



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY of WASHINGTON

### Meeting Minutes

**Date:** Wednesday, January 17, 2018

**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. 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. David Scarsella, Pacific Northwest Diabetes Research Institute (*Community Member*)
  9. Jason Smith, Microbiology (*IBC Vice Chair*)
  10. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
  11. 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 10:02 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 December 13, 2017 meeting.
  - A member made a motion to approve the December 13, 2017 minutes. Another member seconded the motion.
  - The committee voted unanimously, with four abstentions, to approve the December 13, 2017 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. Kim renewed a BUA involving human tissues.
    - Dr. Han added human cells to his BUA letter.
    - Dr. Xu added a new room to his BUA letter.
    - Dr. Landis added a new room to his BUA letter.
    - Dr. Jones-Engel renewed a BUA involving human and non-human primate samples.
    - Dr. Synovec received a new BUA letter for human tissue.
    - Dr. Thompson-Iritani became the PI of the Washington National Primate Research Center's core BUAs. The PI was formerly Dr. Smedley.
    - Dr. Snyder-Mackler received a new BUA for non-human primate blood samples.
    - 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 to approve this month's Biosafety Officer Report.
5. **CATEGORY III-D AMENDMENTS**
  1. Morishima, Chihiro, renewal, *Immunological Assay Development*
    - The biosafety officer presented the project.
    - The lab may use non-human primate blood from primates experimentally exposed to primate lentivirus.
    - 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. Morishima.
    - The Committee voted unanimously to approve the draft BUA for Dr. Morishima.

## 6. INDIVIDUAL PROJECT REVIEWS

2. Adams-Waldorf, Kristina, renewal, *Experimental Model for Chorioamnionitis and Preterm Labor*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a renewal. The overall goal of the research is to understand the pathogenesis of infections that can happen with preterm births in order to develop preventative and therapeutic strategies.
  - A recombinant Group B streptococcus species as well as recombinant E. coli are used on the project. Pregnant non-human primates are inoculated and then tissues and bodily fluids are harvested at the time of delivery. Human blood and placental tissues are also used on the project.
  - The lab was inspected with no deficiencies found. 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. Adams-Waldorf.
  - The Committee voted unanimously to approve the draft BUA for Dr. Adams-Waldorf.
  
3. Bothwell, Mark, renewal, *Neurotrophin Receptor Interactions*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The lab receives induced pluripotent stem (iPS) cells originally from patients with neurological diseases, and then differentiates them into motor neurons and studies their biochemistry.
  - The human iPS cells were produced using Sendai viral vectors, but this work doesn't occur in the Bothwell lab.
  - Various human gene plasmid constructs are used. Several human (as well as mouse and rat) cell lines are used.
  - The lab was inspected with no deficiencies found. All of the required trainings have been completed. The reviewer had some comments about the BUA application, but all of the corrections have now been completed.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bothwell.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bothwell.
  
4. Kavanagh, Terrance, change, *Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered Nanomaterials*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a change to add third-generation lentiviral vectors. These vectors are obtained from a collaborator. They will be transduced into mouse cells.
  - The draft BUA letter was shown.
  - The lab was inspected with no deficiencies found. All of the required trainings have been completed.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kavanagh.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kavanagh.
  
5. Kawasumi, Masaoki, renewal, *Skin Cancer Research*
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The investigator studies UV DNA damage that can cause skin cancer and UV-induced cell signaling pathways.
- Adenoviral vectors, gammaretroviral vectors, and lentiviral vectors will be used in vitro.
- Human and non-human primate cells will also be used. Human cells will be administered to mice.
- The lab was inspected with no deficiencies found. 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. Kawasumi.
- The Committee voted unanimously to approve the draft BUA for Dr. Kawasumi.

6. Kimelman, David, renewal, *Early Fish Development*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab studies the early development of the zebrafish embryo as a model system for human development.
- Transgenic zebrafish are created and used.
- The draft BUA letter was shown. The letter will be edited from “in vitro” to “zebrafish.”
- The lab was inspected with no deficiencies found. All of the required trainings have been completed.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Kimelman.
- The Committee voted unanimously to approve the draft BUA for Dr. Kimelman, contingent upon editing the BUA letter.

