This meeting is open to the public.

Members Present: R. Ingalls (Vice-Chair), J. Barton (arrived at 12:12 PM, left at 1:10 PM), P. R. Varada, E. Sawyer, I. Afasizheva, J. Keeney, B. Slack, R. Georgiadis (by phone at 12:31 PM), E. Loechler (by phone at 1:11 PM), C. Abraham, C. Sulis, R. Morales, T. Winters, R. Timmerman, E. Muhlberger

Guests Present: M. Auerbach (by phone), G. Madico, T. Killeen, N. Yun, J. Connor, N. Dey

Staff Present: S. Ghosh, A. Gibson, J. Hutchinson

Members Absent: X. Brown, K. Tuohey, V. Britton

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 October 2018 Meeting Minutes

The committee was informed of a correction to the October 16, 2018 IBC meeting minutes. For protocol 2345, the following statement was included: “In addition add the following, liquid waste shall be treated to a final concentration of 10% bleach”. This was not discussed at the meeting and should not have been included in the minutes of the meeting.

Motion: Approve as corrected
For: 12
Against: 0
Abstain: 0

II. New Business

A. Safety Committees Report:

Approved Applications/Amendments
Since the October 2018 IBC meeting, 1 new protocol, 6 three-year renewals, 11 amendments and 15 annual renewals have been approved.

B. Research Occupational Health Program Report:
On 10/30/2018, an animal care technician was scratched by a NHP. As the technician tried to change out a grate, the NHP reached through the cage, scratching the technician. The clinical veterinarian reported that the NHP has had no known exposure to biologics or other hazardous agents. The technician is currently being followed by ROHP for treatment of a potential Herpes B exposure. This incident was reported to BPHC.

On 11/6/2018, a PhD student cut her left thumb while wiping off a scalpel blade used on formalin fixed human tissue embedded in paraffin sustaining a “paper cut” wound. This incident is not considered a blood borne pathogen exposure due to the tissue being formalin-fixed for greater than four months. She was evaluated and treated by ROHP.
C. Environmental Health & Safety Report:
For the 10/30/2018 incident, it was noted that the technician was wearing appropriate PPE. The root cause was lack of awareness of procedure, it was reported that the technician is new. To prevent recurrence, the animal care technician will completely remove the grate and pan before attempting to remove organic matter. This will assure that the technician is not in reach when this task is being completed. The technician was retrained on this procedure by his supervisor.

For the 11/6/2018 incident, EHS’s investigation is not complete.

SCP and EHS staff reported receiving clarification from S. Botch, per the action item identified at the September IBC meeting, that the use of human blood is covered under a collaborator’s protocol (1490).

It was reported that the CDC was onsite November 5 - 9 for an inspection, minor findings are being addressed. BU is pursuing CDC approval to conduct BSL-4 animal work.

III. Protocol Review:

A. New Applications

1. 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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<tr>
<td>2352</td>
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<td>Propagation and characterization of viruses</td>
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<td>BUMC/NEIDL</td>
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Primary Reviewer: Elke Muhlberger
Secondary Reviewer: John Connor
Additional Reviewers: Ron Morales
Nadya Yun
Guillermo Madico
James Keeney
Robert Timmerman

Applicable NIH Guidelines: N/A
Protocol Expires: New Application

Meeting Comments: The PI is interested in understanding the biology of viruses to facilitate the development and licensure of therapeutics and vaccines. The PI focuses on viruses that cause severe disease and require BSL-4 containment, such as filoviruses, arenaviruses, bunyaviruses and flaviviruses that are associated with a variety of hemorrhagic fever diseases. Amplification of the virus is a necessary step to generate sufficient experimental material yielded from grown virus stocks. Virus stocks are interrogated to confirm that they have the characteristics needed for downstream studies. The protocol also serves as second-site verification for testing inactivation of BSL-4 material for American Type Culture Collection (ATCC/BEI Resource). Safety testing will involve two serial passages of material on cultured cells, followed by microbiological and immunological testing to ensure virus inactivation. It was noted that PI is very experienced, as are the personnel listed. ROHP has developed Agent Information Sheets for all agents and will coordinate agent specific training prior to conducting work. Reviewers recommended that the protocol reference established BSL-4 SOP’s as applicable including transport and receipt. Members discussed that it may be helpful to add checkboxes or template language in RIMS for BSL-4 protocols based on established SOP’s. It was noted that no animal work can be conducted under this protocol as BU does not currently have approval to conduct animal work in BSL-4 containment. The primary reviewer questioned whether the quantification of viral particles would produce aerosols and that a SOP should be provided.
A member questioned if a higher concentration of Microchem-Plus (10%) would be a more effective disinfectant, it was noted that 5% Microchem-Plus is the appropriate concentration. It was noted that one hour is sufficient for autoclaving solid waste. For use of inactivated materials, this section of the protocol needs to be completed and supporting documentation including certificates of inactivation provided. No DURC concerns were voiced. In response to a member’s request for clarification, EHS staff at the NEIDL indicated that BPHC is notified 30 days prior to shipment of materials. It was noted that no materials will be leaving BSL-4 containment.

