## **Meeting Minutes**

**Date:** Wednesday, May 21, 2014 **Time:** 10:00 AM – 12:00 PM

**Location:** Health Sciences Building T-269

Members

1. Michael Agy, Washington National Primate Research Center

**Present:** 

2. Thea Brabb, Comparative Medicine

3. H.D. "Toby" Bradshaw, Biology

4. Lesley Colby, Comparative Medicine

5. Elizabeth Corwin, Community Member

6. Stephen Libby, Laboratory Medicine

7. Jeanot Muster, Pharmacology

8. Matthew R. Parsek, Microbiology

9. Mei Y. Speer, Bioengineering

10. Eric Stefansson, Environmental Health & Safety

11. Paul Swenson, Community Member, Seattle-King Co. Dept of Public Health

12. Valerie Yerkes, Community Member

Members

13. Jean Haulman, GeoSentinel Site Director, Medical Provider – UW Travel Clinic

Absent:

14. Scott Meschke, Environmental & Occupational Health Sciences

Guests

1. Linda Arnesen, Biosafety Officer, EH&S Research & Occupational Safety

Present:

- 2. Andrea Badger, IBC/Research Coordinator, EH&S Research & Occupational Safety
- 3. Jacqui Bales, Biosafety Officer, EH&S Research & Occupational Safety
- 4. Judy Cashman, Occupational Health Nurse, EH&S Research & Occupational Safety
- 5. Tony Han, Biosafety Officer, EH&S Research & Occupational Safety
- 6. Katia Harb, Assistant Director, EH&S Research & Occupational Safety
- 7. Laury Istvan, Assistant Director, Office of Animal Welfare
- 8. Lesley Leggett, Biosafety Officer, EH&S Research & Occupational Safety
- 9. Glenn McLean, Biosafety Officer, EH&S Research & Occupational Safety

- 1. CALL TO ORDER: Steve Libby called the meeting to order at 10:00. A quorum was present.
- **2. REMINDER:** Steve Libby reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.
- **3. INTRODUCTIONS**: Steve Libby introduced himself and discussed the best ways to contact him with any questions. He discussed how he plans to start assigning both a primary reviewer and a secondary reviewer.

## 4. APPROVAL OF MINUTES:

- Steve Libby sought a motion to approve the minutes from the March 19<sup>th</sup> and the April 16<sup>th</sup>,
   2014 meeting.
- Thea Brabb made a motion to approve the March 19<sup>th</sup> & April 16<sup>th</sup>, 2014 minutes. Jeanot Muster seconded the motion.
- The committee voted unanimously, with three abstentions, to approve the March 19<sup>th</sup> & April 16<sup>th</sup>, 2014 meeting minutes.
- **5. BIOSAFETY OFFICER (BSO) REPORTS**: The BSO reports are for project reviews involving infectious agents and for projects falling under Section III-E and III-F of the *NIH Guidelines*.
  - a. Linda Arnesen's Biosafety Officer Report
    - Steve Libby sought a motion to approve Linda Arnesen's Biosafety Officer Report.
    - Eric Stefansson made a motion to approve Linda Arnesen's Biosafety Officer Report. Lesley Colby seconded the motion.
    - The Committee unanimously voted to approve Linda Arnesen's Biosafety Officer Report.
  - b. Jacqui Bales' Biosafety Officer Report
    - Steve Libby sought a motion to approve Jacqui Bales's Biosafety Officer Report.
    - A question was raised about how Brad Cookson's *Coxiella* strains were grown.
    - Eric Stefansson made a motion to approve Jacqui Bales's Biosafety Officer Report. Mei Speer seconded the motion.
    - The Committee voted unanimously to approve Jacqui Bales's Biosafety Officer Report.
  - c. Lesley Leggett's Biosafety Officer Report
    - Steve Libby sought a motion to approve Lesley Leggett's Biosafety Officer Report.
    - Jeanot Muster made a motion to approve Lesley Leggett's Biosafety Officer Report. Thea Brabb seconded the motion.
    - The Committee voted unanimously to approve Lesley Leggett's Biosafety Officer Report.
  - d. Glenn McLean's Biosafety Officer Report
    - Steve Libby sought a motion to approve Glenn McLean's Biosafety Officer Report.
    - Eric Stefansson made a motion to approve Glenn McLean's Biosafety Officer Report. Jeanot Muster seconded the motion.
    - The Committee voted unanimously to approve Glenn McLean's Biosafety Officer Report.

