



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, February 16, 2022

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 3. Jason Cantera (*Community Member*)
 4. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 6. Richard Grant, Washington National Primate Research Center
 7. David Koelle, Allergy and Infectious Diseases
 8. Stephen Libby, Laboratory Medicine
 9. Scott Meschke, Environmental & Occupational Health Sciences
 10. Susan Parazzoli (*Community Member*)
 11. Jason Smith, Microbiology (*IBC Chair*)
 12. 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 10:01 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.
3. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the January 19, 2022, meeting.
 - A member made a motion to approve the January 19, 2022, minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the January 19, 2022, meeting minutes.
4. **OLD BUSINESS:**
 - At the January 19, 2022, meeting, Dr. Adair's BUA was approved pending additional information regarding nanoparticle use. This BUA is still pending due to IACUC review.
 - At the January 19, 2022, meeting, Dr. Gale's BUA was approved pending clarification of recombinant SIV, gammaretroviral vector work, and avian influenza virus types being used and completion of a successful lab inspection. This BUA is still pending.
 - At the January 19, 2022, meeting, Dr. Veessler's BUA was approved pending training completion. This BUA has been sent out.
 - At the January 19, 2022, Dr. Hyde's BUA was approved pending clarification on VEEV and SARS mutations from the NIH and Occupational Health review. This BUA is still pending application edits and a response from CDC select agent program.
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
 - Dr. Hladik added non-human primate tissue, fluid, etc. that was inadvertently missed during their BUA renewal in March 2021.
 - Dr. Fernandes renewed the BUA for *Cartilage Collagen*. Work includes human blood, tissue, body fluids, cell lines and recDNA.
 - Dr. Pham renewed the BUA *Sample Processing for Clinical Research Studies*. Work includes human blood, tissue, body fluids, and cell lines.
 - Dr. Shankland was approved for a new BUA *(Re)building Kidney (RBK)* with human blood, tissue, body fluid, cell lines and recDNA.
 - Dr. Martin was approved for a new BUA *Biodemography Lab* for work with human blood, tissue, body fluid, cell lines and non-human primate samples.
 - Dr. Hillesland was approved for a new BUA *Studying genetics of evolution in Desulfovibrio vulgaris* for work with E. coli and recDNA, and recombinant Risk Group 1 bacteria.
 - Dr. Mao renewed the BUA for *A Systems Pharmacology approach to predict the effects of pregnancy and infectious disease on transporter-mediated drug disposition* for work with human blood, tissue, body fluid, cell lines and recDNA.

- Dr. Sancak added in vitro work at the Keck Microscope Facility with previously approved agents to the *Role of mitochondrial calcium uptake in health and disease* BUA.
- Dr. Thummel renewed the *CYP3A Regulation* BUA for work with human blood, tissue, body fluid, cell lines, and recDNA.
- Dr. Chen added the Pathology Flow Cytometry Core Facility for use with previously approved agents to the *Druggable pathways in rhabdomyosarcoma* BUA.
- Dr. West added a new room for in vitro and in vivo work with previously approved agents to the *Host genetics and response to infection* BUA.
- Dr. Veesler registered a change to add new inactivated SARS-CoV-2 samples to the *Expression of recombinant proteins using mammalian cell lines* BUA.
- Dr. Hawn added new recombinant strains of Mtb to the *Innate Immunity and Susceptibility to infectious Disease* BUA.
- Dr. Veesler updated rooms, and added SARS-CoV-2 nucleic acid, recDNA, and E.coli to the *Expression of recombinant proteins using mammalian cell lines* BUA.
- Dr. Mitchell added new human cell lines to the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions*.
- Dr. Theberge added human saliva from patients to the BUA *Studying cell signaling and cell-microenvironment interactions with new analytical tools*.
- Dr. Yabuki renewed the BUA *Antibody Development* for work with human cells in a core facility.
- Dr. Darvas withdrew the BUA change to *Genetic analysis of mouse behavior* for animal work and registered new gene inserts for third generation lentiviral vectors in vitro and in vivo.
- Dr. Mullins added a new BSL-2 with BSL-3 practices room to the BUA *HIV-1 and Host Cell Changes in Disease Progression*.
- Dr. Arce-McShane was approved for a new BUA *Sensorimotor Control and Learning* for work with non-human primates.
- Dr. Wendy Thomas added the Pathology Flow Cytometry Core Facility for use with previously approved agents to the BUA *Biological Adhesion in Flow and under Force*.
- Dr. Jung was approved a new BUA *Mechanism of colon cancer metastasis: combined role of activin and TGF-beta signaling* for work with human blood, tissue, body fluid, cell lines, and recDNA.
- Dr. Kanabolo was registered for work with pig tissues in the *Assessment of Urostomy Parastomal Herniation Forces and Prevention Strategies* BUA.
- Dr. Eichler was approved for a new BUA *Northwest Genomics Center* for work with human blood, tissue, body fluid, cell lines and SARS-CoV-2 nucleic acid. This was a PI change from Debbie Nickerson.
- The IBC Chair 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.

