# **INSTITUTIONAL BIOSAFETY COMMITTEE** UNIVERSITY of WASHINGTON

#### **Meeting Minutes**

| Date:<br>Time:      | Wednesday, November 14, 2018<br>10:00 AM – 12:00 PM  |
|---------------------|--|
| Location:           | University of Washington, Foege N130A  |
| Members<br>Present: | <ol> <li>Thea Brabb, Comparative Medicine (Animal Containment Expert)</li> <li>Lesley Colby, Comparative Medicine (Animal Containment Expert)</li> <li>Richard Grant, Washington National Primate Research Center</li> <li>Garry Hamilton (Community Member)</li> <li>David Koelle, Allergy and Infectious Diseases</li> <li>Stephen Libby, Laboratory Medicine (IBC Chair)</li> <li>Scott Meschke, Environmental &amp; Occupational Health Sciences</li> <li>Tina Rogers (Community Member)</li> <li>Jason Smith, Microbiology (IBC Vice Chair)</li> <li>Eric Stefansson, Environmental Health &amp; Safety (Biosafety Officer, Animal Containment Expert)</li> </ol> |

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 10:02 a.m. 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.
- Committee members were reminded to refer any public records requests to EH&S.

## 3. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the October 17, 2018 meeting.
- A member made a motion to approve the October 17, 2018 minutes. Another member seconded the motion.
- <u>The committee voted unanimously to approve the October 17, 2018 meeting minutes.</u> <u>There were two abstentions from members who were not present at the October meeting.</u>

### 4. OLD BUSINESS:

- At the May meeting, Dr. Frevert's BUA was approved pending submission to IACUC.
- At the July meeting, Dr. Patel's BUA was approved pending a lab inspection.
- At the September meeting, Dr. Greninger's BUA was approved pending a successful lab inspection.
- At the October meeting, Dr. Rasmussen's BUA was approved pending a lab inspection.
- At the October meeting, Dr. Stuber's BUA was approved pending a lab inspection and room changes to the BUA letter.
- 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. Furlong renewed a BUA for *Effects-Related Biomarkers of Environmental Neurotoxic Exposures,* using E. coli, non-pathogenic strains in vitro.
    - Dr. Burroughs became the PI of a clinical trial formerly led by Dr. Woolfrey. This BUA involves replication deficient and amphotropic human cells transduced with gammaretroviral vectors.
    - Dr. Yeung added a new BSL-2 laboratory space for the BUA *Liver Tumor Research*.
    - Dr. Kerr's lab moved to a new location. The new laboratory space for work with Klebsiella aerogenes and Pseudomonas aeruginosa was approved.
    - Dr. Ferreira renewed a BUA involving work with human blood, tissue, body fluids, and cell lines used in vitro.
    - Dr. Thaler's lab moved to a new location and removed work with modified rabies virus vector. The new laboratory spaces for work with adeno-associated viral vectors, lentiviral vectors, and rabies virus vector were approved.
    - Dr. Theriot added in vitro work involving canine and human cells, Listeria monocytogenes, and third generation lentiviral vectors.
    - Dr. Palmiter added the ARCF ABSL-1 vivarium for his BUA *Genetrics of Mouse Behavior.*

- Dr. Sokurenko changed rooms listed for work with previously approved agents on their BUA Molecular Adaptation of Uropathogenic E.coli; Pathoadaptive Evolution of Salmonella; Properties of Bacterial Adhesions; Pathogenic Adaptation of Microbial Adhesions; New Statistical Methods for Neutral Phylogenetic Reconstruction.
- Dr. Iritani added the use of previously approved Influenza virus, mouse adapted strains to his BUA *Gene Function in Lymphoiesis and Cancer*.
- Dr. Bumgarner moved the location of his lab for BUA *Bumgarner Lab Genomic Research Projects.*
- Dr. Nilsson added the use of microorganisms for in vitro work to the BUA *Microbial Lipid Extraction.*
- Dr. Bornfeldt's labs moved to a new location. The new laboratory spaces for in vitro and mouse work were approved for her BUAs *Cardiovascular Disease and Diabetes* and *Biology of the Artery Wall/ADAM-mediated Shedding*.
- Dr. Lingappa's lab moved to a new location. The new laboratory space for in vitro work was approved for the BUA *Capsid Assembly Studies*.
- Dr. Chait's lab moved to a new location. The new laboratory space for in vitro work was approved for the BUA *Lipoproteins, Inflammation and Atherosclerosis.*
- Dr. Raskind added the ARCF location for mice to her BUA *Gene Contributions to* Dyslexia Gene Discover in Neurogenetic Disorders; Spinocerebellar-Ataxia Type 14: Animal Models of Human Disease; Genetics of Autism; Genetics of Human Disease.
- Dr. Fuller added WaNPRC vivariums to their BUA *Evaluation of SIV Co-Infection on ZIKV Pathogenesis in Pigtail Macaques.*
- Dr. Lutz added use of non-pathogenic strains of E. coli to the BUA *Point-of-Care Diagnostic Device.*
- Dr. Cabernard's labs moved to a new location. The new laboratory spaces for creation, breeding, and use of transgenic Drosophila and work with snails were approved for the BUAs *Cellular and molecular mechanisms of asymmetric cell division* and *Snail Asymmetry*.
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer</u> <u>Report.</u>
- 6. **DURC REPORT:** The Dual Use Research of Concern Institutional Review Entity (DURC IRE) did not meet this month because there were no applications to review.

