



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, March 21, 2018

Time: 10:00 AM – 12:00 PM

Location: Foegen N-130A

- Members Present:**
1. H.D. "Toby" Bradshaw, Biology (*Plant Expert*)
 2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 3. Richard Grant, Washington National Primate Research Center
 4. Garry Hamilton (*Community Member*)
 5. Kevin Hybiske, Allergy and Infectious Diseases
 6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 7. Scott Meschke, Environmental & Occupational Health Sciences
 8. Jason Smith, Microbiology (*IBC Vice Chair*)
 9. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
 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 10:02 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 February 21, 2018 meeting.
 - A member made a motion to approve the February 21, 2018 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the February 21, 2018 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. Yeung added the Pathology Flow Cytometry Core Facility to his BUA letter.
 - Dr. Swisher renewed a BUA involving human source material.
 - Dr. Reed renewed a BUA involving human source material.
 - Dr. Rieke renewed a BUA involving human and non-human primate tissue.
 - 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. **DURC REPORT**
 - The DURC IRE reviewed a DURC application from the Skerrett lab involving using non-recombinant *Francisella tularensis* (Strain Schu S4). The specific aims of the research are to determine if *F. tularensis* uniquely evades or suppresses the protective responses of alveolar macrophages and to determine if *F. tularensis* induces or suppresses inflammasome activation in alveolar macrophages. One component of this research involves infecting human or murine macrophages with *F. tularensis* (Strain Schu S4) and then harvesting supernatants and cell lysates to measure bacterial replication, gene expression, and protein secretion. Live animals are not used on this project.
 - The lab does not modify the *F. tularensis* in any way. The Schu S4 strain is a naturally-occurring mutant strain.
 - A quorum of DURC IRE members voted that the seven experimental effects do not apply, that the research does not meet the DURC definition, and that a risk mitigation plan is not warranted. The DURC IRE recommended to approve the DURC application.
 - The IBC Chair sought a motion to endorse the DURC IRE's recommendation to approve the DURC application.
 - A member made a motion to approve the DURC application. Another member seconded the motion.
 - The committee voted unanimously to approve the DURC application for Dr. Skerrett.

6. INDIVIDUAL PROJECT REVIEWS

1. Bornfeldt, Karin, change, *Cardiovascular Disease and Diabetes*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request to add a room containing a piece of equipment called a Seahorse, which measures acidification rates. The change also involves adding a new gene insert in AAV.
 - The lab was inspected with no deficiencies identified and 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.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bornfeldt.

2. Cookson, Brad, renewal, *Initiation and regulation of inflammation and development of protective immunity*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - Biotoxins, including diphtheria toxin, are used on the project. SOPs are already in place.
 - The PI still needs to retake the biosafety training.
 - The lab was inspected and no deficiencies were identified.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Cookson.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cookson, pending the completion of the PI's biosafety training.

3. Dhaka, Ajay, renewal, *Transsynaptic Tracing of Somosensory Circuits*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The lab researches hot and cold sensing in mice. A herpes viral vector and a rabies viral vector are used.
 - The lab was inspected and all deficiencies were corrected. 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. Dhaka.
 - The Committee voted unanimously to approve the draft BUA for Dr. Dhaka.

4. Hawkins, David, change, *Epigenomics of Various Stem Cells*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to add lentiviral vectors. The vectors are replication-deficient and do not contain oncogenic inserts.
 - The lab was inspected and there are no outstanding deficiencies. 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. Hawkins.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hawkins.

5. Hladik, Florian, renewal, *Mechanisms of HIV-1 Transmission in Genital Mucosa of Women and the Role of Exosomes in Semen for HIV Infection in the Genital Mucosa of Women*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to investigate the mechanisms by which HIV gains entrance into the host and to explore the molecular nature of exosomes in semen and how they affect the immune system.
 - Recombinant HIV virus is used in the project, as well as human source material.
 - The committee discussed the containment level. HIV is used at BSL-2 with BSL-3 practices.
 - The lab was inspected and there are no outstanding deficiencies. 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. Hladik.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hladik.

6. Hofstetter, Christoph, renewal, *Viral Neuronal Tracing in Rodents with Spinal Cord Injury*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The research project involves using an adeno-associated viral vector (AAV) to label neurons in living rats in order to view neuronal changes after a spiral cord injury without additional tissue staining.
 - The AAV is replication-deficient, and the inserts are non-oncogenic.
 - The lab was inspected and there are no outstanding deficiencies. 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. Hofstetter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hofstetter.