6. BSL-3 INACTIVATION REPORT

- There is no BSL-3 Inactivation Report to review this month.

7. DURC REPORT

- There is no DURC report to review this month.

8. INDIVIDUAL PROJECT REVIEWS

- a. Berg, Celeste, Renewal, *Regulation of tubulogenesis in the Drosophila ovary*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the mechanisms that cells use to communicate with each other to control the growth and shape of tube formation for organ systems.
 - Work includes use of transgenic Drosophila (fruit flies), E. coli, and recDNA at BSL-1.
 - A lab inspection has been completed, and minor findings have been addressed.
 - 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. Berg.
 - The Committee voted unanimously to approve the draft BUA for Dr. Berg.
- b. Crispe, Ian, Renewal, *Innate immune response to hepatocyte death AND adaptive liver tolerance via LSECs AND sessile Kupffer cells in liver tolerance AND innate antiviral immunity in human liver tissue*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how cells and molecules of the liver and greater immune system work together to combat hepatitis virus infections and how they respond to death of hepatocytes in mouse models and human liver tissue.
 - Work includes use of adeno-associated viral vectors in vitro and in vivo and hepatitis B virus. Hepatitis C virus and infected tissues are used at BSL-2 with 3 practices.
 - A discussion occurred as to whether any additional occupational health requirements are needed for work with the hepatitis viruses. The only occupational health requirement is offering of the hepatitis B vaccine for potential bloodborne pathogen (BBP) exposure.
 - A successful lab inspection has been completed, and all deficiencies have been addressed.
 - 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. Crispe.
 - The Committee voted unanimously to approve the draft BUA for Dr. Crispe.
- c. den Hartigh, Laura, Renewal, *Inflammation, Obesity and Atherosclerosis*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how FGF21 expression from different parts of the body as well as gut microbia will impact metabolic diseases.
 - Work includes adeno-associated viral vectors in vitro and in vivo, gut microbia, recDNA, and human blood, tissue, bodily fluid, cell lines at BSL-2.
 - A successful lab inspection has been completed with no deficiencies identified.
 - 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. den Hartigh.
 - The Committee voted unanimously to approve the draft BUA for Dr. den Hartigh.

