
<td>2</td>
<td>2</td>
<td>To add two and delete one personnel and update BSC expiration date</td>
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<td>Early diagnostics and therapeutics for Neurodegenerative diseases</td>
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<td>Defining novel pathways that arrest genetically unstable tetraploid cells</td>
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<td>N/A</td>
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<td>1484</td>
<td>Innate and Adaptive Immunity to Viruses</td>
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<td>N/A</td>
<td>To delete NEIDL laboratory research room and update shared laboratory space</td>
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<td>2264</td>
<td>R01 project (R01AA025080): Brain microRNA-mRNA regulatory networks and alcohol use disorders. R21 project (R21AA023068): Salivary MicroRNAs as Biomarkers for Alcohol Dependence</td>
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<td>To add one and remove one personnel, to update laboratory room from &quot;310&quot; to &quot;315&quot;, to add the Analytical Instrumentation Core</td>
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<td>N/A</td>
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<td>Molecular Biology of Melanoma</td>
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<td>Gene regulation in muscle development</td>
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<td>Development of Klotho enhancers as novel therapeutics for AD</td>
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<td>Metabolic cooperation in natural and synthetic microbial consortia</td>
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<td>To add one personnel and update laboratory location</td>
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</table>