INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, August 17, 2016
Time: 10:00 AM – 12:00 PM

Location: Foege N-130A

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. David Koelle, Allergy and Infectious Diseases
5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
6. Scott Meschke, Environmental & Occupational Health Sciences
7. Matthew R. Parsek, Microbiology
8. Jason Smith, Microbiology
9. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer*)

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 10:08 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 July 20, 2016 meeting.
   - A member made a motion to approve the July 20, 2016 minutes. Another member seconded the motion.
   - The committee voted unanimously, with three abstentions, to approve the July 20, 2016 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
      - The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
      - One member declared a conflict of interest.
      - Dr. Unadkat renewed a BUA involving human source material.
      - Dr. Carlson renewed a BUA involving non-pathogenic strains of E. coli and human source material.
      - Dr. Stoll initiated a new project involving non-pathogenic E. coli strains. The committee discussed these strains. Only K-12 strains are exempt from the NIH Guidelines, and these are BL-21 strains, so they fall under NIH section III-E.
      - Dr. Yager added a virus-like particle (that does not contain genetic material) to his BUA. The particle was approved at BSL-2.
      - Dr. Klavins initiated a new BUA involving human and non-human primate cells, as well as plasmid DNA.
      - The principal investigator of the projects "*Horizontal Gene Transfer in Chlamydia*" and "*CORE Laboratory Procedures: Tissue Culture, Serology, DNA and RNA Amplifications of STIs*" was transferred from Dr. Marrazzo to Dr. Soge.
      - Dr. Koelle added non-recombinant Zika virus (used in vitro) to his BUA approval.
      - Dr. Jiang, Dr. Dhaka added a new room to her BUA approval.
      - The core BUA approval for the Washington National Primate Research Center was renewed. The principal investigator is Jeremy Smedley. The approval covers the use of non-human primates and their tissue, blood, body fluids, and cells in the WaNPRC Facility. Research with infectious agents or recombinant DNA is approved separately per project.
      - Dr. von Moltke received a new BUA approval to work with mouse parasites (*Heligmosomoides polygyrus* and *Nippostrongylus brasiliensis*). The animal work was approved at ABSL-2. Dr. von Moltke is currently doing the work at ABSL-1 at his current institution. The Department of Comparative Medicine is asking for some documentation before ABSL-1 containment is allowed here. The IBC may be seeing this project again if Dr. von Moltke decides to submit a request for ABSL-1 containment.

- 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.

5. INDIVIDUAL PROJECT REVIEWS

1. Raible, David, renewal, *Regulation of Zebrafish Development*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the project is to understand how mechanosensory hair cells develop, respond to damage, and regenerate.
- One of the rooms the Raible lab would like to use for microscopy does not have a sink. The closest sink is found in the restrooms on the other side of the building. The committee discussed this. No biohazardous agents are used in the room. However, the committee is concerned about possible potential chemical exposures. The committee decided that the biosafety officer and industrial hygienist should evaluate any potential chemical exposures. The lab also needs to have a spill kit in place, and the industrial hygienist should ensure that the spill kit itself does not contain potential chemical exposures. Also, a written SOP should be drafted and reviewed by the industrial hygienist.
- The draft BUA letter was shown.
- The training has been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Raible. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Raible, pending industrial hygienist review of potential chemical exposures in the microscopy room.

2. Dhaka, Ajay, new, *Dhaka Zebrafish*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new BUA application. The investigator wants to use transgenic zebrafish. The overall goal of the project is to develop an understanding of how neural crest cells and cranial placode progenitors generate a diverse group of different cell types.
- The draft BUA letter was shown.
- The training has been completed, but the training section on the application should be completed properly. The lab has been inspected.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Dhaka, pending completion of the training section on the BUA application. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Dhaka, pending completion of the training section on the BUA application.

3. Bornfeldt, Karin, renewal, *Cardiovascular Disease and Diabetes*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to investigate the mechanisms whereby diabetes promotes cardiovascular disease and to identify the associated cellular and molecular changes in blood vessels.
- Adeno-associated viral vectors, lentiviral vectors, gammaretroviral vectors, and lymphocytic choriomeningitis virus (Armstrong 53b strain) are used on the project.

- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bornfeldt. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Bornfeldt.

4. Doulatov, Sergei, new, *Hematopoiesis from cord blood and pluripotent stem cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new application. The investigator is interested in studying hematopoiesis as it relates to human development and disease. Human cells, gammaretroviral vectors, lentiviral vectors, and Sendai viral vectors are used on the project.
- A question was raised about animal work. All of the work on this BUA is in vitro.
- The draft BUA letter was shown.
- The trainings have been completed. The investigator has recently arrived at UW and not all of the lab equipment has been set up yet. The biosafety officer will be returning to the lab once it is fully set up.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Doulatov, pending a follow up lab inspection. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Doulatov, pending a follow up lab inspection.

5. Goverman, Joan, renewal, *Cell Analysis Core Facility*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal BUA for a flow cytometry cell sorting core facility located at South Lake Union.
- Users must have their projects approved by the IBC prior to using the facility.
- The lab has clearly defined SOPs for using each piece of equipment and users must be trained and approved to use the equipment prior to use.
- The facility has been inspected and all of the required training is in place. All users are trained on pertinent SOPs.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Goverman. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Goverman.

6. Hu, Shiu-Lok, renewal, *Glycan modification, CD4 independence, and Env Immunogenicity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. Agents used on the project include SHIV, vaccinia virus, and human cells.
- The lab inspection is pending. The required trainings have been completed.
- A discussion occurred about the vaccinia virus. The researchers have been trained on the UW Vaccinia Policy and will be vaccinated in accordance with the policy.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hu, pending completion of 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. Hu, pending completion of the lab inspection.

7. Hybiske, Kevin, renewal, *Chlamydia trachomatis pathogenesis and immune evasion*
- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The lab studies Chlamydia pathogenesis. The overall goal is to understand the molecular nature of pathogenesis on both the host and microbe side of infection.
- *Chlamydia muridarum*, *Chamydia trachomatis* (LGV strains), and *Chlamydia psittaci* strains are used. Human cells and gammaretroviral vectors are also used on the project.
- The BMBL states that in vitro work with *Chlamydia psittaci* and *Chlamydia trachomatis* (LGV strains) should be conducted at BSL-2 with BSL-3 practices. *C. psittaci* is not used in vivo on this project. The BMBL says that animal work with *C. trachomatis* should be done at ABSL-2. The committee discussed this recommendation and would like the biosafety officer to check and make sure that ABSL-2 containment is appropriate.
- A member pointed out that the Chlamydia species nomenclature has changed recently, and the BUA letter may need to be edited to reflect this. The biosafety officer will check.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hybiske. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Hybiske.

8. Lin, Shin, new, *Epigenomics of Heart Failure*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator studies the epigenomics of heart failure.
- Adenoviral vectors and lentiviral vectors are used on the project.
- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lin. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Lin.

9. Lund, Jennifer, renewal, *Evaluating immunity to West Nile virus infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies the role of regulatory T cells in antiviral immunity.
- West Nile Virus is used in vitro and in mice. Tissues will be collected from infected mice and studied.
- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Lund. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Lund.

10. Manoil, Colin, renewal, *Genetic analysis of Gram-negative bacterial pathogens (BSL-2 experiments)*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Manoil lab uses genetic and genomic approaches to characterize essential and antibiotic resistance genes in gram negative pathogens and non-pathogenic surrogates. The lab creates mutants and analyses antibiotic sensitivity.
- *Acinetobacter baumannii*, *Burkholderia thailandensis*, *Pseudomonas aeruginosa*, and *Burkholderia pseudomallei* (strain Bp82) are used on the project. The Bp82 strain of *B. pseudomallei* is exempt from select agent regulations.
- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Manoil. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Manoil.