- **6. INDIVIDUAL PROJECT REVIEWS** (*IBC member Primary Reviewer Reports and Biological Use Authorization (BUA) letters available as separate documents)* 
  - **1.** Bevan, Michael, renewal, *T-Cell Development and Function* 
    - Toby Bradshaw served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Toby Bradshaw presented the Primary Reviewer Report.
    - The lab studies the adaptive immune response in mice infected with pathogens.
    - Infectious agents used include *Listeria monocytogenes*, *Yersinia pseudotuberculosis*, vaccinia virus, vesticular stomatitis virus, and lymphocytic choriomeningitis virus.
    - At the time the Primary Reviewer Report was written, the bloodborne pathogen exposure control plan had not yet been submitted and the training had not yet been taken. However, these have both been completed.
    - The IACUC renewal form has not yet been submitted.
    - The draft BUA letter was shown.
    - Toby Bradshaw made a motion to approve the draft BUA for Dr. Bevan. A second is not needed since he is the Primary Reviewer.
    - The Committee voted unanimously to approve the draft BUA for Dr. Bevan, contingent upon EH&S review of the IACUC renewal form.
  - 2. Chen, Eleanor, change, Druggable pathways in rhabdomyosarcoma
    - Steve Libby served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Steve Libby presented the Primary Reviewer Report.
    - The lab studies the pathways of rhabdomyosarcoma, a type of cancer that causes tumor formation, primarily in children, where muscles attach to the bone.
    - The project involves using lentiviral vectors that contain tumor suppressor genes with reduced expression. Previously, this work would have been conducted at BSL2 with 3 practices, but under the new viral vector subcommittee proposal, the work can proceed at BSL2 because the lentiviral vectors are third generation.
    - The draft BUA letter was shown.
    - An argument was raised that something on the BUA letter needs to specify that only
      third generation lentiviral vectors can be worked at with lowered containment. The
      committee discussed the best way to capture "third generation" on the BUA letter.
      The committee decided that the best way would be to add a new agent to the
      database that says "third generation lentiviral vectors." The wording for this specific
      project should be "Human cells transduced with third-generation lentiviral vectors,
      non-HIV pseudotyped, replication deficient, oncogenic inserts"
    - Steve Libby made a motion to approve the draft BUA for Dr. Chen. A second is not needed since he is the Primary Reviewer.
    - The Committee voted unanimously to approve the draft BUA for Dr. Chen, once the third-generation language has been added to the BUA letter.
  - **3.** Dhaka, Ajay, change, Circuit Tracing Cool Sensation
    - Jean Haulman served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. On behalf of Jean Haulman, Eric Stefansson presented the Primary Reviewer Report.
    - Dr. Dhaka is already approved for a herpes simplex viral vector, and this change is requesting the addition of wild-type herpes simplex virus (type 1).