# 7. INDIVIDUAL PROJECT REVIEWS

- a. Bornfeldt, Karin, new, Vector and Transgenic Mouse Core (VTMC)
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This work from the Vector and Transgenic Mouse Core (VTMC) provides Diabetes Research Center affiliate investigators and members of UW with tools necessary to overexpress, knockdown, knockout, or alter expression of RNAs and proteins of interest in cultured cells, isolated tissues, and rodents.
  - The lab was inspected and no deficiencies were identified.
  - All of the 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. Bornfeldt pending the addition of oncogenes to the BUA letter.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Bornfeldt</u> pending the addition of oncogenes to the BUA letter.
- **b.** Bruchas, Michael, new, *Neuromodulation in Affective Behavior* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project studies signal transduction in the brain by using in vitro studies in mouse and human cells and cell lines, as well as in vivo studies in mice with viral vectors, via intracranial injection, and other recombinant DNA techniques.
  - The most dangerous biohazards include adeno-associated viral vectors and canine adenovirus vectors. None of the inserts are oncogenes. Small, exempted quantities of select agent tetrodotoxin will be used in cultures of live brain slices.
  - The lab has not yet been set up. The biosafety officer will inspect the lab once the investigator moves to the new location and the lab is ready.
  - All of the 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. Bruchas.
  - <u>The Committee voted unanimously to approve the draft BUA for Dr. Bruchas</u> pending a final lab inspection and the addition of III-E to the BUA letter.
- c. Dichek, David, renewal, Gene Transfer in Cardiovascular Disease (Mice)
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project's goal is to understand the mechanisms through which blood vessels become diseased and to develop genetic or other molecular therapies to prevent or reverse blood vessel disease.
  - The greatest biohazards include use of adenoviral vectors, fixing agents, enhanced gene delivery technique involving liposome complex, and oncogenes (which the lab intends to delete in order to minimize oncogenic potential).
  - The lab has not yet been set up. The biosafety officer will inspect the lab once the investigator moves to the new location and the lab is ready.
  - All of the 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. Dichek.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dichek pending a final lab inspection and a correction to the BUA letter adding III-E and gutless adenoviral vectors at BSL 1 and 2, depending on use.
- **d.** Dichek, David, new, *Gene Transfer in Cardiovascular Disease (Rabbits)* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project's goal is to understand the mechanisms through which blood vessels become diseased and to develop genetic or other molecular therapies to prevent or reverse blood vessel disease.
  - The greatest biohazards include use of adenoviral vectors, fixing agents, and enhanced gene delivery technique involving liposome complex.
  - The lab has not yet been set up. The biosafety officer will inspect the lab once the investigator moves to the new location and the lab is ready.
  - All of the 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. Dichek.
- The Committee voted unanimously to approve the draft BUA for Dr. Dichek pending a final lab inspection.
- e. Gerner, Michael, renewal, Organization of Immunity
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project examines how the number and location of antigen presenting cells influence T-cell activation and differentiation by using Listeria monocytogenes, pseudomonas aeruginosa, and Vesicular stomatitis virus in vitro and in mice.
  - The greatest hazards include infection of mice with risk group 2 infectious agents.
  - The biosafety officer will verify that radiation instruments are approved for use at ABSL 2.
  - The lab has not yet been set up. The biosafety officer will inspect the lab once the investigator moves to the new location and the lab is ready.
  - Biosafety training needs to be completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gerner.
  - <u>The Committee voted unanimously to approve the draft BUA for Dr. Gerner pending</u> <u>training completion.</u>
- f. Kueh, Hao Yuan, change, Single-cell analysis of immune cell fate decisions
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab wants to add non-recombinant lymphocytic choriomeningitis virus strains Armstrong 53B and clone 13 to transgenic and wild type mice.
  - The lab was recently inspected, and does not require inspection for this change.
  - All of the 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. Kueh.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kueh.
- g. Murry, Charles, new, Myocardial Infarct Repair (Mice)
  - The assigned IBC Secondary Reviewer presented the Primary Review.
  - This project uses stem cells (ESC and iPSC) from humans and rodents to study their differentiation into cardiovascular cell types. Stem cells are modified genetically by plasmid transfection, gamma retroviral transduction, lentiviral transduction, adenoviral transduction, adeno-associated viral vector transduction, ZFNs, RNAi, and CRISPR/Cas.
  - The greatest biohazardous risk is the production of high titer viruses.
  - A lab inspection is still required.
  - All of the required trainings have been completed.
  - The draft BUA letter was shown.
  - The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Murry.
  - <u>The Committee voted unanimously to approve the draft BUA for Dr. Murry pending</u> <u>a final lab inspection.</u>
- **h.** Murry, Charles, renewal, *Myocardial Infarct Repair (Rats)* 
  - The assigned IBC Secondary Reviewer presented the Primary Review.