11. Neitz, Maureen, renewal, *Genes and photopigments of red-green color vision: exploring circuitry with fMRI; Directed evolution of AAV to identify vectors that transduce photoreceptors and RPE cells when injected into the vitreous*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of this project is to develop therapeutic approaches to slow or prevent blindness in humans by using viral vectors to restore light sensitivity to the retina.
- Adeno-associated viral vectors are used on the project.
- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Neitz. A second is not needed since she is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Neitz.

12. Oshima, Junko, renewal, *International Registry of Werner Syndrome*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the project is to elucidate the genetic mechanisms of aging.
- Lentiviral vectors, gammaretroviral vectors, and foamy viral vectors are used on the project.
- The draft BUA letter was shown.
- The inspection has been completed, and the required trainings have also been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Oshima. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Oshima.

13. Smith, Jason, change, *Antiviral Mechanisms of Defensins*

- One member declared a conflict of interest and left the room.
- The assigned IBC Primary Reviewer presented the Primary Review.
- The investigator wants to add work with wild type *Cryptosporidium parvum* (Iowa strain) and a recombinant *C. parvum* strain that expresses luciferase.

- All of the required trainings have been completed, and the lab was recently inspected.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Smith. 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. Smith.

14. Van Voorhis, Wesley, change, *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium 5. Giardia*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The investigator would like to add the use of Giardia lamblia in vitro and in mice.
- A discussion occurred regarding Giardia intestinalis. This is a subspecies of Giardia lamblia, so only Giardia lamblia is listed on the BUA letter.
- All of the required trainings have been completed, and the lab was recently inspected.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Van Voorhis. A second is not needed since he is the Primary Reviewer.
- The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.

15. Wald, Anna, change, *A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Trial to Evaluate the Safety and Efficacy of Herpes Simplex Virus, Type 2 (HSV-2) Therapeutic DNA Vaccine in Adults with Symptomatic Genital HSV-2 Infection*

- One member declared a conflict of interest.
- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change. The approved protocol is for a phase I/II clinical trial of a DNA vaccine for HSV-2 that consists of two plasmids encoding two different HSV-2 proteins which are and administered to patients in complex with a proprietary liposome complex. Patients received injections on days 0, 28, and 56, and blood and anogenital swabs were collected. The significant change is to add a second trial, which is a phase 2 trial (no dose escalation). There is no change in agent, dose, route of administration, or sampling. The time of administration is the same with the addition of a 4th dose on day 84 and some variation in sample collection times.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wald. 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. Wald.

16. Xia, Zhengui, renewal, *Apoptosis and Neurogenesis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a three-year renewal of a project which contains four subprojects. The first is to better understand the role of extracellular signal regulated kinase (Erk5) in adult neurogenesis in the brain. The second is to examine the molecular mechanisms of dopaminergic cell death in vitro and in vivo to provide new insights concerning the

molecular basis of Parkinson's disease. The third is to focus on the effect of lead and genetic background interaction on adult neurogenesis and hippocampus-dependent learning and memory. The fourth is to understand the molecular mechanisms involved in cadmium exposure and associated cognitive and olfactory impairments.

- Adeno-associated viral vectors (AAV), lentiviral vectors, and amphotropic gammaretroviral vectors are used on the project.
- The BUA application is not yet fully correct. The investigator needs to remove mentions of adenovirus and clarify which oncogenes are used in which vectors. The biosafety officer will verify that the application is correct before the BUA approval letter is sent.
- The draft BUA letter was shown.
- The lab has been inspected and the trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Xia, pending corrections to the BUA application. A second is not needed since she is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Xia, pending corrections to the BUA application.</u>

17. Young, Jessica, new, *Modeling late-onset sporadic Alzheimer's disease using human stem cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The Young lab uses human cells to study genes that increase the risk for late-onset sporadic Alzheimer's disease.
- Human cells transduced with lentiviral vectors or Sendai viral vectors are used.
- The work will be conducted at BSL-2. On one section of the application, Dr. Young marked that BSL-2 with BSL-3 practices would be used, but this is not correct because the lentiviral vectors are third generation.
- 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. Young. A second is not needed since he is the Primary Reviewer.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Young.</u>