- The draft BUA letter was shown.
- Eric Stefansson made a motion to approve the draft BUA for Dr. Dhaka. A second is not needed since he presented the Primary Review.
- The Committee voted unanimously to approve the draft BUA for Dr. Dhaka.
- **4.** Fuller, Deborah, change, *Immunogenicity of conserved elements (CE) therapeutic DNA Vaccine in SHIV infected macaques* 
  - Michael Agy served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Michael Agy presented the Primary Reviewer Report.
  - This change adds the use of AAV in non-human primates.
  - The investigator had previously written that she would acquire the non-human primates from another protocol where they had been challenged with SHIV. This is what merited the BSL2 with 3 containment level. However, the investigator amended her protocol and is going to buy naïve animals specifically for this project. Therefore the work can proceed at BSL2.
  - The draft BUA letter was shown.
  - Michael Agy made a motion to approve the draft BUA for Dr. Fuller. A second is not needed since he is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- 5. Garden, Gwenn, renewal, Cell-Cell Communication in Neurodegeneration
  - Thea Brabb served as the Primary Reviewer and Linda Arnesen served as the Biosafety Officer Reviewer. Thea Brabb presented the Primary Reviewer Report.
  - The lab studies interactions between cells in neurodegenerative diseases including Alzheimer's disease and other neurodegenerative diseases such as Huntington's disease and Kennedy's disease.
  - The lab utilizes transgenic mice, and various biohazardous agents, including lentiviral vectors, AAV, and human cell lines.
  - The letter does not mention that oncogenic inserts are present in the AAV. The letter should be amended to reflect this.
  - The draft BUA letter was shown.
  - Thea Brabb made a motion to approve the draft BUA for Dr. Garden. A second is not needed since she is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Garden, contingent upon correction of the BUA letter.
- **6.** Hu, Shiu-Lok, renewal, HIVRAD: Core B: Virology/Immunology
  - Mei Speer served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Mei Speer presented the Primary Reviewer Report.
  - This protocol is for the Primate Research Center HIVRAD Core B. The core develops macaque HIV models to represent human HIV infection and AIDS that may be used for vaccine testing and mechanistic studies of HIV.
  - A discussion occurred regarding the supercoiled primate lentivirus. The full genome
    is present, which necessitates BSL 2 with 3 practices containment. The letter must
    be amended to list BSL 2 with 3 containment for the agent "Plasmid DNA containing
    full length supercoiled primate lentivirus."
  - The draft BUA letter was shown.

- Mei Speer made a motion to approve the draft BUA for Dr. Hu. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Hu, contingent upon revising the letter to reflect the BSL 2 with 3 practices work.
- 7. Koelle, David, change, Development of novel Rotavirus vaccines for vaccination of humans
  - Eric Stefansson served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Eric Stefansson presented the Primary Reviewer Report.
  - The investigator is combining several protocols into one. The work with two strains of HSV that is being added to this project is already approved on another BUA letter.
  - The strains that will be used are HSV-2 strain 186 (wild type) and HSV2 strain 333 TK- (naturally occurring attenuated mutant strain).
  - The draft BUA letter was shown.
  - HSV-2 in mice is listed as NIH Section NA. However this is a risk group 2 agent going
    into a transgenic animal, so it should be listed as III-D\*.
  - Eric Stefansson made a motion to approve the draft BUA for Dr. Koelle. A second is not needed since he is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Koelle, contingent upon listing III-D\* on the BUA letter.
- 8. Lagunoff, Michael, renewal, Molecular Virology of Human Herpes Virus 8
  - Valerie Yerkes served as the Primary Reviewer and Jacqui Bales served as the Biosafety Officer Reviewer. Valerie Yerkes presented the Primary Reviewer Report.
  - The goal of the research is to understand how viruses cause infection by altering host cell gene expression and metabolism.
  - The investigator uses a wide variety of viruses, including herpes viruses, vaccinia virus, dengue virus, adenoviruses, and retroviruses.
  - The investigator will offer vaccinia virus vaccinations to all laboratory workers who
    handle cultures infected with vaccinia. The investigator must also inform staff that
    exposure to more than one strain of Dengue virus means that they are increased
    risk for hemorrhagic fever.
  - The draft BUA letter was shown.
  - Valerie Yerkes made a motion to approve the draft BUA for Dr. Lagunoff. A second is not needed since she is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lagunoff.
- **9.** Lingappa, Jaisri, renewal, *Capsid Assembly Studies* 
  - Paul Swenson served as the Primary Reviewer and Glenn McLean served as the Biosafety Officer Reviewer. Paul Swenson presented the Primary Reviewer Report.
  - The goal of the project is to understand how the capsids of HIV1 other retroviruses, retrotransposons, and alphaviruses are assembled inside cells.
  - The researcher will be working with various viruses at BSL 2 and BSL 2 with 3 practices, including HIV1, HIV2, SIV, MLV (murine leukemia virus), and RSV (respiratory syncytial virus).
  - The draft BUA letter was shown.
  - Paul Swenson made a motion to approve the draft BUA for Dr. Lingappa. A second is not needed since he is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lingappa.