7. Kawasumi, Masaoki, change, *Skin Cancer Research*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request to add new non-oncogenic gene inserts and to administer human and mouse cells transduced with a lentiviral vector to mice.
 - An inspection was not required for this change because it was recently inspected. 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.

8. Paragas, Neal, renewal, *Pathophysiology of kidney disease*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a three-year renewal. The lab studies mucosal immune responses to bacterial urinary tract infections. A recombinant bioluminescent E. coli strain is used in a catheterized mouse model.
 - The work is done under ABSL-2 containment practices.
 - The lab was inspected and there are no outstanding deficiencies. 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. Paragas.
 - The Committee voted unanimously to approve the draft BUA for Dr. Paragas.
9. Soetedjo, Robijanto, renewal, *Neurophysiology of saccade adaptation*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the project is to implement optogenetics in the brains of non-human primates, using AAV vectors carrying various light-gated ion channels and visible marker genes.
 - No oncogenic inserts are used in the AAV vectors.
 - The lab was inspected and there are no outstanding deficiencies. 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. Soetedjo.
 - The Committee voted unanimously to approve the draft BUA for Dr. Soetedjo.
10. Stempien-Otero, April, change, *Macrophages in Cardiac Fibrosis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change to use mouse cells transduced with lentiviral vectors in a mouse model.
 - The work will be conducted at ABSL-2.
 - The lab was inspected and there are no outstanding deficiencies. 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. Stempien-Otero.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stempien-Otero.
11. von Moltke, Jakob, change, *Initiation of Type 2 Immune Response*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request to use wild-type *Bacteroides thetaiotaomicron* in a transgenic animal, which falls under section III-D of the NIH guidelines and is represented on the BUA letter as III-D*. The work will be conducted at ABSL-2.
 - The required trainings have all been completed, but the lab still needs to be inspected.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. von Moltke.
 - The Committee voted unanimously to approve the draft BUA for Dr. von Moltke, pending a successful lab inspection.
12. Xu, Libin, renewal, *The role of lipids in human diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of the research is to characterize the biological consequences of disrupted lipid metabolism in human diseases and in drug-resistant gram-positive pathogens.
 - Human and mouse cells will be transfected with lentiviral vectors. Recombinant strains of *Enterococcus faecalis*, *Enterococcus faecium*, and *Staphylococcus aureus* are also used.

- Parts of the BUA application imply that human cells will be administered to mice, but the biosafety officer has confirmed that this is not the case. The application will be changed to clarify that no in vivo work occurs on the project.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Xu.
- The Committee voted unanimously to approve the draft BUA for Dr. Xu, pending clarification of whether human cells are administered to mice.

SUBCOMMITTEE REPORTS:

13. Bruckner-Lea, Cindy, new, *RNA Analysis of Eastern Equine Encephalitis Virus and Venezuelan Equine Encephalitis Virus: BSL3 (PHAA 70788)*

- Three members of the IBC and a biosafety officer served as the Subcommittee Reviewers. The biosafety officer presented the Subcommittee Report.
- The research will analyze purified RNA from Eastern Equine Encephalitis Virus (EEEV) and Venezuelan Equine Encephalitis Virus (VEEV) to evaluate nucleic acid for qPCR assays. RNA will either be obtained by an outside contractor or the viruses will be purchased and grown in Vero cells and then the RNA extracted.
- The viruses to be used in the research include:
 - EEEV BeAr436087 – South American (Brazil) strain and exempt from Select Agent regulations. Avirulent in human and horses.
 - EEEV FL93-939 – North America strain and subject to Select Agent regulations. Known to be virulent in humans and horses.
 - VEEV TRD – subtype IA Trinidad and subject to Select Agent regulations.
 - VEEV 68U201 – subtype IE and exempt from Select Agent regulations. No documented cases for equine epizootics.
- All viruses used on the project are wild-type. No recombinant materials will be used or generated.
- The work is not yet fully registered with the CDC Select Agent Program. No research will proceed until the federal select agent registration process is completed. The biosafety officer will add a note to the front page of the BUA letter clarifying that CDC registration is still required.
- A medical management plan is in place for working with these agents. An investigational vaccine is available at USAMRIID. EH&S will not be requiring or recommending that personnel use this experimental vaccine, but the PIs and researchers working on the project will be informed of the vaccine availability.
- The committee discussed this and would like EH&S to report back whether personnel on this project decide to receive the vaccination.
- The committee discussed the SOPs for this project. The SOPs are still being written and have not yet been finalized. The committee would like to see the final SOPs when they are available.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Bruckner-Lea. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Bruckner-Lea.

