Meeting Agenda

Location: Evans 720

August 13, 2013

Start time: 12:03 PM

End time: 3:00 PM

Present: A. Henderson, W. He, J. Barbercheck, T. Winters, C. Sulis, J. Levin, S. Ghosh, F. Gibson, E. Helmerhorst, K. Kirsch, E. Muhlberger, B. Slack, D. Stearns-Kurosawa (Left 2:50PM), R. Timmerman, J. Keeney, N. Bhadelia (Arrived 2:00PM)

Absent: K. Tuohey, R. Morales, R. Ingalls, R. Georgiadis, J. Gonsalves, N. Broude, J. Barton

Guests: P. Duprex (Arrived 12:25 PM; Left 1:00PM), S. Morash (Left 12:50PM), S. Butler, S. Reno, A. Lanoue, S. Mahida,

Staff: E. Ward

I. Review of July Minutes

Recommendation: Approve
For: 15
Against: 0
Abstain: 0

II. New Business

A. IBC Training Session:

1. Review of Emergency Response Plan for Animals

The Director of BU Lab Animal Services provided the committee with an overview of the updates to the Emergency Response Plan for Animals. These changes are in response to the new federal OLAW guidelines. The changes were a result of concerns that arose during Hurricane Sandy. The changes will go in effect in September and make BU compliant. The Director would like to have IBC members input on biological priorities.

2. Q & A with an IBC Principal Investigator

Dr. Paul Duprex has been at BU for over three years and has an extensive IBC application to cover the use of multiple viruses. The PI is interested in looking at virus as a coin with two sides. Side 1 - Are the vaccines we have effective? Side 2 - The flip side is trying to understand attenuation. The PI discussed his work with the committee including clarifying how recombinant virus swapping works. More on the PI's work is available online in a mini-series called "This Week in Virology."

B. Chairperson Report – *Nothing to report*

C. Technical Committees Report

Approved Applications/Amendments:

This month, 12 applications and 12 amendments and renewals were approved.

D. Biosafety Report:

1. Research Occupational Health Program Incident Report

No incidents involving biological agents this month. The Y. pestis agent specific training has been completed.

2. Updates from Environmental Health & Safety – *Nothing to report*

III. Protocol Review:

Meeting is not closed

A. New Submissions

1. Protocol 1814

"Development of Novel Field-Appropriate Differential Diagnostics of Multiple Pathogens and Their Drug Sensitivities Based on PNA-RCA Method and DNA Aptamer Biosensors."
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: The goal is to develop a new test to help doctors rapidly diagnose serious foodborne disease. This test detects bacteria that cause severe diarrhea, fever, and other symptoms after someone eats or drinks contaminated food or water. The test will detect the presence of these foodborne bacteria in stool samples from sick people. It is important to our public health to diagnose sick people quickly before they can expose other people to disease without realizing it.
Meeting Comments:

- This is a protocol from a new PI in the College of Engineering. The application is to use technology where peptides are used in bacteria to detect particular pathogens in samples. They will test this using DNA in bacteria and then spike stool samples with a variety of BSL-2 bacteria for testing.
- The biosafety risk is BSL-2, human discarded samples, and the transport of DNA, culturing and spiking risk.
- One of the community members had concerns about the safety of transporting samples from BUMC to CRC. The Biosafety Officer confirmed that the packaging and method of transport is appropriate for the materials.

The PI needs to:

- Please clarify and better define what PNA-RCA method is.
- This is a hospital based project as it uses discarded human samples from BMC. Please indicate this on the Materials Used in Research section and contact the BMC Epidemiologist.
- Please specify where you will be growing bacteria. And make sure to list the people in the clinic who will be doing the cultures.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

2. Protocol 1825

"Defining novel pathways that arrest genetically unstable tetraploid cells."
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: The vast majority of human cancer cells are aneuploidy, meaning that they possess a different number of chromosomes than normal, healthy cells. Because abnormal chromosome numbers can be detrimental to cell growth, cancer cells have been forced to adapt to this genetic defect. This proposal is focused on identifying those adaptations, with the long term goal of specifically targeting them with new anti-cancer therapies.
Meeting Comments:

- This is an application from a new recruit to BU. The PI is interested in understanding aneuploidy. The overall goal is to better understand how cells recognize aneuploidy and use this in cancer treatments. The project will involve live cell imaging at different stages of cell division.
- The primary reviewer sent the PI a number of comments prior to the meeting including: editing the project description to be more specific, detailed and to link it to the procedures. The PI promptly replied and was responsive to all requests. The PI made all changes prior to the meeting.

ROHP & LST: Complete for all personnel.
Recommendation: Approved
For: 15
Against: 0
Abstain: 0

3. Protocol 1758

"Targeting candidate genes for drug addiction in mice"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 1
Campus: BUMC
Layman's Description: The goal is to create mice that will be used to validate candidate genes that we previously identified in a genetic screen for sensitivity to drugs of abuse, including psychostimulants and opioids. Validation of these candidate genes will lead to further characterization of the neurobiological mechanisms by which genetic variation affects behavior and could lead to the development of novel therapeutics for preventing and treating addiction to drugs of abuse.
Meeting Comments:

- This PI is interested in addiction and genes that potentially regulate addiction. The project involves rDNA work using AAV at BSL-1 as well as deleting genes using a new technique that is designed to cleave out particular genes.
- The project will also use a mouse model. The project also proposes making transgenic animals; however, there are not enough details of this part of the project. It seems like it might be a future project. If this is the case, it should be removed and added via amendment when they are ready to conduct these experiments.

The PI needs to:

- Remove the mouse cell lines and bovine serum as these are not considered biohazards.
- Please provide more details and clarifications on decontamination.
- Please confirm that you are using a biological safety cabinet and not a fume hood.
- Remove that sharps will be autoclaved and update the PPE that will be worn in the lab as discussed with EHS.

- Provide more details on the transgenic animals or remove and add via amendment when this part of the project is ready to begin.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

B. 3-year Resubmissions

4. Protocol 714

"Myokines and the Cardiac Secretome in Patients with Heart Failure (previously called ROS in heart family patients)"
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: The Project is to identify molecules in the blood that can be used to assist diagnosis and treatment and improve prognosis.
Meeting Comments:

- The PI is interested in correlating biomarkers with heart conditions. The project will involve a blood draw, transportation of the materials and analysis using ELIZA.
- The community member had no safety concerns.

The PI needs to:

- Complete the transportation section.
- This is a hospital based project as materials are collected at BMC. Please indicate this on the Materials Used in Research section and contact the hospital epidemiologist.
- Please clarify how the urine will be used in the lab procedures section or remove it from the Other Potentially Infectious Materials section.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

5. Protocol 608

"The Role of Macromolecular Assemblies in Poliovirus Replication"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: When a person is infected with poliovirus, the membranes inside the infected cells undergo dramatic changes. These changes are important for the poliovirus to make additional copies of its gene, and then package these genes in to new virus particles. The proposed studies will improve our understanding of the cellular changes that occur in infected cells, with the aim of discovering new ways to stop the viral infection. We plan to stop viral infections by disrupting the viruses' ability to alter the cellular membranes.
Meeting Comments:

- This is a straight forward protocol looking at the arrangement of the cell membranes during infection with the Poliovirus.
- The PI is in biophysics and a few members raised concerns about the PI's experience with viruses. The chair reminded the committee that the PI trained

under a collaborator three years ago when this project was first reviewed by the IBC, and now has 3 years' experience. This satisfied the concerned members.
- The description of virus inactivation was detailed nicely. The reviewer had a question regarding the use of 70% ethanol instead of bleach. But after some research the primary reviewer found that other polio researchers use this method.
- All personnel have received agent cards from ROHP.