- This project uses stem cells (ESC and iPSC) from humans and rodents to study their differentiation into cardiovascular cell types. Stem cells are modified genetically by plasmid transfection, gamma retroviral transduction, lentiviral transduction, adenoviral transduction, adeno-associated viral vector transduction, ZFNs, RNAi, and CRISPR/Cas.
- The greatest biohazardous risk is the production of high titer viruses.
- A lab inspection is still required.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- The IBC Secondary Reviewer made a motion to approve the draft BUA for Dr. Murry.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Murry pending</u> <u>a final lab inspection.</u>
- i. Neitz, Maureen, new, Rat AMD Gene Therapy
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project's goal is to study new treatments for age-related macular degeneration (AMD), neovascular or wet AMD. The goal is to determine whether long-term prevention of choroidal neovascularization in a rat model of AMD can be achieved using adeno-associated virus delivery of the gene for aflibercept.
  - The human cell line, adeno-associated viral vectors, and fixing agents are the only hazards identified.
  - The lab was inspected and no deficiencies were identified.
  - All of the 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. Neitz.
  - The Committee voted unanimously to approve the draft BUA for Dr. Neitz.
- j. Reh, Thomas, new, Retinal Ganglion Cell Replacement in Optic Neuropathies
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project's goal is to implement a retinal damage model in squirrel monkeys and inject retinal cells derived from human ESCs and iPSCs to see if they will functionally integrate into the retina.
  - The greatest biohazard risk to personnel is accidental inoculation with a gene transfer vector, which could cause a local inflammatory response.
  - Inserts are located in the table on the BUA application. Items 27 and 32 on the BUA application should not be checked.
  - The lab was inspected and no deficiencies were identified.
  - All of the 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. Reh.
  - <u>The Committee voted unanimously to approve the draft BUA for Dr. Reh pending</u> <u>changing macaque to squirrel monkey and changing the two boxes listed above on</u> <u>the BUA application.</u>
- **k.** Steinmetz, Nicholas, new, *Brain-wide neural circuits underlying cognition and behavior in mice* 
  - The assigned IBC Primary Reviewer presented the Primary Review.

- This project aims to understand the neural mechanisms underlying perception, cognition, and action in mice. The lab will breed transgenic mice with synthetic genes designed as fluorescent markers, fluorescent reports of voltage or calcium activity, and light-sensitive opsins for manipulating neural activity. They will express these genes by injecting adeno-associated viral vectors systemically or locally within the brain.
- Exposure to tissue, blood, or body fluids of mice is the greatest biohazardous risk.
- The lab has not yet been set up. The biosafety officer will inspect the lab once the investigator moves to the new location and the lab is ready.
- All of the 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. Steinmetz.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Steinmetz</u> pending a successful lab inspection.
- I. Yang, Xiaoming, renewal, Interventional Oncology (Rats)
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project uses a rat model system to study the use of radiofrequency heatingenhanced gene therapy or chemotherapy to treat human pacreatobiliary, hepatic, and esophageal malignancies.
  - The greatest biohazardous risks come from use of lentiviral vectors and T-VEC during injection into the rats.
  - T-VEC information, replication capabilities, and biosafety levels were discussed by the committee.
  - The lab was inspected and no deficiencies were identified.
  - All of the 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. Yang.
  - The Committee voted unanimously to approve the draft BUA for Dr. Yang.
- m. Yang, Xiaoming, renewal, Interventional Oncology (Rabbits)
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This project uses a rabbit model system to study the use of radiofrequency heatingenhanced gene therapy or chemotherapy to treat human pacreatobiliary, hepatic, and esophageal malignancies.
  - The greatest biohazardous risks come from use of lentiviral vectors during injection into the rabbits.
  - BSL 2 MRI protocols address decontamination of the spaces.
  - This project is pending IACUC submission.
  - The lab was inspected and no deficiencies were identified.
  - All of the 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. Yang.
  - The Committee voted unanimously to approve the draft BUA for Dr. Yang.

- 8. SUBCOMMITTEE REPORTS: There were no subcommittee reports to review this month.
- 9. FOR YOUR INFORMATION:
  - **NIH Incident Reports:** A follow up to an incident involving an individual who was bitten on the fingertip by a squirrel monkey that had been inoculated with adeno-associated virus was presented. The NIH OSP stated that the University's response was appropriate, and that no further action was required.
  - ABSA Conference: Committee members who attended shared their experiences.
  - **Proposed Changes to** *NIH Guidelines:* The comment period was extended regarding the proposed changes to *NIH Guidelines.* UW IBC has already submitted their comments.
- **10. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 11. MEETING ADJOURNED AT APPROXIMATELY 11:52 A.M.