14. Skerrett, Shawn, new, *Human Alveolar Macrophage Interactions with Francisella tularensis*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- The overall goal of the research is to explore the interaction of *Francisella tularensis* with human alveolar macrophages and compare this to the interaction with mouse alveolar macrophages.
- Human and mouse alveolar macrophages will be infected with either *Francisella tularensis* (strain Schu S4), the highly virulent human pathogen, or with *Francisella novicida*, a strain that is highly virulent for mice, but has low virulence for humans. At certain time points after infection, samples will be taken from the cultures to measure bacterial growth, gene expression, and protein secretion.
- Human alveolar macrophage will be harvested by bronchiolar lavage. Mouse macrophages will be harvested by lavage.
- All work with *Francisella tularensis* SchuS4 will be performed at BSL-3. *Francisella novicida* is a Risk Group 2 pathogen and can be worked at BSL-2 containment.
- *Francisella tularensis* is a Select Agent pathogen. The lab does not modify the *F. tularensis* in any way. The Schu S4 strain is a naturally-occurring mutant strain that was not created with recombinant DNA technology.
- The draft BUA letter was shown. A note will be added to the face page of the BUA letter to clarify that that CDC registration is still required and that no research will proceed until the federal select agent registration process is completed
- There is an investigational vaccine for *Francisella tularensis* available at USAMRIID. EH&S will not be requiring or recommending that personnel use this experimental vaccine, but the PIs and researchers working on the project will be informed of the vaccine availability.
- A member made a motion to approve the draft BUA letter for Dr. Skerrett. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett.

OTHER VOTING ITEMS:

- Biohazardous Waste Manual
 - The University of Washington's Biohazardous Waste Manual has been updated.
 - Summary of Changes:
 - Clarification on treatment procedures for extracted human teeth. Extracted teeth (without amalgam) are considered human pathological waste and are to be incinerated prior to disposal. Teeth containing amalgam are collected by EH&S for treatment at an off-site facility.
 - Scope of manual broadened to include all UW campuses.
 - Links were updated and language was clarified throughout.
 - Contact information was updated.
 - Reference to Waste Characterization Determinations was removed as Seattle/King County Public Health has discontinued the program.
 - The committee recommended that one section of the waste manual be updated to reflect that extracted teeth are considered human pathological waste.
 - With that update, a member made a motion to approve the 2018 update to the Biohazardous Waste Manual. Another member seconded the motion.
 - The Committee voted unanimously to approve the 2018 update to the Biohazardous Waste Manual.

FOR YOUR INFORMATION:

- Not-for-cause surprise CDC inspection
 - At the end of February, the CDC performed a not-for-cause surprise inspection of the Select Agent Program. A full report has not yet been received, but the inspection went well and all feedback is expected to be minor. The inspection team noted that the UW Occupational Health Program is one of the best they have seen and that the UW Program is very proactive.
- NIH Reportable Incident
 - On February 28, 2018, an employee sustained a percutaneous needlestick injury that had been used in a procedure involving a non-human primate who had been previously vaccinated in November 2017 with a recombinant vesicular stomatitis virus vaccine containing the Zika virus coding region. The NHP was subsequently challenged with Zika virus. Subsequent cerebral spinal fluid tests performed on the macaque were all negative for Zika virus RNA.
 - The employee did not follow the SOP of disposing sharps in the sharps container immediately after use. The nearest sharps container was in the procedure room, but not in close proximity to the actual procedure. The employee was wearing the appropriate PPE and followed proper post-exposure protocols, including immediately washing his hands with an NHP scrub kit for 15 minutes, reporting the incident to his supervisor, and going to the emergency room for care. The employee is receiving follow-up care from the Employee Health Center.
 - The employee & supervisor have reviewed the standard operating procedures for using sharps. A sharps container will be placed in the surgical area so that it is more easily accessible.
 - The incident has been reported to NIH.
- NIH Reportable Incident Response
 - The NIH responded to our report of the incident where an employee sustained a bite from a non-human primate previously experimentally infected with SHIV. This incident was discussed at the February 21, 2018 IBC meeting. The NIH stated that our response to the incident was appropriate and no further action is required at this time.
- NIH Reportable Incident Response
 - The NIH responded to our report of the incident where an employee received a cut on his finger while changing an animal cage. The employee was not sure if the cut was from the clean or the dirty cage. The animal that was in the dirty cage had been infected with SHIV in 2015 and maintains a low, but persistent plasma viral levels of the virus. This incident was discussed at the February 21, 2018 IBC meeting. The NIH stated that our response to the incident was appropriate and no further action is required at this time.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

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

MEETING ADJOURNED AT APPROXIMATELY 11:27 a.m.