Changes/Clarifications Required:

Research Project Description:

Q2- 1. Describe in more detail what will happen to the agents once they have been received by the NEIDL and include who will be receiving the shipment, referencing established SOP’s as applicable.

Q3- 1. Indicate if aerosol formation is a concern in the Virocyte particle counter and whether a SOP describing the use of the Virocyte particle counter has been developed.

2. It is indicated that culture stirrers and shakers will be used in the BSL-4 lab and that plating and colony counting are performed. Describe these procedures and the safety measures in more detail and clarify if a SOP has been developed describing the use of stirrers and shakers.

3. Describe in more detail the storage and inventory procedures in the laboratory.

4. Clarify where plaque assay will be done and if the BSC will be used.

5. Clarify if centrifugation will be done and if so, describe precautions taken.

6. Revise to indicate that the amplified virus stock samples will also be included in the agent inventory.

7. Amend the following in describing liquid and solid waste handling procedures to reflect the current BSL-4 SOP’S. The committee suggested the following edits:

a) “Liquid waste is handled in the BSC and dispensed into a Microchem-Plus solution. The final Microchem-Plus concentration must be at least 5%. The container is let to stand overnight (at least 12 hours) and then the mixture is disposed of down the sink”.

b) “Solid waste that was in direct contact with infectious material (pipette tips, pipettes, tubes, tissue culture vessels) will be submerged in containers filled with Microchem-Plus (final concentration at least 5%). After overnight incubation, the solid materials will be separated from the disinfectant and autoclaved.

Solid waste that was not in direct contact with infectious material (gloves, paper towels) will be collected inside the BSC in containers lined with an autoclave bag. The bag will be sprayed down prior to removal from the BSC, placed into a waste collection container outside of the BSC double-lined with red bags and autoclaved”.

PPE and SE:

Q1- Check “Vortexing” if samples will be vortexed.

Q7A and 7B- Amend the following in describing liquid waste handling procedures to reflect the current BSL-4 SOP’S as stated above.

Q10- 1. Please remove the reference to storage of virus stock in liquid nitrogen in room 215 as there is no liquid nitrogen facility there.

2. Clarify what types of tubes aliquots will be stored in.

Q11- 1. Remove, “using Eppendorf tubes” and indicate storage in gasket-sealing shatterproof vials. Describe how samples will be transported inside the BSL-4 laboratory.

2. Include language that the removal of inactivated materials will follow the Inactivation Plan approved by the RO and accompanied with certificates of inactivation.

Materials Used in Research: Select the N/A as the highest animal biosafety level.

Hazardous Biological Agent (Section A):

1. List all Ebola virus species separately.

2. Add Vero cells or any other NHP cells and any human cell lines in use.


4. Spell out the acronyms “HP” and “AP” for Ebola viruses.

5. Clarify if Nipah and Hendra complex viruses are a single virus species or are two different virus species as is commonly known.
6. Remove references to animal work with Ebola and Marburg virus in section A.4 as ABSL-4 level animal work is currently not permitted in the NEIDL.

Inactivated Biological Samples (Section I): For use of inactivated materials, please complete this section of the protocol and provide supporting documentation including certificates of inactivation.