7. MacLellan, Robb, renewal, *Cardiac development and growth, and cardiac regeneration*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The overall goal of the research is to understand the cellular and molecular mechanisms underlying the limited ability of cardiac regeneration.
- Adeno-associated viral vectors (AAV), adenovirus, and lentiviral vectors will be used on the project. Plasmids and CRISPR/Cas9 techniques are used. Various human, non-human primate, rat, and mouse cell lines are also used. Human embryonic and induced pluripotent stem cells are used.
- The in vivo work has been removed from the BUA. Transgenic mice are created in the Comparative Medicine core and their tissue is used, but no biohazardous agents are administered to animals on this project. This work is covered under the transgenic core BUA and does not need to be listed on this lab’s BUA, so the reference to creating transgenic mice will be removed.
- The lab was inspected with no deficiencies found. All of the required trainings have been completed. The reviewer had some comments about the BUA application, but all of the corrections have now been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. MacLellan.
- The Committee voted unanimously to approve the draft BUA for Dr. MacLellan, contingent upon editing the letter to remove animal work.

8. Mizumori, Sheri, renewal, *Neuromodulatory Control of Reward Neurocircuitry*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goal of the research is to understand how different brain regions interact during learning and how this impacts decisions made in response to altered reward expectations.
  - Adeno-associated viral vectors and canine adenoviral vectors will be used in a rat model.
  - The lab was inspected with no deficiencies found. 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. Mizumori.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mizumori.
  
9. Neitz, Maureen, new, *Opsin gene splicing assay using viral mediated gene delivery in gerbils*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goal of the research is to develop genetic tests and treatments for common visual disorders.
  - This is a new project from an established investigator. This BUA supports a newly submitted IACUC protocol involving adeno-associated viral vectors administered in a gerbil model.
  - The lab was inspected with no deficiencies found. 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.
  
10. Sancak, Yasemin, new, *Role of mitochondrial calcium uptake in health and disease*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a new application from an investigator new to UW. The lab will investigate mitochondrial function in cells. The lab will transduce tissue culture cell lines with third generation lentiviral vectors and expression vectors containing genes thought to regulate the mitochondrial pathway.
  - The biosafety officer has performed a preliminary inspection, but the lab is still in the process of being set up. Another inspection will be required once everything is in place. 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. Sancak.
  - The Committee voted unanimously to approve the draft BUA for Dr. Sancak, pending a lab inspection after the lab is fully set up.
  
11. Tian, Rong, renewal, *Energetics and Metabolism of the Heart*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This is a renewal application. The group researches the roles of cell metabolism and mitochondrial function in the pathogenesis of human heart diseases.
  - AAV, lentiviral vectors, and adenoviral vectors are used. No oncogenes are involved.

- The committee discussed the disposal of unused drugs. The Environmental Programs section of the Environmental Health & Safety department collects excess chemicals.
- A discussion occurred about the lentiviral vectors. The investigator didn't specifically include on the BUA application that the vectors are VSV-pseudotyped. The biosafety officer will ask her to clarify that.
- The IACUC protocol hasn't yet been submitted. The biosafety officer will need to review that once it is submitted.
- The lab was inspected with no deficiencies found. 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. Tian.
- The Committee voted unanimously to approve the draft BUA for Dr. Tian, pending clarification that the lentiviral vector is VSV-pseudotyped and pending the submission of the IACUC protocol.

**12. Woodward, Joshua, renewal, *Pathogenesis of Listeria monocytogenes and Staphylococcus aureus***

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The goal of the research is to characterize the mechanisms by which *Listeria monocytogenes* and *Staphylococcus aureus* are able to infect and replicate within the eukaryotic host and to define the host innate immune response.
- A variety of Risk Group 2 agents are used on the project including *Listeria monocytogenes*, *S. aureus*, herpes simplex virus 1, and ecotropic gammaretroviral vectors.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Woodward.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward.