The PI needs to:
- Remove mention of using radiation to disinfect as this is not standard procedure.
- Correct a few administrative details.
- Remove animal use or describe how animals will be used.
- Clarify who is actually doing the biohazard work. And make sure to complete the infectious agents training for all individuals working with these agents (currently only one person has experience listed).
- Please state if you will be importing polio, as transportation of this agent requires CDC/USDA permits, or state that all samples have already been transported to BU.

ROHP: Still working with one individual.
LST: Complete for all personnel.
Recommendation: Approved Pending
For: 14
Against: 0
Abstain: 1

6. Protocol 734

"Neurogenetic Processes in the Fetal Neocortex"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 1
Campus: BUMC
Layman's Description: These experiments will determine the role of gene and protein signaling in brain development and function. Knowledge about the basic development biology of the brain is gathered. Brain development Down syndrome is also measured in mouse models of the disorder.
Meeting Comments:
- This protocol is interested in the role of gene and protein signaling in neurological disorders. The project uses mouse models. There is mention of use of human cell lines, but this is not clear. More information will need to be provided.
- Overall, this is a straight-forward protocol with no major concerns. The PI needs to provide some more clarification throughout the protocol to just clear things up.

The PI needs to:
- Correct administrative items (i.e. lab coordinator information, change the anticipated starting date, typos, etc.).
- Please provide a title for all personnel (i.e. Associate Professor, post-doc) and make sure to answer "state how many years of experience, when and where" for all personnel.
- If human cells (HOG) are being injected into mice please describe the procedures here. If not, please remove in all other places. If human cells are being introduced into mice, these mice will be treated under ABSL2 please change.
- Please remove the amendment information and incorporate into the maneuver section of the experimental procedures are still required for this application.
- The Transgenic mice listed in this section are not described in the maneuver section. Please include a description in the maneuver section of the experiments that will be performed with these animals.

- In the PPE section, check surgical mask, update BSC certification date, add to the disinfection of surgical instruments and provide more information on biohazardous materials storage.
- Under Materials Used in Research, please check box for Live Animal Use and change to BSL-2 as human cells will be used.
- In Hazardous Biological Agents, change the ABSL to 2 instead of 1 if human cells will be used in animals.
- In the Recombinant DNA section, please list all of the vectors that will be used for prokaryotic and animal experiments.
- Update the Boston Public Health Commission form to match the rest of the application.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

7. Protocol 709

"Neuroimmunomodulation within the Eye"
Category: Bhz/rDNA
Biosafety Level: 1
Animal Biosafety Level: 1
Campus: BUMC
Layman's Description: Over 2 million American will suffer from inflammation within the eye this year. Many will impair sight and some will go blind. Current medications are only for short term use and can cause many other health problems. Also, the medications do not stop what causes the disease. We are working on the best way to make active within the inflamed eye a pathway that naturally stops the causes the disease. We hope that this will stop and permanently protect the eye from inflammation, and save sight.
Meeting Comments:
- This project is looking at a mechanism responsible for protecting neuro- peptides.
- Animal mouse model,
- This is a very straight forward protocol using standard procedures and an animal mouse model. There are no major red flags. The PI does need to address some housekeeping items and add some more clarification.

The PI needs to:
- Please provide a title (i.e. Associate Professor, Post-doc), a descriptive role (i.e. PI, research technician) and answer "state how many year's experience, when and where" for all personnel.
- In the lab procedures description of the subconjunctival injection of his expression plasmid into the mice, the PI indicates he will use a single use syringe and needle. Please clarify how the syringe is filled safely, whether a luer lock syringe is used to mitigate the risk of creating aerosol, and if the injections are done in a hood or in the open with appropriate protection. Please clarify how animal carcasses are bagged and stored until disposed of by LASC.
- In the Materials Used in Research, please select BSL-2 for the highest BSL required for this project, check box for Hazardous agent and provide information for that section and check box for Live Animal Use
- Please complete the Hazardous Biological Agents section.
- Please update the Boston Public Health Commission form to match the rest of the application.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15

