



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, April 15, 2015

Time: 10:00 AM – 12:00 PM

Location: Health Sciences Building T-269

- Members Present:**
1. Michael Agy, Washington National Primate Research Center
 2. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 3. H.D. "Toby" Bradshaw, Biology (*Plant Expert*)
 4. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 5. Elizabeth Corwin (*Human Gene Transfer Expert; IBC Vice Chair*)
 6. William Glover, Washington State Public Health Laboratories (*Community Member*)
 7. Jean Haulman, UW Travel Clinic
 8. David Koelle, Allergy and Infectious Diseases
 9. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 10. Scott Meschke, Environmental & Occupational Health Sciences
 11. Jeanot Muster, Pharmacology
 12. Matthew R. Parsek, Microbiology
 13. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
 14. Paul Swenson, Seattle-King Co. Dept. of Public Health (*Community Member*)

1. **CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:02 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 March 18th, 2015 minutes meeting.
 - A member made a motion to approve the March 18th, 2015 minutes. Another member seconded the motion.
 - The committee voted unanimously, with one abstention, to approve the March 18th, 2015 meeting minutes.
4. **BIOSAFETY OFFICER (BSO) REPORT:** The BSO report is for project reviews involving infectious agents and for projects falling under Section III-E and III-F of the *NIH Guidelines*.
 - a. Biosafety Officer Report
 - Dr. Horner, Dr. Shendure, and Dr. Kelly each added new space for work with previously approved agents.
 - Dr. de Boer and Dr. Becker each renewed a BUA (Biological Use Authorization) involving work with human source material.
 - Dr. Liu received a new BUA approval for four strains of commensal mouth bacteria, which will be administered to the teeth of pigs.
 - Dr. Yager renewed a BUA involving many wild type strains of Risk Group 1 and Risk Group 2 bacteria, including *Staphylococcus aureus*, *Salmonella typhi*, *Bacillus cereus*, and *Bordetella pertussis*.
 - Dr. Merrikh renewed a BUA involving work with *Bacillus cereus* and *Bacillus thuringiensis* for use in insects. A discussion occurred regarding *Bacillus cereus*. This is listed as BSL-1 (biosafety level 1) on Dr. Merrikh's letter, but as BSL-2 on Dr. Yager's BUA letter. EH&S will look into this and determine if BSL-1 containment is appropriate for the Merrikh lab or whether BSL-2 containment should be used. For now, the Merrikh project will be removed from the biosafety officer report.
 - Dr. Dodd added three new species of non-recombinant Risk Group 2 bacteria, *Enterococcus faecium*, *Pseudomonas aeruginosa*, and pathogenic strains of *E. coli*.
 - 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, except for Dr. Merrikh's project, which will be presented again after EH&S investigates. Another member seconded the motion.
 - One member declared a conflict of interest.
 - The Committee unanimously, with one abstention, voted to approve this month's Biosafety Officer Report, except for Dr. Merrikh's project.
 - *Update: Dr. Merrikh is planning to expand her studies and has submitted a BUA application to use additional Risk Group 2 bacteria. Her work will be assigned to a Primary Reviewer and presented to the IBC in May.*

5. CATEGORY III-D AMENDMENTS

1. Ladiges, Warren, change, *Cancer Consortium Xenograft Resource*
 - The biosafety officer presented an overview of the project and requested change.
 - The lab is adding transfected cells for use in mice. The IBC has already reviewed this work. Dr. Chen is approved for this agent on her protocol, and she will be the person doing the work with mice on the Ladiges protocol.
 - The assigned IBC member endorsed the biosafety officer's review.
 - The draft BUA letter was shown.
 - The assigned IBC member made a motion to approve the draft BUA for Dr. Ladiges. A second is not needed since he endorsed the review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.

6. INDIVIDUAL PROJECT REVIEWS

2. Chait, Alan, change, *Lipoproteins, Inflammation and Atherosclerosis*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab researches inflammation associated with diabetes and obesity.
 - The PI is requesting to add AAV (adeno-associated viral vectors) for both in vitro use and in vivo use in mice.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chait. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chait.
3. Chamberlain, Jeffrey, change, *Gene Therapy for Neuromuscular Disorders of Canines*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the Chamberlain lab is to understand and develop treatments for muscular dystrophies and other disorders of muscle.
 - The PI is requesting to add plasmid DNA for use in dogs.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chamberlain. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain.
4. Chamberlain, Jeffrey, change, *Gene Therapy for Neuromuscular Disorders*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The PI is requesting to add plasmid DNA for use in mice.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chamberlain. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain.
5. Clark, Edward, renewal, *Lymphocyte Activation (Role of CD22 & Syk Kinase)*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal of an existing project. The overall goal of the research is to understand how effective antibodies against West Nile virus (WNV) can be induced in order to create WNV vaccines.