**13. Yadav, Smita, new, *Signaling in neuronal development and disease***

- The assigned IBC Primary Reviewer presented the Primary Review.
- The lab researches how dysfunction of kinase signaling pathways can lead to neurodevelopmental and psychiatric disorders.
- A third generation lentiviral vector and human cell lines are used on the project.
- The biosafety officer has performed a preliminary inspection, but the lab is still in the process of being set up. Another inspection will be required once everything is in place. 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. Yadav.
- The Committee voted unanimously to approve the draft BUA for Dr. Yadav, pending a lab inspection after the lab is fully set up.

**14. Yazdan-Shahmorad, Azedah, new, *Novel neural technologies for neurorehabilitation***

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a new BUA from a new investigator. The research will involve AAV and lentiviral vectors used in a primate model to track the gene expression in brain tissue and photosensitive genes.

- The training has been completed, but the lab is still in the process of being set up. An inspection will be required once everything is in place.
- The IACUC protocol hasn't yet been submitted. The biosafety officer will need to review that once it is submitted.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Yazdan-Shahmorad.
- The Committee voted unanimously to approve the draft BUA for Dr. Yazdan-Shahmorad, pending a lab inspection after the lab is fully set up and the submission of the IACUC protocol.

#### **SUBCOMMITTEE REPORTS:**

**15.** Cowan, Andrew, new, *A phase I study of B-cell maturation antigen (BCMA)-specific chimeric antigen receptor T cells in combination with LY3039478, a small molecule inhibitor of gamma secretase, in patients with relapsed or persistent multiple myeloma*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- The primary objective of this phase I clinical trial is to evaluate the safety of adoptive therapy with ex vivo expanded autologous CD8+ plus CD4+ T cells transduced to express a human BCMA-targeting CAR for patients with relapsed or treatment refractory multiple myeloma.
- Autologous T cells are transduced with a self-inactivating, VSV-G pseudotyped, HIV-1 based third generation lentivirus.
- The subcommittee also reviewed the consent forms and found them to sufficiently explain the biosafety risks involved with this protocol.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Cowan. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Cowan.

#### **UPDATES:**

**16.** Unadkat Lab

- At the November 2017 meeting, the committee discussed the Unadkat laboratory conditions. The biosafety officer inspected the lab in July 2016 and found many deficiencies, and visited the lab three more times to help them correct these deficiencies. In September 2017, the Lab Safety Survey team surveyed the Unadkat lab and they also found many deficiencies.
- In response to the Lab Safety Survey Team's findings, the biosafety officer visited the lab and identified deficiencies involving sharps not being disposed of properly and biohazard waste that was improperly packaged. The IBC decided that a more frequent lab inspection cycle is appropriate for this lab. The committee voted that the biosafety officer should perform a surprise inspection in January and report the findings at the January meeting.
- The lab inspection was performed and no deficiencies were found. Appropriate practices have been maintained in the laboratory.

- The committee discussed the next steps and decided that the biosafety officer should revisit the lab in about nine months (September or October) and report the results of the lab inspection back to the committee.
- The Committee voted unanimously for the Unadkat lab to be inspected in September or October 2018 with the findings reported at the following IBC meeting.

**17. NIH Gain-of-Function Research Update**

- The National Institutes of Health announced that it is lifting a funding pause on gain-of-function experiments involving influenza, SARS, and MERS viruses.
- New guidelines relating to “potential pandemic pathogens” have been released. Research involving potential gain-of-function research with this category of agents will be carefully evaluated. Funding agencies will perform these reviews and determine if a risk/benefit analysis or a risk mitigation plan are needed.
- A link with more information can be found at <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research>.

**ISSUES FROM THE FLOOR & PUBLIC COMMENTS:**

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

**MEETING ADJOURNED AT APPROXIMATELY 11:50 a.m.**