INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, July 20, 2016
Time: 10:00 AM – 12:00 PM

Location: Foege N-403

Members Present:
1. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
2. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
3. Richard Grant, Washington National Primate Research Center
4. Garry Hamilton (*Community Member*)
5. David Koelle, Allergy and Infectious Diseases
6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
7. Scott Meschke, Environmental & Occupational Health Sciences
8. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)
9. 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 10:03 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. **SPECIAL PRESENTATION:**
   - Several representatives from the Office of Research were introduced. They discussed the ESCRO (Embryonic Stem Cell Research Oversight) committee and requirements for research with embryonic stem cells. ESCRO oversees and approves all research involving the creation of embryonic stem cell lines and iPSCs (induced pluripotent stem cells) transplanted into animals or humans. ESCRO is responsible for verifying that federal funding is only used for human embryonic stem cell lines that appear in the NIH stem cell registry. The ESCRO approval period is 3 years, and they currently have about 15 applications. There is one ESCRO meeting per year.

4. **APPROVAL OF MINUTES:**
   - The IBC Chair sought a motion to approve the minutes from the June 17, 2016 meeting.
   - A member made a motion to approve the June 17, 2016 minutes. Another member seconded the motion.
   - The committee voted unanimously to approve the June 17, 2016 meeting minutes.

5. **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
      - The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
      - Dr. Murry, Dr. Salipante, and Dr. Fuller each added a new room to their respective approvals.
      - Dr. Zagotta renewed a project involving human cells, recombinant baculovirus, and yeast.
      - Dr. Scott added the Pathology Flow Cytometry Core Facility to his BUA approval.
      - Dr. Chatterjee renewed a project involving non-exempt strains of non-pathogenic *E. coli* and human cells.
      - Dr. Averkiou received a new approval for a project involving human source material.
      - Dr. Banerjee received a new approval for *Dictyostelium discoideum*, a species of amoeba, and human cells.
      - Dr. Cattolico received a new approval for a project involving transgenic algae.
      - Dr. Sarikaya renewed a project involving human source material and non-recombinant *Streptococcus mutans*.
      - Dr. Mougous received an updated BUA letter reflecting that recombinant Risk Group 1 microorganisms tested on whole animals requires approval at a minimum of ABSL-2 containment.
      - Dr. Hoofnagle received a new approval for human source material.
      - Dr. Sen, an investigator at UW Bothell, received an approval to examine crow feces for *E. coli*, *Campylobacter*, and *Salmonella* species.

- 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.

6. INDIVIDUAL PROJECT REVIEWS

1. Chatterjee, Champak, change, *Histone SUMOylation*
- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change requesting to add an amphotrophic gammaretroviral vector and transfected human cell lines.
- The lab has been inspected and all required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chatterjee. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Chatterjee.

2. Koelle, David, change, *Koelle Laboratory at UW*
- One member declared a conflict of interest.
- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change requesting to add a DNA vaccine to be administered to mice.
- The lab has been inspected and all required trainings have been completed.
- The draft BUA letter was shown.
- The IBC member who declared the conflict of interest left the room.
- The IBC Primary Reviewer 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, with one abstention, to approve the draft BUA for Dr. Koelle.

3. Darvas, Martin, renewal, *Genetic analysis of mouse behavior*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The Darvas laboratory studies how genes affect the function of the nervous system and how genes regulate animal behavior.
- Canine adenoviral vectors, adeno-associated viral vectors, and lentiviral vectors are used in mice.
- The draft BUA letter was shown.
- The biosafety officer clarified that lentiviral vectors are listed as ABSL-1 when used in mice because the vectors are third-generation.
- The lab was inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Darvas. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Darvas.

4. Chapuis, Aude, new, *Phase I/II study of Autologous (central memory/naïve) CD8+ T cells that have been transduced to express a WT1-specific T cell receptor for treatment of AML*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- This is a clinical trial. A lentiviral vector is used. The lentiviral vector construct is identical to that used in another clinical trial led by Dr. Chapuis, approved by the IBC in 2015. The patient population in each trial is slightly different. The trial approved in 2015 was for participants with mesothelioma and non-small cell lung cancer. The newly submitted clinical trial is for participants with acute myeloid leukemia.
- The subcommittee reviewers reviewed the proposed consent forms and found that they accurately state potential risks involved with the study.
- The draft BUA letter was shown.
- The IBC Subcommittee Reviewer made a motion to approve the draft BUA for Dr. Chapuis. A second is not needed since he is the Subcommittee Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Chapuis.