**Biosafety Training:** The PI and laboratory staff need to complete agent specific training before starting work.

**BUA Site Assessment:** Approved.

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

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<tr>
<th>For</th>
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B. 3-Year Renewals

2. Bhz/rDNA

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<tr>
<td>2092</td>
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<td>Analysis of small RNA processing during vertebrate embryogenesis</td>
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Primary Reviewer: Barbara Slack
Secondary Reviewer: Erin Sawyer

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

**Protocol Expires:** 12/18/2018

**Meeting Comments:** The PI is interested in how the different stages of embryogenic development are controlled. Specifically, how microRNA processing impacts vertebrate embryogenesis and the dynamic role of RNA-binding proteins during development. Most of the experiments will be performed in zebrafish. Embryos will be microinjected with messenger RNA coding for wild type or mutant RNA-binding protein. Molecular analysis of the development of these diverse sets of fish embryos to adult fish will be utilized to test research objectives. CRISPR technology and lentiviral vectors will be used in some experiments to make specific mutations of certain genes. It was noted that waste disposal is well described.

**Changes/Clarifications Required:**

- Research Project Description: Q3- Provide the IACUC protocol number for the currently approved protocol.
- PPE and SE: Q5- Update the BSC certification date.
- Hazardous Biological Agent (Section A): Since lentCRISPRv2 is being used in fish embryos, update the ‘Live Animals With Agent’ question with the currently approved IACUC protocol.
- Recombinant DNA (Section H): Update the IACUC protocol in the animal experiments section.

Update the applicable NIH Guidelines section in Q19 to “Section III-D-1-a; III-D-2-a, Section III-E-1”.

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

**BUA Site Assessment:** Approved.

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

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3. Bhz/rDNA

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</table>
Deregulated miRNA Expression in Bipolar Disorder

Primary Reviewer: Inna Afasizheva
Secondary Reviewer: Robin Ingalls

Applicable NIH Guidelines: Section III-E-1; Appendix G-II-B

Protocol Expires: 12/11/2018

Meeting Comments: The protocol focuses on regulation of gene expression by micro RNA interference (RNAi) in the brain. In particular, they study RNAi influence on development of the cortical cells following reduction of the number of surrounding nerves glial cells. It has been shown that overexpression of miRNA-149 leads to reduction of the glial cells in the brain of Bipolar Disorder patients and they propose to use the established rat model of depression to study the mechanism. Members discussed that it is not clear if the PI intends to conduct work in animals at this time. Additional details are needed throughout the protocol if animal work will be done. If the PI does not intend to conduct animal work at this time, these references should be removed from the protocol. EHS indicated that the biosafety cabinet needs to be certified and that they will review the revised submission to determine if the decontamination procedures are appropriate for surgical instruments.

Changes/Clarifications Required:

Research Project Description:
Q2- Clarify the work you intend to conduct with human brain tissue.
Q3- 1. Describe the work that will be done in rats. If animal work will not be conducted, this language should be removed from the protocol.
   2. Describe in detail the PPE that will be worn during animal work.
   3. Describe in detail the utilization of human tissue and cleaning of the environment.
   4. Describe the process for pre-screening non-fixed human samples for prions and infectious disease.
   5. Describe the work that will be done with AAV and rodent neurons that is listed in the biohazards table and in the rDNA section. If this work will not be conducted, it should be removed from the protocol.
   6. Include the currently approved IACUC protocol number.
   7. For pathology, describe in detail the decontamination procedures.

PPE and SE:
Q1- Check all animal laboratory procedures that have the potential to produce aerosols if rats will be used.
Q4- Check the PPE that applies to your proposed work with animals.
Q5- Update the BSC certification date.
Q7B- Include the following statement “leftover human tissue will be placed in boxes marked for incineration.”

Materials Used in Research:
1. Select the highest animal biosafety level for your work. Check “Live Animal Use”.
2. Contact the hospital epidemiologist C. Sulis with respect to the use of unfixed human brain samples obtained from brain banks (at BMC, MGH and in Europe).
Recombinant DNA (Section H): If rDNA work is being done, please update the applicable NIH Guidelines section in Q19 to “Section III-E-1 and Appendix G-II-B”.

Biosafety Training: The PI needs to complete Laboratory Safety Training.
BUA Site Assessment: Biosafety Cabinet certification expired. EHS needs to recheck the decontamination procedures after the revised submission is received.
Motion: Conditional Approval (Primary and Secondary Member Review).