- 10. Palmiter, Richard, renewal, Genetics of Mouse Behavior
  - Jeanot Muster served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Jeanot Muster presented the Primary Reviewer Report.
  - The lab focuses on understanding neural circuits that control behavior. The research involves viral vectors AAV and CAV2.
  - A lab inspection must be successfully completed.
  - Some of the lab staff still need to take BBP training.
  - The draft BUA letter was shown.
  - Jeanot Muster made a motion to approve the draft BUA for Dr. Palmiter. A second is not needed since he is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. Palmiter, contingent upon completion of the lab inspection and necessary training.
- **11.** Scott, John, renewal, AKAP structure and Function
  - Scott Meschke served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. On behalf of Scott Meschke, Steve Libby presented the Primary Reviewer Report.
  - The investigator studies the role of 'A' kinase anchoring proteins (AKAPs) in heart disease, diabetes, and neuronal function.
  - A discussion of corridor use occurred. Eric and Lesley will look into this issue further.
  - The draft BUA letter was shown.
  - Steve Libby made a motion to approve the draft BUA for Dr. Scott. A second is not needed since he presented the Primary Review.
  - The Committee voted unanimously to approve the draft BUA for Dr. Scott.
- **12.** West, Timothy, renewal, *Host genetics and response to infection* 
  - Matthew Parsek served as the Primary Reviewer and Lesley Leggett served as the Biosafety Officer Reviewer. Matthew Parsek presented the Primary Reviewer Report.
  - The primary goal of the research is to understand the response of humans to infectious bacteria, using *Burkholderia thailandensis* and *Burkholderia pseudomallei* as pathogens.
  - The draft BUA letter was shown.
  - Matthew Parsek made a motion to approve the draft BUA for Dr. West. A second is not needed since he is the Primary Reviewer.
  - The Committee voted unanimously to approve the draft BUA for Dr. West.

## **SUBCOMMITTEE REPORTS:**

- **13.** Disis, Mary, new, A Phase I Trial of the Safety and Immunogenicity of a Multiple Antigen Vaccine (STEMVAC) in HER2 Negative Advanced Stage Breast Cancer Patients
  - Elizabeth Corwin, Steve Libby, and Jean Haulman served as the Subcommittee Reviewers and Linda Arnesen served as the Biosafety Officer Reviewer. Elizabeth Corwin presented the Subcommittee Report.
  - The research aims to use a plasmid carrying genes encoding epitopes of resistance with the hope that this will elicit a durable Type 1 helper response against the cancer cells.

- The study will enroll patients with either stage 3 or non-bulky stage 4, HER2
  negative breast cancer patients who are not currently receiving cytotoxic
  chemotherapy and have either no measurable disease or bone only metastatic
  disease.
- The plasmid vaccine will be manufactured at FHCRC under BSL-3 practices. It will then be administered at UWMC under BSL2 containment.
- The investigator did not answer two questions on the BUA application, 25 and 26.
- The draft BUA letter was shown.
- The Committee voted unanimously to approve the draft BUA for Dr. Disis, contingent upon completing the two BUA application questions.

## FOR YOUR INFORMATION:

- Andrea Badger presented the proposed revisions to the BUA application and the BUA change form. There will be a new form for project changes involving the change of principal investigator.
- A subcommittee about environmental release is in the process of being formed. Glenn McLean, George Sanders, Charles Frevert, Toby Bradshaw, Andrea Badger, and Thea Brabb will be invited to join the subcommittee.

**MEETING ADJOURNED AT APPROXIMATELY 12:04.**