5. Sandmaier, Brenda, renewal, *A Phase 1/2 Dose Escalation Study Evaluating Safety and Feasibility of BPX-501 T Cells after Partially Mismatched, Related, T Cell-Depleted HSCT*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal of a clinical trial. The research seeks to investigate the safety and feasibility of a method to minimize the risk of graft vs. host disease for patients who receive a stem cell transplant from a non-HLA identical donor.
- The NIH RAC performed an initial review and declared that a full, in-depth review was not required.
- The subcommittee reviewers reviewed the proposed consent forms and found that they accurately convey the potential risks of participating in the study in a manner that is clearly understandable.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Sandmaier. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Sandmaier.

6. Raines, Elaine, renewal, *Biology of the Artery Wall/ADAM-mediated Shedding*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to define the molecular mechanisms involved in the initiation and resolution of inflammatory responses with a particular focus on formation of lesions of atherosclerosis.
- Both amphotropic and ecotropic gammaretroviral vectors are used. Amphotropic gammaretroviral vectors are used in vitro, while eoctropic gammaretroviral vectors are used in vitro and in mice. Human and non-human primate cells are also used on the project.
- The lab has been inspected and all required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Raines. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Raines.

7. Elkon, Keith, renewal, *Genetic, Cellular, and Molecular Studies in SLE (Apoptosis)*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the project is to define the molecular basis of autoimmune diseases such as lupus and rheumatoid arthritis, to uncover the pathways leading to the autoimmune disease.

- Human and non-human primate cells are used on the project. Adeno-associated viral vectors are also used.
- UV irradiation of mice also occurs on this project. The EH&S radiation safety office is reviewing this work.
- The lab has been inspected and all required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Elkon. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Elkon.

8. Hille, Bertil, renewal, *Molecular Properties of Ionic Permeability of Nerve; Electric Studies of Excitation, Secretion and Contraction; Trafficking mechanisms for secretory vesicles in pancreatic duct epithelial cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- Adenoviral vectors and human cells are used on the project.
- A question was raised about Dr. Hille's animal protocol. Dr. Hille has an animal protocol, but no biological agents are administered to animals, so the animal protocol and BUA are not associated.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hille. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Hille.

9. Ho, Rodney, renewal, *Targeting Drug to HIV Sanctuary in Lymphatics*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal of an ongoing project with the goal of developing methods of targeting drugs to HIV reservoirs in lymphatic tissues. The researchers use SHIV (simian human immunodeficiency virus) as a model of human HIV infection.
- The work is conducted at BSL-2 with BSL-3 practices.
- The investigator did not finish one section of the BUA application, the microorganism table. This should be completed.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Ho. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Ho.

10. Kawasumi, Masaoki, new, *Skin Cancer Research*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new investigator, but the project has been previously approved. Dr. Kawasumi is becoming the PI of the project "Skin Cancer Research." Previously Dr. Nghiem has been the PI of this project.
- Human cells are used in mice. Adenoviral vectors, gammaretroviral vectors, lentiviral vectors, and Epstein-Barr virus is used in vitro.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kawasumi. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Kawasumi.

11. Kueh, Hao, new, *Single-cell analysis of immune cell fate decisions*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to understand how immune cells make fate decisions, and how these decisions are controlled. The investigator will use quantitative imaging to follow the regulation of key immune fate regulatory genes in single, developing cells, and combine these measurements with mathematical modeling.
- Gammaretroviral vectors and lentiviral vectors are used.
- The draft BUA letter was shown.
- The PI was recently hired and has not yet arrived and set up a lab. The approval will be pending the lab inspection. Several BUA application questions can only be completed once the lab is set up. The lab inspection and BUA application will be fully completed once the investigator arrives. The required trainings have been taken.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kueh, contingent on the lab inspection. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Kueh, contingent on the lab inspection.