For: 14
Against: 0
Abstain: 0

4. Bhz
Primary Reviewer: Rosina Georgiadis
Secondary Reviewer: Ed Loechler

Applicable NIH Guidelines: N/A

Protocol Expires: 12/01/2018

Meeting Comments: The PI is interested in the structure of human blood vessels at a microscopic level with the goal of identifying fine structures and biochemical compositions of the vessel membrane that contribute to the stiffness of the vessel wall. Specifically, the PI is interested in the structural differences between normal and diabetic individuals to identify contributing factors for blood vessel stiffness in those patients. The lab receives unfixed arterial tissue from the National Disease Research Interchange and from collaborators at the Boston University Alzheimer’s Disease Center. All tissue samples are mechanically tested using a biaxial tensile tester. In other experiments, collagen and elastin compositions of the tissues are measured. Additionally, small sections of tissue are fixed in 10% formalin and shipped to Mass Histology for Movat staining and then slides are returned for observation under a microscope. The committee discussed the guidelines for the disposal of human tissue. Human tissue wastes must be discarded in dedicated biohazard boxes marked specially for incineration (in small pieces that fit in the boxes). Disposal of such boxes should be coordinated promptly through EH&S.

Changes/Clarifications Required:
PPE and Safety Equipment:
Q7A- Remove the description of solid waste disposal procedures.
Q7B- There is no need to disinfect solid waste with 70% ethanol or 10% fresh bleach prior to disposal in red biohazard waste boxes.

Agreement Policy: Check the last box regarding ROHP clearance requirement.

Biosafety Training: The PI’s Laboratory Safety Training needs to be updated.

BUA Site Assessment: Approved.

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

5. Bhz

Primary Reviewer: Carmela Abraham
Secondary Reviewer: Ron Morales

Applicable NIH Guidelines: N/A

Protocol Expires: 12/18/2018

Meeting Comments: The PI is interested in the pathophysiology of health problems associated with preterm birth. This protocol will study the production of cytokines and interferons by the placental cells and associated functional changes brought to those cells. Unfixed human placental tissues and cells derived from those tissues from first to second trimester terminations will be used in the study. Formalin-fixed placental tissues will be
used for histology and analysis of DNA and RNA, whereas fresh frozen unfixed tissues will be used for cell isolation and functional analysis. Placental tissues are obtained from Boston Medical Center through IRB approved studies of the PI and her collaborators. The protocol clearly describes the laboratory procedures for isolation, purification and culture of placental cells. Analysis of relevant immune receptors is also described. The PI communicated with hospital epidemiologist C. Sulis to address BMC infection control issues. Clarification was provided that the current version of the protocol no longer includes any work with Chlamydia.

**Changes/Clarifications Required:**
Research Project Description:
Q3- Please clarify whether a cryostat or a microtome is being used for tissue sectioning.

**Biosafety Training:** Dr. Pudney’s Laboratory Safety Training needs to be updated.

**BUA Site Assessment:** Approved.

R. Ingalls recused herself from the vote.

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

**For:** 13  
**Against:** 0  
**Abstain:** 0  
**Recuse:** 1

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

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<th>Amendments</th>
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<td>NEIDL Pathology Collaborative Service</td>
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<td>Single Neuron Mechanisms of Sensory-Motor Learning</td>
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<td>Replication and Transcription of Filoviruses Early Host Immune Response in Protection against Filovirus Infection</td>
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<td>Development of Tissue Engineering Solutions for Pediatric Vascular Surgical Repair and Reconstruction</td>
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<td>2332</td>
<td>Investigations of negative-strand virus and alphaherpesvirus biology</td>
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<td>1643</td>
<td>Mechanisms of Autoimmune Disease</td>
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<td>Longevity and endoplasmic reticulum stress resistance</td>
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<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</td>
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<td>1) Exosome Pathway as a Novel Therapeutic Target of Tauopathy, 2) Exosome-mediated propagation of pathogenic tau protein, 3) Microglia and Exosomes in Tauopathy Development, 4) Development of New PSP Mouse Model, 5) Evaluation of STX6 Silencing on the Novel AAV-Based PSP Mouse Model, 6) Novel TREM2 Reporter Platform for Drug Discovery, 7) Characterization of Microglial Wnt signaling in maternal immune activation-related autism, 8) Proteomic and RNA profiling of Exosomes in CTE biospecimens, 9) Targeting the miR-155 and APOE-TREM2 pathways to restore dysfunctional microglia in Alzheimer’s disease</td>
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**Annual Renewals**