- West Nile virus is used both in-vitro and in mice on this project. This agent is used at BSL-2 with BSL-3 practices and ABSL-2 with ABSL-3 practices (animal biosafety level).
 - Training has been completed, and the lab inspection has been conducted.
 - 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 she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Clark.
6. Drury-Stewart, Danielle, new, *HLA-Engineered Universal Donor Stem Cells*
- The IBC chair presented the Primary Review on behalf of the assigned IBC Primary Reviewer.
 - This is a new project involving transducing human or mouse cells with AAV, lentiviral vectors, and Sendai viral vectors. No animal work is conducted on this protocol.
 - The PI works for an outside company, Universal Cells. All work will be conducted at UW core facilities (Immunology Cell Analysis Facility and Ellison Stem Cell Core).
 - The required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Chair made a motion to approve the draft BUA for Dr. Drury-Stewart. A second is not needed since he endorsed the Primary Review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Drury-Stewart.
7. Heinecke, Jay, change, *Cardiovascular Disease and Diabetes Program Project*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab researches heart disease and diabetes.
 - This is a change. The investigator has requested to add the Armstrong strain of LCMV (lymphocytic choriomeningitis virus) and AAV for use in vitro and in mice.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Heinecke. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Heinecke.
8. Muster, Jeanot, new, *South Lake Union Aquatics*
- One member declared a conflict of interest.
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is an application designed to serve as a core BUA for the South Lake Union aquatics facility. Each user of the Aquatics facility will have his or her own BUA letter.
 - The draft BUA letter was shown. The breeding and use of transgenic zebrafish are listed on the letter.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Mr. Muster. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously, with one abstention, to approve the draft BUA for Mr. Muster.
9. Pasupathy, Anitha, new, *2-photon imaging in awake monkey visual cortex*
- The assigned IBC Primary Reviewer presented the Primary Review.

- The Pasupathy lab researches the relationship between brain activity and higher-level cognitive functions such as visual perception, recognition, memory, and decision-making.
- This is a new BUA application from an established investigator. AAV will be administered to macaques.
- The work will be conducted at BSL-2.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pasupathy. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Pasupathy.

10. Storm, Daniel, change, *Ca2+ sensitive Adenylyl Cyclases and Neuroplasticity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Storm lab researches the molecular and cellular mechanisms for memory formation.
- This change requests the addition of lentiviral vectors for in-vitro use.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Storm. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Storm.

11. Tempel, Bruce, renewal, *Auditory Neurogenetics*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The Tempel lab researches the molecular mechanisms involving in hearing and hearing loss.
- Agents used on this project include human and non-human primate blood, as well as lentiviral vectors used in mice.
- The training has been completed, but the lab inspection still needs to be conducted.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Tempel. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Tempel, contingent upon the lab inspection.

SUBCOMMITTEE REPORTS:

12. Chapuis, Aude, new, *Phase I/II study in WT1-expressing non-small cell lung cancer and mesothelioma, comparing cellular adoptive immunotherapy with polyclonal autologous central memory to naive CD8+ T cells that have been transduced to express a WT1-specific T cell receptor*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report, which is attached.
- This is a new phase I/II study involving participants with advanced non-small cell lung cancer or mesothelioma. A lentiviral vector will be used to transduce T cells isolated from the participant's blood. The lentivirus contains genes expressing a characterized WT1 (Wilms' tumor) specific T-cell receptor.
 - The Wilms' tumor antigen is considered a possible therapeutic target in this study because it is involved in regulation of gene expression and transformation

of cells to a malignant phenotype. It is overexpressed in 30-80% of non-small cell lung cancers and 100% of mesotheliomas.

- The UW IBC is reviewing this study because the transduced cells will be re-infused into participants at the UW Clinical Research Center (CRC).
- The subcommittee reviewed the informed consent documents and recommends adding language in the consent form explicitly informing patients that while they may drop out of the study, the genetically modified cells cannot be removed once administered.
- The RAC (Recombinant DNA Advisory Committee) performed an initial review of this study and determined that an in-depth review and public RAC discussion was not required.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Chapuis. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Chapuis.
- The recommended change to the consent form will be communicated to the PI

FOR YOUR INFORMATION:

- EH&S has been working on preparing for the new DURC (Dual Use Research of Concern) policy, which comes into effect in September.
 - A DURC review committee, which will be a subcommittee of the IBC, is in the process of being formed.
 - The 15 agents and toxins included in the DURC policy overlap with the Select Agents and Toxins List from the Federal Select Agent Program. One difference, however, is that there are no exempted quantities of Botulinum neurotoxin (Botox). The DURC committee will be required to review every project involving any quantity of Botox.
- The IBC meetings will be moved to a larger room starting in June.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 11:40 am.