INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, November 18, 2015
Time: 10:00 AM – 12:00 PM

Location: Foege N-130A

Members Present:
1. H.D. "Toby" Bradshaw, Biology *(Plant Expert)*
2. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
3. Elizabeth Corwin (*Human Gene Transfer Expert; IBC Vice Chair*)
4. Stephen Libby, Laboratory Medicine (*IBC Chair*)
5. Scott Meschke, Environmental & Occupational Health Sciences
6. Jason Smith, Microbiology
7. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
8. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

Commonly Used Abbreviations
IBC: Institutional Biosafety Committee
BSO: Biological Safety Officer
BUA: Biological Use Authorization
BSL: biosafety level
PI: Principal Investigator
IACUC: Institutional Animal Care and Use Committee
NIH: National Institutes of Health
DURC: Dual Use Research of Concern
SOP: standard operating procedure

1. **CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:04 am. A quorum was present.

2. **REMINDER:** The IBC Chair 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. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the October 21, 2015 minutes meeting.
   - A member made a motion to approve the October 21, 2015 minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the October 21, 2015 meeting minutes.

4. **OTHER VOTING ITEMS**
   - Policy about waste from rabbits experimentally exposed to syphilis
     - The Department of Comparative Medicine asked that a risk assessment be performed to determine the safest and most practical way of disposing of waste and soiled bedding from rabbits experimentally exposed to *Treponema pallidum*.
     - An EH&S biosafety officer performed the risk assessment. Several *T. pallidum* experts were consulted, and a literature search was also performed.
     - The conclusion of the risk assessment was that all waste and materials in contact with waste from rabbits experimentally exposed to *Treponema pallidum* or genetically modified versions of this organism will be handled and treated as ABSL-2 waste, because the presence of *T. pallidum* could not be ruled out. ABSL-2 waste requires sterilization prior to disposal (steam sterilization or incineration) as described in the UW Biohazardous Waste Management Plan.
     - The waste must be treated as ABSL-2 waste, meaning either steam sterilized or incinerated before disposal. Discarding bedding into the sanitary sewer without sterilization is no longer acceptable.
     - The committee discussed this recommendation and whether the document is clear enough that the current Garbeling procedure is no longer acceptable. The committee decided the wording was clear enough as stated in the document.
     - A member made a motion to approve the proposed risk assessment, and require that all waste and materials in contact with waste from rabbits experimentally exposed to *Treponema pallidum* will be handled at ABSL-2 and sterilized prior to disposal. Another member seconded the motion.
     - The committee voted unanimously to approve the proposed risk assessment, and require that all waste and materials in contact with waste from rabbits experimentally exposed to *Treponema pallidum* will be handled at ABSL-2 and sterilized prior to disposal.

5. **DUAL USE RESEARCH OF CONCERN (DURC) REPORT***:* The DURC Report is an overview of projects that were presented at the DURC Institutional Review Entity meeting.

   a. DURC Report
      - The DURC Institutional Review Entity (IRE) met in October and reviewed five DURC applications, submitted by four investigators.

- Dr. Gross submitted a DURC application for his use of Botulinum neurotoxin. The DURC IRE determined that this research is not considered dual use research of concern.
- Dr. Katze submitted a DURC application for work with Ebola virus and Marburg virus. This research is conducted at a BSL-4 facility in another state. No Ebola virus or Marburg virus is used at UW. The UW IRE reviewed this project because some of the grant money used to support this project passes through UW. The DURC IRE discussed the project and determined that this research is not considered dual use research of concern.
- Dr. Manoil submitted a DURC application for work with *Burkholderia pseudomallei*. He is working with strains that are specifically exempted from the regulations. The DURC IRE determined that this research is not conducted dual use research of concern.
- Dr. West submitted two DURC applications for work with *Burkholderia pseudomallei*. The experiments involve generating a pool of *B. pseudomallei* transposon mutants. The goal of the research is to identify genes that are required for bacterial persistence. Any bacterial mutants that are constructed are expected to be less resistant to antimicrobial agents. None of the experiments conducted on this project are attempting to confer enhanced antimicrobial resistance to *B. pseudomallei*. The DURC IRE determined that this research is not considered dual use research of concern.