Against: 0
Abstain: 0

8. Protocol 725

"Gene expression and cell analyses in systemic sclerosis."
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: We will take skin and blood sample from patient with systemic sclerosis to identify alterations in level of factors in the circulation or in the way that cells from these patients are regulate. Once we identify these alterations we will try to understand what causes these changes by treating cells from these patients in culture with factors that people might be normally be exposed to as consequence of infections, to see how and whether such exposures might lead to systemic sclerosis.
Meeting Comments:

- This is an umbrella protocol covering a number of IRB protocols. The projects utilize skins cells and samples of skin biopsies.
- There are no safety concerns, but the application is lacking the necessary details. PI needs to update the protocol to include these details before approval can be granted.

The PI needs to:

- Since this is an umbrella protocol for a number of IRBs, please choose a general title for your IBC and add the IRB titles and dates to the Research Project Description Brief Project Description section.
- Change the anticipated starting date.
- Please provide a title (i.e. Associate Professor, post-doc), a descriptive role (i.e. PI, research assistant), and answer the question "state how many years of experience, when and where" for all personnel. The PI needs to complete the rDNA/IBC Policies training in RIMS.
- In the Research Laboratory Facility Information, make sure all lab spaces have been listed and provide the lab inspection date and function of the room for all spaces.
- In the Personal Protective Equipment and Safety Equipment, provide the current recertification dates for all biological safety cabinets and answer the biohazardous materials storage and transport questions.
- Under Materials Used in Research, check Other Potentially Infectious Materials and yes that this is a Hospital Based Project.
- Please provide the IRB Approval Number and expiration date for the human material samples listed in Other Potentially Infectious Materials
- Make sure to check all boxes in the Agreement Policy.

ROHP: Still working with two individuals.
LST: Still pending for PI.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

9. Protocol 720

"Clinical Trials in Systemic Sclerosis, Systemic Lupus Erythematosus, Vasculitis and Sjogrens"
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC

Layman's Description: Blood samples from patients with systemic sclerosis, vasculitis, Sjogren's syndrome or systemic lupus erythematosus entered into clinical trials are processed and sent for analyses.
Meeting Comments:
- This is an umbrella IBC protocol that provides coverage for multiple clinical trials examining various diseases. There are no safety concerns. The project involves setting up a tissue bank and for collection, processing and shipping of blood.
- A few administrative items need to be addressed prior to approval.

The PI needs to:
- In the Grant Funding Information section, please change the anticipated starting date and since this is an umbrella protocol for a number of IRBs, please choose a general title for your IBC and add the IRB titles and dates to the Research Project Description Brief Project Description section.
- Please add the PI to the Personnel List as the PI must be listed here. Also, the PI needs to complete the rDNA/IBC Policies training in RIMS (this is required annually for all IBC PIs). Please provide a title (i.e. Associate Professor, post-doc) and a descriptive role (i.e. PI, research assistant) for all personnel.
- Please add E535 and E527 as these are listed as storage locations and make sure the BSL is listed as BSL-2.
- In the Personal Protective Equipment and Safety Equipment section, provide the current recertification dates for all biological safety cabinets and answer the biohazardous materials storage and transportation questions.
- Under Materials Used in Research, check yes that this is a Hospital Based Project.
- Provide the IRB Approval Number and expiration date for the human material samples.
- Make sure to check all boxes for Agreement Policy

ROHP: Still working with one individual.
LST: Still pending for PI.
Recommendation: Approved Pending
For: 14
Against: 0
Abstain: 1

10. Protocol 638

"The Fuel Sensing Enzyme AMPK in the Pathogenesis of Prostate Cancer"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 2
Campus: BUMC
Layman's Description: This Project will investigate whether an enzyme, called AMPK, found in the body has an effect on the growth of prostate cancer. We will attempt to understand whether the production of this enzyme, is decrease by prostate cancer and whether specific drugs can allow the body to make more AMPK. These studies will help understand how prostate cancer works and possible treatments that involve increasing AMPK.
Meeting Comments:
- This is a very simple application. The PI is interested in artificial activation to induce AMPK in vitro and cell culture. The project involves use of live animals. The animal work is described well.
- There are a lot of typos and few issues regarding awkward statements. Otherwise this project is straight forward and there are no major issues or concerns.