- d. Duan, Zhijun, Renewal, *Development of Cell Growth Switch*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the structure and function of the genome to understand the molecular mechanisms underlying human development and tumorigenesis.
 - Work includes human induced pluripotent stem (iPS) cells made with plasmids, lentiviral vectors, and human blood, tissue, body fluids, and cell lines at BSL-2.
 - A successful lab inspection has been completed, and all deficiencies have been addressed.
 - 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. Duan.
 - The Committee voted unanimously to approve the draft BUA for Dr. Duan.
- e. Erasmus, Jesse, New, *RNA Vaccines*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies novel self-amplifying RNA vaccine platforms for manufacturing seasonal influenza and COVID-19 vaccine.
 - Mice will be exposed to a nanolipid recDNA vaccine and then challenged with two influenza viruses: the wildtype Influenza A/H1N1/H1N1/California/04/09 strain at ABSL-2 and the recombinant Influenza A/Vietnam/H5N1-deltaH5-Pr8 at the BSL-2 with BSL-3 practices.
 - A discussion occurred regarding spatial and temporal separation of different influenza strains. The biosafety officer will confirm with the PI that different influenza viruses will not be used in the same animal cage or in the biosafety cabinet at the same time.
 - Lab Inspection is not required because all work is done in animal vivarium.
 - All required trainings have been completed.
 - Influenza vaccination must be offered prior to start of work.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Erasmus.
 - The Committee voted to approve the draft BUA for Dr. Erasmus with one abstention pending clarification on separation of influenza strains.
- f. Giacani, Lorenzo, Renewal, *Studies on the pathogenesis of syphilis and human treponematoses*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the pathogenesis of human treponematoses to elucidate how these pathogens effectively infect and evade host immune response. They use *Treponema pallidum* as well as other species that are not pathogenic in humans to study the effects of infection in rabbits, evaluate antibiotic resistance in the transformed bacteria and to eventually develop an effective vaccine.
 - This lab uses *Borrelia burgdorferi* to carry certain *T. pallidum* antigens in immunization experiments in rabbits at ABSL-2 to provide an immune response in place of adjuvants or pathogenic treponemas.
 - A successful lab inspection has been completed with no deficiencies identified.
 - 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. Giacani.
 - The Committee voted unanimously to approve the draft BUA for Dr. Giacani.
- g. King, Mary-Claire, Change, *King Lab Research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies genes responsible for complex traits in humans.
 - The lab is adding work with Sendai viral vectors to generate human induced pluripotent stem (iPS) cells.
 - A lab inspection was not required for this change.
 - 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. King.
 - The Committee voted unanimously to approve the draft BUA for Dr. King.
- h. Lieber, Andre, Renewal, *Stem cell and gene therapy of cancer and hematological diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies using viral vectors to deliver genes into tumor or stem cells.
 - This lab uses adenoviral vectors, transduced human cells, and transduced non-human primate cells in mice at BSL-2/ABSL2.
 - A discussion occurred regarding the lab's method for transporting biohazards. It was not clearly described in the application. The biosafety officer will seek clarification.
 - A lab Inspection will be conducted after the IBC meeting.
 - 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. Lieber.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lieber pending successful completion of the lab inspection and clarification of their transport method for biohazards.
- i. Scott, John, Change, *AKAP Structure and Function*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the roles of A Kinase anchoring proteins in heart disease, diabetes, diabetic hypertension, etc.
 - This change adds adeno-associated viral (AAV) vectors in mice.
 - A lab inspection was not required for this change.
 - 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. Scott.
 - The Committee voted unanimously to approve the draft BUA for Dr. Scott.
- j. Steinmetz, Nicholas, Renewal, *Neural mechanisms underlying visual perception, cognition and action in mice.*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the neural mechanisms underlying perception, cognition and action.
 - This lab uses adeno-associated viral (AAV) vectors in mice at ABSL-1.
 - A successful lab inspection has been completed, and all deficiencies have been addressed.
 - 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. Steinmetz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Steinmetz.
- k. Theberge, Ashleigh, Renewal, *Studying cell signaling and cell-microenvironment interaction with new analytical tools.*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how chemical interactions between different cell types within an organ with or without microbes contribute to disease.
 - This lab several Risk Group 1 and 2 wildtype and recombinant bacteria and fungi as well as SARS CoV-2 nucleic acid and samples from COVID-19 patients at BSL-2.
 - A discussion occurred regarding appropriate disinfectants for work with fungi in the laboratory. It was noted that 10% bleach is an appropriate disinfectant as well as ethanol. An IBC member mentioned that BSL-2 is appropriate for laboratory work with all species of *Aspergillus* and *Fusarium* fungi. It was also noted that lentiviral vectors at BSL-2 were missing from the BUA approval letter.
 - Another discussion occurred regarding aflatoxin and if additional safety guidance should be provided to the lab. It was noted that laboratory work with aflatoxin-producing fungi is not a usual route of exposure to aflatoxin; the toxin is usually a byproduct of fungus growing on grains. However, additional safety information will be provided to the lab.
 - A successful lab inspection has been completed, and all deficiencies have been addressed.
 - 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. Theberge.
 - The Committee voted unanimously to approve the draft BUA for Dr. Theberge pending an edit to the BUA letter to include lentiviral vectors, clarification on whether fungal strains are recombinant, and additional safety guidance on aflatoxin.
- l. Von Moltke, Jakob, Change, *Initiation of Type 2 Immune Responses*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the initiation of type 2 immune responses that mammalian immune systems generate upon encountering parasitic worms or allergens.
 - This change adds murine adenoviral vectors in mice and in vitro.
 - A brief discussion occurred regarding an error on the BUA approval letter.
 - No lab inspection was required for this change.
 - 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. von Moltke.
 - The Committee voted to approve the draft BUA for Dr. von Moltke with one abstention pending a correction to the BUA approval letter.