- The IBC Chair sought a motion to approve this month's DURC Report.
- The Committee unanimously voted to approve this month's DURC Report.

6. INDIVIDUAL PROJECT REVIEWS

1. Childers, Martin, renewal, *Induced pluripotent stem cells (iPSC) derived dystrophin-deficient Cardiomyocytes for High throughput Screening*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The overall goal of the research is to further identify potential effective drugs that are potentially beneficial for Duchenne muscular dystrophy patients with heart problems.
- This project was originally scheduled to be reviewed at the October meeting, but was moved to the November meeting because the description of the research on the application was still unclear. These problems have since been corrected. Agents used on this project include human induced pluripotent stem cells, adeno-associated viral vectors, and Sendai viral vectors. No animal work is conducted on this particular project.
- The principal investigator still needs to complete the biosafety training. If the investigator doesn't finish the training, he will be sent a formal letter from the IBC.
- Most lab inspection deficiencies have been corrected, however, the investigator still needs to order centrifuge safety cups.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Childers. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Childers, contingent upon completion of the biosafety training and resolving the last remaining lab inspection deficiency (involving centrifuge safety cups).

2. Clark, Edward, change, *Lymphocyte Activation (Role of CD22 & Syk Kinase)*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request. The investigator wishes to add non-recombinant Salmonella Typhimurium for use in vitro and in transgenic mice.
- The lab has previously been inspected, and the training is up-to-date.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Clark. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Clark.

3. Gerner, Michael, new, *Organization of Immunity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of the research is to examine mechanisms involved in the immune response, in the hope of developing better vaccine strategies and novel immunotherapies.
- Recombinant *Pseudomonas aeruginosa* will be used on the project.
- The draft BUA letter was shown.
- The training has been completed, but the lab still needs to be inspected. The investigator has just moved his laboratory to UW, and the lab is still in the process of being set up.
- The primary review noted that tamoxifen needs to be added to the IACUC protocol.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gerner. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Gerner, pending the successful completion of the lab inspection.

4. Kavanagh, Terrance, new, *Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered Nanomaterials*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new project from an established investigator. Lentiviral vectors and human cells will be used.
- The lab has been inspected, and the training is up-to-date.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kavanagh. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Kavanagh.

SUBCOMMITTEE REPORTS:

5. Landis, Charles, new, *HBV-001*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report, which is attached.
- This clinical trial aims to evaluate the safety and effectiveness of a plasmid-based gene therapy administered to patients with chronic hepatitis B infection. The administration will occur at Harborview Medical Center.
- The investigator needs to answer questions 11 and 55 on the BUA application.
- The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Landis. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Landis, pending completion of questions 11 and 55 on the BUA application.

7. **BIOSAFETY OFFICER (BSO) REPORT***:* The Biosafety Officer Report includes (1) projects involving recombinant or synthetic nucleic acids covered under section III-E and III-F of the *NIH Guidelines,* (2) proposals involving non-recombinant biohazardous agents requiring BSL-1 and BSL-2 containment, and (3) administrative updates, such as room additions.

   b. Biosafety Officer Report
      - Dr. Furlong, an established investigator, received two new BUA approvals involving non-pathogenic *E. coli* strains and human source material.
      - Dr. Chiu added the cell sorting facility to his approval.
      - Dr. Maier and Dr. Himmelfarb each renewed a BUA for human source material.
      - Dr. Sodora renewed a BUA involving non-recombinant simian immunodeficiency virus.
      - A project involving human and non-human primate source material was transferred from Dr. Clowes to Dr. Kenagy.
      - Dr. Dacey renewed a BUA involving human and non-human primate source material.
      - Dr. Smith added non-pathogenic strains of *E. coli* to his approval.
      - Dr. Ho added new space to his approval.
      - Dr. Murry, an established investigator, received a new BUA approval for human source material.
      - Dr. Matute-Bello, an established investigator, received a new BUA approval involving human cells and non-recombinant *Staphylococcus aureus*.
      - A project involving the creation of transgenic mice was transferred from Dr. Ladiges to Dr. Hsu.
      - The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
      - A member made a motion to approve this month's Biosafety Officer Report. Another member seconded the motion.
      - The Committee unanimously voted to approve this month's Biosafety Officer Report.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:
There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 11:15 a.m.