The PI needs to:
- Please change the anticipated starting date to 09/20/2013 and delete the Amendment in the Change Summary section.

- Please provide more information for all lab spaces (i.e. BSL, Lab Inspection dates and function of rooms).
- In the laboratory procedures section, please fix the typo in line 9 of the lab procedures where it says 70$ ethanol. It should say 70% ethanol. And clarify the cell lines that will be used and describe the work that will be done or remove.
- Please remove the Amendment at the end of this section. The material added via the amendment on 8/26/11 should be incorporated into the project description since this is a three year renewal.
- In the Personal Protective Equipment and Safety Equipment sections, describe the safety precautions and disposal for sharps and uncheck disposable scrubs. Please clarify the statement "We dispose biohazard wastes into biohazard boxes; apply 10% bleach to cells that are used to produce adenovirus, retrovirus and lentivirus." It sounds like you are pouring bleach into the biohazard boxes. Please see item 8 where you say "we use 10% fresh bleach for disinfecting liquid and 70% ethanol for spraying or wiping contaminated area." I did not see any mention of wiping down work spaces with ethanol in your procedure descriptions so that should be updated as well. Also, please update the procedures to include this information to indicate where bleach and ethanol are used to decontaminate work surfaces.
- In the Hazardous Biological Agents section, remove BSL-1 E. coli strains from this section, clarify the cell lines that will be used (only human and monkey cells need to be listed) and update the IACUC information.
- Please check all boxes in the Agreement Policy.

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 14
Against: 0
Abstain: 1

11. Protocol 610

"Saliva and Asthma"
Category: Bhz
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: The goal of this project is to determine the cause of an asthma attack in an individual person. The number one cause of an asthma attack is an infection from a virus or bacteria. We plan to use a new way to measure the amount and type of infection in the saliva of person with asthma. Before testing our method on people with asthma, we need to find out if our new method works. We plan to test our method on culture of bacteria and virus. We will then test this with our new equipment. This will allow us to know how effective our device is. This will also let us know that our information is reliable.
Meeting Comments:
- This project is to test a new way to measure titer of infection in saliva of asthma.
- The procedures include collecting samples, spiking samples with bacteria and virus. It is not clear which virus/bacteria will be used this needs to be clarified. .
- There was no community concerns related to this project.

The PI needs to:
- Please change the anticipated starting date to 09/09/2013
- Please provide the title (i.e. Associate Professor, Post-doc) for all personnel.
- In the Laboratory Procedures section, the sample collections and storage is well described, but the description of the actual experimental procedures is missing. Also, the bacteria and viruses used should be part of the description of the laboratory procedures, as well as their cultivation and disposal methods.

- In the Personal Protective Equipment and Safety Equipment, confirm no vortexing of samples? Otherwise check box for vortexing. Please answer Q-7 (treatment for biohazardous wastes) making sure to separate by liquid and solid waste. A biological safety cabinet seems indispensable for the studies proposed by this lab. Please provide the biological safety cabinet information.
- Under Materials Used in Research, please check that this is a hospital based project and hazardous biological agents will be used.
- Please provide the information for the strains of bacteria and viruses in addition to the clinical sample types.
- Please specify the sites of clinical sample collection (building and room numbers).

ROHP & LST: Complete for all personnel.
Recommendation: Approved Pending
For: 13
Against: 2
Abstain: 0

12. Protocol 609

"Structure and Function of Histone Chaperones; The Structure Basis of Protein Biogenesis; Structural Biology of Apoptosomes and Related Signaling Complexes; Structural Biology of the Type IVb Protein Secretion System of Legionella Pneumophila"
Category: rDNA
Biosafety Level: 1
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: The aim of our research is to understand how a particular protein or protein complex functions at the molecular level (by visualizing its shape). In order to do so, large amounts of highly purified protein is needed. Using either bacterial or insect cells as a "protein factory", we produce the quantities of protein(s) that are needed. Using standard biochemical methods we will then further purify each protein to the level necessary for crystallization and visualization in the electron microscope.
Meeting Comments:

- This is a straight forward protocol that involves using standard techniques to look at proteins and structure.
- The community member has no major issues with this project. The layterms are a little technical, but ok.