- m. Zhang, Miqin, Renewal, *Molecular MR Imaging of Tumors*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the biological performance of nanoparticle systems that demonstrate specific targeting against tumors.
 - This lab uses gammaretroviral vectors in vitro and in rats and mice.
 - A lab inspection has been performed, but the findings are still pending resolution.
 - 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. Zhang.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zhang pending successful completion of the lab inspection.

9. SUBCOMMITTEE REPORTS:

- n. Colby, Lesley, Renewal, *Department of Comparative Medicine SLU 3.1 BSL3/ABSL3 Facility*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This application covers all BSL-3 and ABSL-3 rooms in the SLU 3.1 BSL3/ABSL-3 facility managed and operated by the Department of Comparative Medicine.
 - This application lists biological agents approved for BSL-3 containment and practices.
 - The BSL-3 facility is inspected regularly by EH&S (at least 3 times per year) and is certified by an outside contractor.
 - All required trainings have been completed.
 - Each agent in use in the BSL-3 has a medical management plan in place.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Colby. Another member seconded the motion.
 - The Committee voted to approve the draft BUA for Dr. Colby with one abstention.
- o. Sims, Amy, New, *Venezuelan Equine Encephalitis As a Vector for Heterologous Gene Expression*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab studies the host response to wildtype and attenuated strains of Venezuelan equine encephalitis virus (VEEV).
 - This lab will use Venezuelan equine encephalitis virus at BSL-3. The lab will also use human and non-human primate cell lines as well as recombinant DNA.
 - All required trainings have been completed.
 - A medical management plan is in place for VEEV.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Oxford. Another member seconded the motion.
 - The Committee voted to approve the draft BUA with for Dr. Sims with one abstention.

- p. Wong, Kit, Renewal, An Open-Label, Multicenter, Phase ½ Study of RP1 as a Single Agent and in Combination with PD1 Blockade- in Patients with Solid Tumors.
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab studies how effective and safe the investigational product RP1 is and when used in combination with Nivolumab to treat cancer in patients with solid tumors.
 - This lab uses oncolytic recombinant herpes simplex virus 1 (HSV-1) strain RP1.
 - A discussion occurred as to whether those administering the study product should be giving occupational health information about possible exposure to HSV-1 and if post-prophylaxis medication should be made available.
 - An inspection of the administration site is still pending.
 - All required trainings have been completed.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Wong. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wong pending successful completion of an inspection at the administration site and occupational health information in case of accidental exposure to the study product.

10. FOR YOUR INFORMATION:

- The IBC chair presented a recent approval for cells transduced with third generation lentiviral vectors along with relevant sections of the NIH Guidelines to support this work falling under Section III-E rather than III-D. This would apply only to cells transduced with third generation lentiviral vectors, not to work with the vector itself.

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:59 A.M.