

IBC Meeting Minutes

Location: 88 E. Newton Street,
2nd Floor, Conference Room C/D

September 21, 2010

Start time: 12:00PM

End Time: 2:00PM

Present: A. Henderson, T. Winters, R. Morales, T. Brauns, S. Ghosh, J. Gonsalves, F. Gibson, R. Ingalls, C. Sulis, K. Bossart, K. Tuohey, K. Kirsch

Absent: N. Broude, J. Barton, G. Bain, K. Hardcastle

Staff: B. Xiarhos, I. Adams

Guests: E. Beer, C. Richards, L. Bethune

I. Introduction

- 1. We are holding this annual IBC PUBLIC MEETING today pursuant to Section 2.03 of the Boston Public Health Commission's Biological Laboratory Regulation.**
- 2. Introduction of IBC Members: All members were introduced**
- 3. Questions will be taken at end of meeting**

II. Review of August Minutes

Recommendation: Approved

For: 11

Against: 0

Abstained: 1

III. New Business

A. Chairperson Report

1. The primary goal of the IBC Chair has been to facilitate research and Investigator's projects and the effort by the reviewers to reach out to PI's is appreciated.

B. Technical Committees Report

1. **Approved applications:** 8 of the 14 applications reviewed at last month's meeting have been approved.
2. **Public Meeting Attendance:** The notice for the public meeting was in the Boston Herald, on the IBC website, and on the Office of Research Compliance website, and letters were sent to City Hall and the Boston Public Health Commission. Ideas for increasing attendance were discussed including changing the meeting time to after work hours and utilizing community news sources. There may be more interest in the public meeting as risk assessments are done for future work.

C. Biosafety Report-Annual IBC Biosafety Report: The report was presented by the Director of Research Safety and discussed active BSL-3 protocols at BU.

The institution conducts work on both campuses. The IBC reviews rDNA and Biohazardous work and helps to put together policies and procedures which are implemented by Environmental Health and Safety (EHS) in the labs. EHS helps to prepare SOPs, conduct BUA Risk Assessments and liaise with outside regulatory agencies. A new role for EHS this year involves comprehensive inspections: a review of labs four times a year and most common findings were reviewed. The number of people trained by EHS has been steadily going up, including specialized training for select agents and BSL3 work. Future updates include Lab Safety Coordinators, Select Agent and Toxins regulatory changes, Dual Use Research of Concern (DURC), and continued discussion about BU's "culture of safety".

IV. Protocol Review:

Meeting is not closed

A. New Submissions

1. New Submissions

1) Protocol #1371

Title: "Neuroimmunomodulation Within The Eye"

Category: rDNA

Biosafety level: BSL-2

Brief Protocol Description: Over 2 million Americans will suffer from inflammation within the eye this year. Many will have impaired 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 of inflammation. We hope that this will stop and permanently protect the eye from inflammation, and save sight.

PI needs to:

- Indicate protocol is BSL-1 since no work at BSL-2
- List vectors in rDNA section and BPHC form
- provide a Biosketch

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

2) Protocol #1372

Title: "Ultra-specific in situ detection of short sequences in human genomic DNA under non-denaturing conditions"

Category: Bhz

Biosafety level: BSL-2

Brief Protocol Description: This project is designed to test the method we have developed for detection of specific genes in bacteria for labeling individual genes on human cells. The method is based on the use of artificial molecules, called peptide nucleic acids or PNAs. This will entail an enormous improvement in DNA diagnostics and will be beneficiary for a wide range of biomedical or clinical researchers.

PI needs to:

- make it clear that bacteria work is in the past
- specify place of sharps disposal
- check boxes in Agreement policy

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

3) Protocol #1374

Title: "Sulfur cluster assembly and mechanism and Bacterial cell division"

Category: rDNA/Bhz

Biosafety Level: BSL-1

Brief Protocol Description: Research in the Perlstein Lab is focused on understanding how iron is acquired and used by living things. Iron is essential for life and we study both how proteins use

iron to conduct the chemistry of life and how iron is acquired by living things. These experiments will provide the groundwork needed to understand and treat human diseases related to defects in iron biochemistry

We also study how bacterial cells divide in an effort to combat the problem of super-bugs, bacteria that are resistant to one or more antibiotics. If we can understand the biochemistry of how bacteria grow, then we can develop new inhibitors of bacterial growth, which could be used to treat dangerous bacterial infections.