The PI needs to:

- Please change the anticipated starting date to 09/13/2013.
- 1. Please provide the title (i.e. Associate Professor, post-doc) for all personnel.
- Please add W324 and W325 in the Research Laboratory Facility Information section.
- In the Laboratory Procedures, please clarify: Are you generating genetic materials? Where are you getting the sources for human DNA and Legionella genes? Is this material already at BU in your lab?

ROHP: Still working with two individuals.
LST: Complete for all personnel.
Recommendation Approved Pending
For: 15
Against: 0
Abstain: 0

13. Protocol 983

"Redox Regulations of SERCA by Nitric Oxide; SIRT-1, Polyphenols, and Endothelial Oxidants; Redox Regulation of p21ras in Angiogenesis; Modification of Cardiovascular

Proteins by Metabolic Disease; Sir2 Regulates AMPK and Lipid Metabolism in Diabetes; Aortic Stiffness in Hypertension in Obese Mice"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 2
Campus: BUMC
Layman's Description: We are determining how diabetes and lipids contribute to vascular disease. In cultured vascular cells of mice and rats that have similar vascular disease induced by diet or by genetic manipulation, we are studying why vascular cell function is abnormal and how to correct it. We do this by altering the genes in the cells in culture and animal, to determine which are most important in treating vascular disease. This involves injection of vectors in tail vein for liver expression and in femoral artery and hindlimb muscle for hindlimb infection.
Meeting Comments:

- This project is looking at cardio vascular disease using human materials as well as in mouse and rat models to look for an effect on cell signaling and tissue pathology for contribution to pathogenesis.

The PI needs to:

- Please change the anticipated starting date to 9/21/2013.
- Please answer "State how many years' experience, when and where" for all personnel.
- In the Research Project Description section, please re-read this section and edit the description and terminology for clarity. It is unclear what is replication competent and what is replication incompetent. Some of the terminology doesn't make sense and causes confusion from a safety perspective.
- Under Materials Used in Research, please check "live animal use" and that this is a hospital-based project.
- In Hazardous Biological Agents, please provide the source of the viral vectors.
- Please provide the IRB approval number or exemption information.
- Update the Boston Public Health Commission Form to match the rest of the application.
- Please make sure all boxes are checked (i.e. ROHP will be contacted immediately after a potential exposure).

ROHP: Still working with one individual.
LST: Complete for all personnel.
Recommendation: Conditionally Approved
For: 15
Against: 0
Abstain: 0

14. Protocol 1539

"Use of Kidney Specimens to Identify Endogenous Antigens in Membranous Nephropathy"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: N/A
Campus: BUMC
Layman's Description: This project will use tissue sections from human kidney biopsies (that would otherwise have been discarded) for two purposes: (1) Tissue sections on glass slides will be stained with antibodies against relevant kidney proteins to assess their relative locations within the kidney, for the purpose of better understanding the kidney disease membranous nephropathy. (2) Human antibodies that are causative of disease in similar autoimmune kidney disorders will be eluted (removed) from the kidney tissue and used in an immunoblotting protocol to determine if they recognize known kidney proteins. The proteins (for example, the

human phospholipase A2 receptor) will be produced by cells in culture, using standard recombinant DNA technology.
Meeting Comments:
- This is a pretty straight forward project. The PI is interested in kidney disease and is looking to identify biomarkers for autoimmune diseases.
- There is no objection as related to the community.

