



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, December 16, 2015

Time: 10:00 AM – 12:00 PM

Location: Foegen N-130A

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. H.D. "Toby" Bradshaw, Biology (*Plant Expert*)
 3. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 4. Elizabeth Corwin (*Human Gene Transfer Expert; IBC Vice Chair*)
 5. David Koelle, Allergy and Infectious Diseases
 6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 7. Scott Meschke, Environmental & Occupational Health Sciences
 8. Jason Smith, Microbiology
 9. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
 10. 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 10:06 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 November 18, 2015 minutes meeting.
 - A member made a motion to approve the November 18, 2015 minutes. Another member seconded the motion.
 - The committee voted unanimously, with 2 abstentions, to approve the November 18, 2015 meeting minutes.
4. **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.
 - a. Biosafety Officer Report
 - Dr. Curnow, Dr. Gao, Dr. Rostomily, Dr. Foy, and Dr. Dale added new rooms to their respective approvals.
 - Dr. Hebert renewed a BUA letter involving human blood.
 - Dr. Mulligan renewed a BUA letter involving plasmid DNA.
 - Dr. Yager added a new species of non-recombinant bacteria to his approval.
 - Dr. Jiang, Dr. Pepple, and Dr. Karchin each received a new BUA letter involving human source material.
 - Dr. Marrazzo renewed a BUA letter involving human and non-human primate source material and wild-type bacteria.
 - Dr. McLean received a new BUA involving several species of non-recombinant bacteria.
 - Dr. Nghiem added non-recombinant Epstein-Barr virus to his approval.
 - Dr. Bruce renewed a BUA letter involving several species of non-recombinant bacteria, including *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*.
 - Dr. Katze added a new non-recombinant virus, herpesvirus saimiri, to his approval.
 - 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, with one abstention, to approve this month's Biosafety Officer Report.

5. INDIVIDUAL PROJECT REVIEWS

1. Altemeier, William, change, *Inflammatory Response Modulation by Mechanical Ventilation*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request. The investigator wants to add recombinant *S. aureus* and *P. aeruginosa*. These agents will be used in vitro and in mice.
 - The draft BUA letter was shown.

- The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Altemeier. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Altemeier.
2. Chen, Eleanor, change, *Druggable pathways in rhabdomyosarcoma*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request. The investigator wants to add adeno-associated viral vectors (AAV) and lentiviral vectors. The AAV will be used in vitro, and the lentiviral vectors will be used in vitro and in mice.
 - The draft BUA letter was shown.
 - The lab has previously been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer 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.
3. Disis, Mary, renewal, *Evaluation of Immunity to Cancer in a Rodent Model*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to develop diagnostic tools and treatments for cancer.
 - Plasmid DNA, human cells, and lentiviral vectors are used on the project.
 - A discussion occurred about humanized mice. A question was raised about whether the lentiviral vectors are used in humanized mice. The biosafety officer will check.
 - The third generation lentiviral vectors are administered at ABSL-1.
 - The draft BUA letter was shown.
 - The lab was inspected and some issues are in the process of being resolved. The required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Disis. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis, pending completion of the lab inspection.
4. Doherty, Dan, change, *Joubert Syndrome and related disorders*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request. The investigator is adding lentiviral vectors and gammaretroviral vectors. Human cells are also used on the project.
 - The draft BUA letter was shown.
 - The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Doherty. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Doherty.
5. Murry, Charles, renewal, *Myocardial Infarct Repair*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab uses stem cells to study their differentiation into cardiovascular lineages such as cardiomyocytes, endothelial cells, and smooth muscle cells.