PI needs to:

-simplify Laymen's Terms

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

4) Protocol #1376

Title: "Dissecting Mechanisms of Melanoma development and progression using adenoviral/lentiviral vectors"

Category: rDNA/Bhz

Biosafety level: BSL-2

Brief Protocol Description: The goal of this project is to determine the causes of the deadly skin cancer, melanoma, and how this cancer spreads. We will turn off or turn on specific genes in the cells of this cancer and see how that affects the growth and ability to spread.

PI needs to:

-check yes for 'Is rDNA gene efficiently expressed' and complete Host-Vector-Donor system on BPHC form

-add pLenti to rDNA table

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

2. 3 Year Resubmissions

5) Protocol #1048

Previously tabled

Title: "Macrophage - Muscle Precursor Cell Interactions in the Context of HIV-1"

Category: Bhz

Biosafety Level: BSL-2 with special practices of BSL-3, ABSL-1

Brief Protocol Description: The HIV infected population is aging due to success of antiviral treatments. To better understand HIV and aging, we are studying muscle cells and their

interaction with blood cells, since this interaction is predicted to change with aging and result in declines in muscle health.

PI needs to:

- provide statement that all waste is being collected
- remove references to BSL-3
- clarify if exempt IRB is needed

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

6) Protocol #225

Title: "The Cellular and Molecular Biology of Insulin Action Organization of Insulin Signaling in Adipocytes, Role of Caveolae Activation of Hexose Transport by Insulin"

Category: rDNA/Bhz

Biosafety level: BSL-2, ABSL-1

Brief Protocol Description: Diabetes is a disease characterized by high blood sugar (glucose) and has many causes although over nutrition (over eating) and obesity seem to be the major reasons for the high incidence of type 2 diabetes worldwide. Our lab studies the route by which nutrients, fats and carbohydrates, enter cells through their cell surface structures called membranes. A number of protein molecules participate in the cellular entry of fats and carbohydrates and we study their interactions at the molecular level by a variety of modern biological techniques.

PI needs to:

- lab maneuvers section: add specifics about rDNA work, describe homogenization and vortexing, describe PPE, describe use of radioactive material, describe work with transgenics
- fill out agreement policy
- complete Host-Vector-Donor system on BPHC form
- indicate how materials are stored and where
- clarify replication competence of vectors
- list 293 cells under Hazardous Biological agents

Recommendation: Conditionally Approved

For: 12

Against: 0

Abstained: 0

7) Protocol #571

Title: "1. NO, SERCA, and Oxidative Stress in Atherosclerosis 2. Oxidants, Eicosanoids, and Endothelium in Diabetes 3. Oxidative Modifications in Cardiovascular Disease 4. Angiotensin-induced Oxidants and Vascular Cell Phenotype 5. Insulin resistance, endothelial oxidants, and Ras 6. Bimodal modulation of interleukin-1beta-induced signaling and gene expression by

angiotensin II in vascular smooth muscle cells 7. Sir2 Regulates AMPK and Lipid Metabolism in Diabetes”

Category: rDNA/Bhz

Biosafety Level: BSL-2, ABSL-2

Brief Protocol 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 animals, to determine which are most important in treating vascular disease.

Recommendation: Approved

For: 12

Against: 0

Abstained: 0

8) Protocol #1002

Title: “Metabolic Pathway Impairment in Schizophrenia and Autism; Aptamer Targeting of Tumor Cells; Rolling Circle Amplification; Molecular Reactions on Cyclic Polyolefin”

Category: rDNA/Bhz

Biosafety Level: BSL-2

Brief Protocol Description: Comparative DNA Analysis: The goal of these experiments is to identify DNA/RNA/ protein differences between samples. The compared samples will be different tissues from the same individual or the same tissue from different individuals. The results of these experiments will help us determine how our DNA/RNA/proteins change as a function of development, age or disease.