The PI needs to:
- Please change the anticipated starting date to 9/29/2013.
- Please answer "State how many years' experience, when and where" for all personnel.
- Please provide the current lab inspection date for X531 and specify the function of the room.
- In the Personal Protective Equipment and Safety Equipment section, please provide the serial number for the Biological Safety Cabinet, elaborate on the PPE and procedures that will be used with the microtome in the sharps description and add more to the waste disposal description (i.e. solid and liquid waste).
- Under Materials Used in Research, check Hazardous Biological Agents as human cell lines are indicated.
- Please add the human cell lines to the appropriate section.
- In the Recombinant DNA section, please provide the Donor information for Prokaryotic Experiments and the Vector information for the Eukaryotic Experiments. Also, please answer questions 15 and 16 relating to viral vectors. These two answers need to be corrected, so that they are consistent with each other.
- Please complete the Boston Public Health Commission Form to be consistent with the rest of the application.

ROHP: Still working with one individual.
LST: Still pending for one individual.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

15. Protocol 1203

"1) Exosome- mediated Dissemination of Tau Aggregation in Alzheimer's disease; 2) Invention and Clinical Application of Protein Kinase Inhibitors; 3) Clinical Evaluation of LRRK2 inhibitors on inflammatory Responses in Crohns and Parkinson's diseases; 4) The Cellular Mechanism of Tau Dissemination"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 1
Campus: BUMC
Layman's Description: There are many devastating diseases that affect the human brain that we still know very little about (such as Alzheimer's and Parkinson's disease and Traumatic Brain Injury). In order to better understand these diseases, and to come closer to finding potential cures, an understanding of how the smallest of molecules function is vital. For this study, we propose to introduce some molecules that are key player in those diseases in to cells so that we can best understand the exact role they play in causing the disease, and therefore how we can potentially cure it. Introduction of these molecules in to cells, however, requires the use of some minor potentially hazardous agents. Without the use of such agents, a proper understanding of how these brain diseases function con not be achieved.
Meeting Comments:

- This is a well written protocol looking at diseases that affect the human brain. The lab procedures are well described, however, there is some confusion regarding competent vs. incompetent virus. The PI needs to add some clarification.
- The project also involves live animal experiments.

The PI needs to:

- Please answer "State how many years' experience, when and where" for all personnel.
- Please re-read the Research Project Description section and clarify if the virus is replication competent or replication incompetent. In some places it says competent and others incompetent, please correct for consistency.
- In the Personal Protective Equipment and Safety Equipment, please describe the safety precautions and disposal practices for sharps. Specify that "fresh" bleach will be used and remove autoclave waste as this is not standard BU practice.
- In Hazardous Biological Agents, please remove E. coli K12 as this is BSL-1. And change the BSL for human cell lines to BSL-2.
- Complete the Boston Public Health Commission Form to reflect the rest of the application.

ROHP: Still working with one individual.
LST: Complete for all personnel.
Recommendation: Approved Pending
For: 15
Against: 0
Abstain: 0

IV. Amendments

A. Amendments for Committee Review:

1. Protocol 1461

"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"
Category: Bhz/rDNA
Biosafety Level: 2
Animal Biosafety Level: 2
Change: Use of a viral vector to deliver message for expression of GFP and optogenetic molecules to neurons in the monkey brain.
Campus: BUMC
Layman's Description: Studies focus on understanding the how the brain functions in learning and memory. To do this, studies use the rhesus monkey as this animal has both mental capacities and brain organization most similar to humans. The goal is to determine how normal aging, brain damage similar to stroke and the effects of high blood pressure impair brain function. All monkeys are tested on tasks designed to measure their mental or brain functions and then the brains are studied to identify the changes and mechanisms responsible for the impairments produced by normal aging, stroke and high blood pressure.
Recently, studies have focused on the use of induced Pluripotent Stem cells (iPSC), which are stem cells derived from a person's own skin cells. These cells have potential as treatment for a variety of diseases. The cells can differentiate into a wide variety of cell types, including brain cells. The purpose of the present study is to assess the feasibility of injecting iPSC developed from human skin cells into the brains of rhesus monkeys as a possible treatment from stroke.