- Various viral vectors are used on the project, including adeno-associated viral vectors, adenoviral vectors, and lentiviral vectors. Embryonic stem cells and induced pluripotent stem cells are used.
 - The draft BUA letter was shown.
 - The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Murry. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Murry.
6. Oberst, Andrew, change, *Programmed Cell Death and Immunity*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change. The investigator wants to add recombinant plasmid DNA, administered to mice. The work will be conducted at ABSL-1.
 - The draft BUA letter was shown.
 - The lab has previously been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Oberst. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oberst.
7. Rajagopal, Lakshmi, renewal, *Ascending GBS Infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The overall goal of the research is understand how virulence factors and their regulatory systems affect Group B Streptococcus associated with preterm birth. Wild-type and recombinant strains of *Streptococcus agalactiae* are used.
 - The draft BUA letter was shown.
 - The lab has previously been inspected, and the required trainings have been completed.
 - A footnote needs to be added to the BUA letter (the one about wildtype & recombinant species).
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Rajagopal. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rajagopal, pending correction of the BUA letter.
8. Regnier, Michael, renewal, *Cardiac Kinetics, Cooperative Activation, Cardiac Repair*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab studies cardiac muscle function and repair. AAV, adenoviral vectors, and lentiviral vectors are used. Human cells in mice and rats are also used.
 - The draft BUA letter was shown.
 - Non-exempt strains of E. coli are used, so they need to be added to the BUA letter under section III-E.
 - The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Regnier. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Regnier, contingent upon correction of the BUA letter.

9. Ruohola-Baker, Hannele, renewal, *microRNA Function in Human Embryonic Stem Cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to identify and understand the functions of the key microRNAs in human embryonic stem cells.
 - Human cells are used, as well as lentiviral vectors.
 - There are some agents listed on the BUA application that are not present on the IACUC protocol, and vice versa. The biosafety officer will verify that these two documents match before the BUA letter is sent out.
 - The draft BUA letter was shown.
 - The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Ruohola-Baker. A second is not needed since he is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ruohola-Baker, pending agents on the BUA application and the IACUC protocol matching.
10. Wang, Wang, renewal, *Role of mitochondrial reactive oxygen species in cardiac function and dysfunction*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to study the role of mitochondrial respiration and reactive oxygen species in normal heart function regulation and in oxidative stress-related disease.
 - Adeno-associated viral vectors, adenoviral vectors, and lentiviral vectors are used on the project. Human cell lines are also used.
 - Non-exempt strains of E. coli are used, so they need to be added to the BUA letter under section III-E.
 - The draft BUA letter was shown.
 - The lab has been inspected, and the required trainings have been completed.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wang. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wang, contingent upon correction of the BUA letter.
11. Yang, Xiaoming, renewal, *Interventional Oncology*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab utilizes in vitro and in vivo models with the goal of developing new technologies of radiofrequency heating enhanced gene therapy for human hepatic and esophageal malignancies.
 - Plasmid DNA and lentiviral vectors are used, as well as human cells. Pigs, mice, and rats are used on the project.
 - The lab was inspected and is in good condition. The training has been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Yang. A second is not needed since she is the Primary Reviewer.
 - The Committee voted unanimously to approve the draft BUA for Dr. Yang.

SUBCOMMITTEE REPORTS:

12. Turtle, Cameron, new, *A Phase 1b study of JCAR014, autologous T cells engineered to express a CD19-specific chimeric antigen receptor, in combination with durvalumab for relapsed/refractory B-cell non-Hodgkin lymphoma*
- 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 gene therapy trial with the aim of evaluating the safety and tolerability of JCAR014 (CD19-specific CART cells) in combination with durvalumab. Participants in this study have refractory or relapsed B-cell lymphoma. A fourth-generation lentiviral vector is used.
 - The consent forms were reviewed, and the subcommittee felt that they are clearly worded and present the possible risks of the treatment in a straightforward manner. The NIH Recombinant DNA Advisory Committee reviewed the study and determined that the study did not require an in-depth review.
 - The draft BUA letter was shown.
 - The investigator is primarily associated with Fred Hutchinson Cancer Research Center. The biosafety officer is checking with FHCRC to confirm that Dr. Turtle has taken the FHCRC biosafety training.
 - A member made a motion to approve the draft BUA letter for Dr. Turtle. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Turtle, pending verification of the biosafety training record.

FOR YOUR INFORMATION:

- The IBC Freezer subcommittee met and is considering several issues, including whether PIs should register or declare biohazardous agents that are in freezer storage only, and whether annual inventory checks should be recommended or required. A written proposal will be presented to the committee at a later meeting.
- The IBC Chair talked about the training policy for IBC members. Members should take the online biosafety training, bloodborne pathogens training, and DURC training once every three years.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

MEETING ADJOURNED AT APPROXIMATELY 11:25 a.m.