Aptamer Targeting of Tumor Cells: The goal of these experiments is to identify DNA or RNA sequences that bind to tumor cells in order to develop new treatments.

Ligation Mediated Rolling Circle Amplification: The goal of these experiments is to identify methods of detecting mutations in DNA.

PI needs to:

-clarify if exempt IRB is needed

-Complete the Host-Vector-Donor system on the BPHC form

-Simplify DNA Therapeutics in Project Description and remove discussion of DNA into rodents

-remove rat and rodent information from Potentially Infectious Materials

-detail the variety of tissues, where they come from, how they are obtained, transported and handled, and what is done with them

Recommendation: Conditionally Approved

For: 12

Against: 0

Abstained: 0

9) Protocol #1068

Title: “07-071 (1068) The Efficacy of Mirtazapine in Depressed Cocaine Dependent Subjects”

Category: Bhz

Biosafety level: BSL-2

Brief Protocol Description: This research study will be looking at the safety of the medication Mirtazapine (Remeron) in people who have both cocaine dependence and depression. The objective of this study is to attempt to discover if taking this medication will help reduce cocaine use and improve depression.

Recommendation: Approved

For: 12

Against: 0

Abstained: 0

10) Protocol #1079

Title: "07-072(1079) A double blind, placebo-controlled, parallel group design study with 4 treatment groups; levetriacetam, zonisamide, topiramate, and placebo control."

Category: Bhz

Biosafety level: BSL-2

Brief Protocol Description: The goal is to determine effectiveness of medication(s) against placebo (sugar pill) in alcohol dependent individuals. If the medications work better than the sugar pill, future large-scale clinical trials can be done.

PI needs to:

- simplify first three sentences of Project description, clarify what biochemical analysis will be performed on blood, clarify how human specimens are transported and what tests are done
- clarify if blood will be analyzed offsite and if so clarify transport and handling

Recommendation: Conditionally Approved

For: 12

Against: 0

Abstained: 0

11) Protocol #791

Title: "Mechanisms regulating megakaryocyte and smooth muscle cell endomitosis and polyploidy"

Category: rDNA/Bhz

Biosafety level: BSL-2, ABSL-2

PI needs to:

- add details about the vectors being employed and the lentiviral system
- simplify the Laymen's Terms
- check 'pipetting infectious liquids'
- clarify ABSL
- fill out Hazardous Biological Agents for 293 cells
- provide more detail for eukaryotic experiments
- clarify transport and indicate leakproof and shatterproof container
- add specifics to Host-Vector-Donor system on BPHC form

Recommendation: Conditionally Approved

For: 12

Against: 0

Abstained: 0

V. Amendments

1) Protocol #1314

Title: "Transcriptomics and Epigenomics of chronic Obstructive Pulmonary Disease (COPD), Lung Genomics Research Consortium, Airway Response to Tobacco Smoke (ARTS), Genetic Determinants of Epithelial DNA Damage in Smokers 2001-246G"

Category: Bhz

Biosafety Level: BSL-2

Brief Amendment Description: Addition of IRB protocols and personnel

PI needs to:

-provide record of approved IRBs from outside institutions

-indicate personnel being added

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

2) Protocol #1157

Title: "Co-factors influencing HIV-1 mucosal transmission"

Category: rDNA/Bhz

Biosafety Level: BSL-3

Brief Amendment Description: Addition of Primary Human Tissue

PI needs to:

-clarify if exempt IRB is needed

Recommendation: Approved Pending

For: 12

Against: 0

Abstained: 0

APPROVED EXPEDITED AMENDMENTS:

1) Protocol #955

“IMPAACT/ACTG/ATN PROTOCOLS AT BMC; Immunogenicity of Pneumo Conj. Vaccine in HIV Infected Children with HAART...”