12. McGuire, John, renewal, *Epithelial regulation of tissue repair and inflammation*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the proposed work is to understand how the epithelium regulates tissue and organ responses to injury and infection in health and disease, and how specific injury responses regulate resolution of disease or contribute pathologically in disease processes with chronic epithelial injury.
- *Pseudomonas aeruginosa* and pneumonia virus of mice (PVM) are used in vitro and in transgenic mice. Human cells are used in vitro.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. McGuire. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. McGuire.

13. Pepper, Marion, change, *The Differentiation and Protective Function of CD4+ memory T cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The investigator is requesting to immunize mice with an RNA-containing nanoparticle.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pepper. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Pepper.

14. Tian, Rong, change, *Energetics and Metabolism of the Heart*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The investigator is requesting to add lentiviral vectors and liposome complexes to study the effect of key genes on cardiac metabolism.
- The draft BUA letter was shown.
- The lab has been inspected and all required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Tian. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Tian.

15. Merrikh, Houra, change, *Mechanisms of replication conflict processing*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The investigator is requesting to add recombinant *Mycobacterium tuberculosis*, as well as several risk group 2 agents: *M. smegmatis, E. faecalis, S. pneumoniae, and S. Typhimurium.*
- The committee discussed the planned experiments with M. tuberculosis. The committee would like more details about what results she is anticipating, and what actions she will take if antibiotic resistant mutants spontaneously occur.
- The SOPs have not yet been submitted to the BSO for review.
- BSL-3 training is in process. Work with Mycobacterium tuberculosis will not occur until the SOPs have been reviewed by the BSO and training has been completed.
- The biosafety officer said that work with the risk group 2 agents is ready to proceed. The BSL-2 lab space has been inspected and although the BSL-3 in-person training is still in process, the standard online biosafety training required for BSL-2 work has been completed.
- The draft BUA letter was shown.
- The IBC Subcommittee Reviewer made a motion to approve the proposed work with Risk Group 2 agents, and to postpone approval of the proposed work with Mycobacterium tuberculosis pending clarification of planned experiments, BSL-3 training, and biosafety officer review of the SOPs. The work with Mycobacterium tuberculosis will be reviewed at an upcoming IBC meeting. A second is not needed since he is the Subcommittee Reviewer.
- The Committee voted unanimously to approve the proposed work with Risk Group 2 agents, and to postpone approval of the proposed work with Mycobacterium tuberculosis to a future meeting (pending clarification of planned experiments, BSL-3 training, and biosafety officer review of the SOPs).
- Post-Meeting Update: Dr. Merrikh decided to withdraw her application to work with M. tuberculosis. A BUA letter listing the Risk Group 2 agents listed above was sent.

FOR YOUR INFORMATION:

- NIH Reportable Incident
  - Last month, the committee was informed of an incident where a researcher sustained an injury while working with recombinant Mycobacterium tuberculosis in a lab. The researcher was using an ultra-fine point permanent marker to label tissue culture plates, which contained human cells infected with M. tuberculosis. As the researcher put the cap back on the pen, he punctured his gloves with the tip of the pen and tore the skin on his finger. He followed

proper post-exposure steps and performed first aid, and reported the incident appropriately and sought medical assistance from the Employee Health Center. The laboratory and facility replaced these markers with felt-tipped pens. This incident was reported to NIH OBA and they replied that our response to the incident was sufficient and no further information is required.

- NIH Reportable Incident
    - An NIH report was submitted in response to the clarification from the Office of Biotechnology Activities that experiments involving recombinant Risk Group 1 microorganisms used in whole animals must be conducted at a minimum of ABSL-2 containment. All approvals have now been reissued stating that ABSL-2 containment is required. NIH OBA replied to our incident report and determined that our response to the incident was sufficient and no further information is required.
    - Two investigators worked with EH&S to provide scientific rationale to the NIH to lower containment to ABSL-1 for several murine *Plasmodium* strains that do not have the potential to infect human cells. The NIH accepted and approved the scientific rationale, and stated that waste containing the recombinant *Plasmodium* mouse strains should be decontaminated. The animal carcasses will be autoclaved before disposal. The NIH also indicated that particular attention be paid to sharps safety.

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

MEETING ADJOURNED AT APPROXIMATELY 12:10 p.m.