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<td>1) Exosome Pathway as a Novel Therapeutic Target of Tauopathy, 2) Exosome-mediated propagation of pathogenic tau protein, 3) Microglia and Exosomes in Tauopathy Development, 4) Development of New EW PSP Mouse Model, 5) Evaluation of STX6 Silencing on the Novel AAV-Based PSP Mouse Model, 6) Novel TREM2 Reporter Platform for Drug Discovery, 7) Characterization of Microglial Wnt signaling in maternal immune activation-related autism, 8) Proteomic and RNA profiling of Exosomes in CTE biospecimens, 9) Targeting the miR-155 and APOE-TREM2 pathways to restore dysfunctional microglia in Alzheimer’s disease</td>
<td>2</td>
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<td>To add LPS to the high hazard chemical list</td>
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of Microglial Wnt signaling in maternal immune activation-related autism, 8) Proteomic and RNA profiling of Exosomes in CTE biospecimens, 9) Targeting the miR-155 and APOE-TREM2 pathways to restore dysfunctional microglia in Alzheimer's disease

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<td>Epithelial Stem Cells in Homeostasis and Diseases</td>
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<td>840</td>
<td>Molecular Genetics Core Facility</td>
<td>2 personnel</td>
<td>To update shared laboratory space</td>
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<td>2152</td>
<td>A Rapid and Sensitive Antibiotic Susceptibility Test for Urinary Tract Infections</td>
<td>2 personnel</td>
<td>To add one and delete three personnel and update funding source</td>
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<td>1957</td>
<td>Longevity and endoplasmic reticulum stress resistance</td>
<td>2 personnel</td>
<td>To delete one personnel</td>
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<td>Plasmid &amp; virus construct preparation and use for studies on the regulation of skeletal muscle wasting and pathology</td>
<td>2 personnel</td>
<td>No changes</td>
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<td>1820</td>
<td>NIH R01 EB00262 Local regulation of angiogenesis by microenvironmental cues; NIH R01 EB008396 Engineering Multicellular Tissue Structure, Function, and Vascularization; NIH R01 HL73305 Stiffness, Cadherins, Integrons, and Mechanosodium Signaling; NIH UH2 EB017103 Integrated Heart-Liver-Vascular Systems for Drug Testing in Human Health and Disease; NIH R01 Mechanoelectrical interactions between cardiac myofibroblasts and myocytes; NIH &quot;Building a Human Adipose Depot&quot; Pilot Program: Engineered human fat depots on a chip HFSP Architecture/force relationship and migration mechanics of macrophage podosomes; NIH ApoE Arterial Biomechanics and Cardiovascular Disease; NSF Collaborative Research: The Effects of Extracellular Matrix Alignment of Cellular Mechanotransduction in 3D Architectures; PharmAkea Evaluation of LOX(L) Family Inhibitors on Matrix Remodeling in an Engineered 3D Microtissue Mechanical Testing</td>
<td>2 personnel</td>
<td>To update shared equipment and room locations, to add two and delete two personnel</td>
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<td>Empirical and computational analyses of striatal MSNs and FSIs and of L5 CPNs in the Q175 and DN17 models</td>
<td>1 personnel</td>
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<td>Genome Analysis Based on the Integration of DNA Sequence and Shape; Chemical Probing of RNA Tertiary Structure in a Whole Transcriptome at Single-Atom Resolution</td>
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<td>Repeat-containing RNA Binding Proteins of Trypanosomes</td>
<td>N/A</td>
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<td>2247</td>
<td>Mechanisms of Extinction Memory Enhancement for Cocaine Addiction Treatment</td>
<td>2 personnel</td>
<td>To add one personnel</td>
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<td>Liver development and regeneration</td>
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<td>To add two personnel and add Proteomics Core</td>
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<td>2 N/A</td>
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<td>Innate Immune Responses to Neisseria and Chlamydia; Role of the Innate Immune System in Pathogen Induced Chronic Inflammation</td>
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<td>897</td>
<td>Ah Receptor, Androgen Receptor and Estrogen Receptor: Controlling Receptor Activation and Breast Cancer Growth</td>
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