Biosafety level: BSL-2, ABSL-2

Expedited change: Addition and removal of personnel

2) Protocol #587

“Host-pathogen interactions in Neisseria meningitidis, Neisseria gonorrhoeae and Porphyromonas gingivalis”

Biosafety level: BSL-2 with special practices of BSL-3, ABSL-2

Expedited change: Addition and removal of personnel

3) Protocol #1349

“Design principle of novel neuromodulation therapies”

Biosafety level: BSL-2

Expedited change: Addition of personnel

4) Protocol #899

“Determinants of Cell Fate and Differentiation in the Developing Lung; Hemangioblast Transplantation for Reconstitution of Lung Endothelium; Stem cell Reconstitution of the Lung Alveolus”

Biosafety Level: BSL-2, ABSL-2

Expedited change: Addition of IRB protocol

5) Protocol #1235

“A potential target site to decrease outflow resistance; Matricellular Proteins in Trabecular Meshwork Increase Intraocular Pressure; The Mechanical Basis of Primary Open Angle Glaucoma; Spectral Domain OCT Doppler Assesses Aqueous Outflow; Spectral Domain OCT Doppler Assesses Aqueous Outflow”

Biosafety Level: BSL-2

Expedited change: Addition of personnel, IRB protocol, and lab space

VI. Renewal of Protocols with Minor Changes

1) Protocol # 1250

“Cytoprotective role of HSP72 in renal epithelial cell injury; The cytoprotective role of hexokinase during metabolic stress; HATPase and AQP2: Regulation of targeting and recycling in IMCD cells”

Biosafety Level: BSL-2

Change: delete lab staff

2) Protocol # 1226

“The role of microRNA and RNA in cancer growth and metastatic potential”

Biosafety Level: BSL-2

Change: delete lab staff, change title

3) Protocol # 1140

“BRI—Effects of mercury contamination on the immune function and stress physiology of temperature bat species”

Biosafety Level: BSL-2

Change: add lab staff

4) Protocol # 1139

“1 Toxin Studies relevant to : 1) Primate model and pathogenesis of anthrax sepsis; 2) Translation of immunologic technologies from basic research into pre-clinical nonhuman (baboon) models to evaluate protection from B. anthracis; 3) Shiga-toxins: Pre-clinical animal model development and therapeutic testing; 4) Development, validation and standardization of a non-human primate model of anthrax to evaluate new immunologic technologies derived from basic research.”

Biosafety Level: BSL-2 with special practices of BSL-3

Change: delete/add lab staff

5) Protocol # 1154

“1) Primate model and pathogenesis of anthrax sepsis; 2) Development, validation and standardization of a non-human primate model of anthrax to evaluate new immunologic technologies derived from basic research; 3) Translation of immunologic technologies from basic research into pre-clinical nonhuman (baboon) models to evaluate protection from B. anthracis.”

Biosafety Level: BSL-2 with special practices of BSL-3

Change: delete/add lab staff

6) Protocol # 1188

“Replication and Transcription of Filoviruses; Early Host Immune Response in Protection Against Filovirus Infection; Interaction of Filoviruses and SARS-coronavirus with the Innate Immune System

Biosafety Level: BSL-2

Change: delete/add lab staff

7) Protocol # 955

“PACTG/ACTG Protocols at BMC: Immunogenicity of Pneumo. Cong. Vaccine n HIV Infected Children with HAART...”

Biosafety Level: BSL-2

Change: delete lab staff

8) Protocol # 1221

“RNA visualization in live cells”

Biosafety Level: BSL-2

Change: delete lab staff

9) Protocol # 878

“Neurodevelopmental Toxicity (fish); Zebrafish gene expression”

Biosafety Level: BSL-1

Change: delete/add lab staff

VII. Renewal of Protocols with no Proposed Changes

1) Protocol # 1142

“PEC—Foraging behavior and diversity of bats in a pecan agroecosystem in Texas: Assessing the ecosystem services provided by insectivorous bats”

Biosafety Level: BSL-2

2) Protocol # 1141

“ITR—Physiological ecology of Brazilian free-tailed bats in natural and agricultural ecosystems”

Biosafety Level: BSL-2

3) Protocol # 1157

“Co-factors influencing HIV-1 mucosal transmission”

Biosafety Level: BSL-3

VIII. Questions

No questions were asked at the end of the meeting.