The retrovirus we will inject has been widely used over the past decade to label adult born neurons.
Meeting Comments:
- This lab is interested in stroke using animal models (rodent, monkey). The project involves fate mapping to see what happens to neurons under stroke conditions.
- This amendment involves the addition of experiments to intervene. The project will involve iPS cells injected into monkey and monitoring to see improvement of animals (receiving and infusing into animal model). The procedures will include using viral vectors received from a collaborating PI on the CRC campus to tag the cells.
- This amendment makes this project a Bhz/rDNA project.

The PI needs to:
- Update personnel list.
- Clarify how materials will be transported between campuses.
- Link to the IBC protocols that produce the viral vectors and iPS cells.

ROHP: Still working with one individual.
LST: Still pending for four individuals.
Recommendation: Approved Pending
For: 14
Against: 0
Abstain: 0

V. Approved Expedited Amendments & Annual Renewals

1. Protocol 1781

"Regulation of HIV transcription and Latency by Cellular Mechanisms"
Biosafety Level: BSL2, special practices of BSL3
Animal Biosafety Level: N/A
Type: Amendment
Expedited Change: Addition of personnel

2. Protocol 1444

"Bone Study"
Biosafety Level: BSL2
Animal Biosafety Level: N/A
Type: Amendment
Expedited Change: Addition of lab space

3. Protocol 850

"Transformation of Cells by the REL Oncogene (not funded now) Sea Anemone NF-kB Signaling (NSF)"
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Type: Annual Renewal
Expedited Change: Updates to personnel and administrative information

4. Protocol 799

"Intracellular Receptors and Gonoccal Induction of Proinflammatory Cytokines"
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Type: Annual Renewal
Expedited Change: Updates to personnel

5. **Protocol 798**

"Pathogen Induced Inflammation, Innate Immunity and Atherosclerosis"
Biosafety Level: BLS-2
Animal Biosafety Level: ABSL-2
Type: Annual Renewal
Expedited Change: Updates to personnel

6. **Protocol 1417**

"Minority-Based Community Clinical Oncology Program at BMC"
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Type: Amendment
Expedited Change: Addition of IRB

7. **Protocol 914**

"Functional role of p130CasBCAR1 in breast cancer. Molecular mechanisms controlling cell growth and transformation. Regulation of ErbB and cSrc signal transduction by p130Cas/BCAR1 in normal and cancerous mammary gland. Molecular mechanisms in kidney function and disease."
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Type: Amendment
Expedited Change: Updates to personnel

8. **Protocol 664**

"Lysyl Oxidase Propeptide: Breast Cancer Inhibitor. Pancreatic Cancer Inhibitor"
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Type: Amendment
Expedited Change: Updates to personnel

9. **Protocol 487**

"Respiratory syncytial virus polymerase protein and promoter interactions (R01); Respiratory syncytial virus transcription and RNA replication complexes (pending) Mechanisms for RNA recognition within nucleocapsids of the Mononegavirales (pending) Development of an in vitro assay for the Ebola virus polymerase (Alios BioPharma) Investigation of RSV RNA replication initiation"
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Type: Amendment
Expedited Change: Change in lab space

10. **Protocol 1336**

"Effects of gene knockdown (Sigma-1 receptor, CRF and CRF-1 receptor, TrkB, etc.) on signal transduction systems."
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-2
Type: Annual Renewal
Expedited Change: Updates to personnel

11. Protocol 1046

"Molecular Pathogenesis of Vesicoureteral Reflux"
Biosafety Level: BSL-2
Animal Biosafety Level: N/A
Type: Annual Renewal
Expedited Change: Updates to personnel

12. Protocol 829

"How Environmental Chemicals Suppress Immunity, The AhR in mammary tumorigenesis, Genomic signatures of carcinogenicity"
Biosafety Level: BSL-2
Animal Biosafety Level: ABSL-1
Type: Annual Renewal
Expedited Change: No changes