INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, March 16, 2022
Time: 10:00 AM – 12:00 PM

Location: Zoom

Members Present:

1. Thea Brabb, Comparative Medicine *(Animal Containment Expert)*
2. Jason Cantera *(Community Member)*
3. Lesley Colby, Comparative Medicine *(Animal Containment Expert)*
4. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
5. Richard Grant, Washington National Primate Research Center
6. Kevin Hybiske, Allergy and Infectious Diseases *(IBC Vice Chair)*
7. David Koelle, Allergy and Infectious Diseases
8. Scott Meschke, Environmental & Occupational Health Sciences
9. Susan Parazzoli *(Community Member)*
10. Jason Smith, Microbiology (*IBC Chair*)
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 10:00 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 February 16, 2022, meeting.
   - A member made a motion to approve the February 16, 2022, minutes. Another member seconded the motion.
   - The committee voted to approve the February 16, 2022, meeting minutes with one abstention.

4. **OLD BUSINESS:**
   - At the February 16, 2022, meeting, Dr. Erasmus's BUA was approved pending clarification on separation of influenza strains. The PI clarified that they will not use more than one influenza strain per study and will not use or combine two different strains in a biosafety cabinet. This BUA has been sent out.
   - At the February 16, 2022, meeting, Dr. Lieber's BUA was approved pending successful completion of the lab inspection and clarification of their transportation method for biohazards. These items were completed, and this BUA has been sent out.
   - At the February 16, 2022, meeting, Dr. Theberge's BUA was approved pending an edit to the BUA letter to include lentiviral vectors, clarification on whether fungal strains are recombinant, and additional safety guidance on aflatoxin. These items were completed, and this BUA has been sent out.
   - At the February 16, 2022, meeting, Dr. Von Moltke's BUA was approved pending a correction to the BUA approval letter. The BUA letter was edited to remove III-D*. This BUA has been sent out.
   - At the February 16, 2022, meeting Dr. Zhang's BUA was approved pending successful completion of the lab inspection. This BUA has not been sent out.
   - At the February 16, 2022, meeting, Dr. Wong's BUA was approved pending successful completion of an inspection at the administration site and occupational health information in case of accidental exposure to the study product. These items were completed, and this BUA has been sent out.

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. Disis renewed their BUA for *Ongoing Research at UWMC Translational Research Unit (TRU)* that includes human blood, tissue, body fluids, cell lines.
      - Dr. Zheng added transgenic plant work and a new BSL-1 room to their *Protein Structural Biology* BUA.
      - Dr. Hladik added the work with tissues infected with SIV and a new room to their *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* BUA.

- Dr. Hille's BUA *Roles of p120 catenin during gastrulation in Zebrafish embryos* was registered.
- Dr. Ailion added the Pathology Flow Cytometry Core Facility and a new human cell line to their *Dense-core Vesicles* BUA.
- Dr. Muczynski renewed their BUA *Kidney Immunological Research* for work with Epstein-Barr virus and human blood, tissue, body fluids, cell lines.
- Dr. Nakamura renewed the BUA for *NR2E3 Signaling to treat inherited retinal disease* for work with human and non-human primate blood, tissue, body fluid, cell lines, recDNA, and E. coli.
- Dr. Stergachis added the Pathology Flow Cytometry Core Facility with previously approved agents to the *Single-molecule chromatin architectures of disease-associated non-coding genetic variants* BUA.
- Dr. Jarvik renewed the *Pacific Northwest Undiagnosed Disease Network* BUA for work with human blood, tissue, body fluid, cell lines, and recDNA.
- Dr. Lopez added new rooms, shared core facilities, human cell lines, and recDNA to the *A-Alpha Bio* BUA.
- Dr. Gale added new rooms as well as the use of inactivated materials and recombinant DNA to the *Host genetics and response to infection* BUA.
- Dr. Regnier added previously approved agents to a new room to the *Rodent Striated Muscle* BUA.
- Dr. Fuller added a new room for BSL-2 and BSL-3 practices work to the *DNA Vaccine Therapy* BUA.
- Dr. Folch added new III-F recDNA work to previously approved rooms for the *Microfluidic analysis of neuronal development and function* BUA.
- Dr. Liao renewed their *Immune responses in gynecologic cancers* BUA that included mouse cells transduced with third generation lentiviral vectors.
- Dr. Stevens added new lab space for work with previously approved agents for their *Regenerative Technologies* BUA.
- Dr. Stevens added new lab space for work with previously approved agents for their *Regenerative Technologies* BUA.
- 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.
- <u>The Committee unanimously voted to approve this month's Biosafety Officer Report.</u>

6. BSL-3 INACTIVATION REPORT

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

7. DURC REPORT

- Dr. Khaing received approval for use of Botulinum neurotoxin. This work does not meet the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- <u>The Committee unanimously voted to approve this month's DURC Report.</u>

8. INDIVIDUAL PROJECT REVIEWS

a. Abitua, Philip, New, *Abitua: General Research*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the evolution of developmental novelties by comparing homologous cells across distantly related species.
- Work includes use of transgenic *Nothobranchius furzeri* (killifish), *Danio rerio* (zebrafish), *Ciona savignyi* (sea squirt), E. coli, and recDNA at BSL-1.
- A lab inspection has been completed, and 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. Abitua.
- The Committee voted unanimously to approve the draft BUA for Dr. Abitua.

b. Bajjalieh, Sandra, Renewal, *Cell Biology of the Neuron*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies molecular events that produce and regulate neuronal function.
- Work includes use of lentiviral vectors and human blood, tissue body fluids and cell lines at BSL-2.
- A successful lab inspection has been completed, but deficiencies have not yet been addressed.
- Trainings have not been completed.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bajjalieh.
- The Committee voted unanimously to approve the draft BUA for Dr. Bajjalieh pending completion of a successful lab inspection and completion of the biosafety training by the PI.

c. Cornell, Robert, New, *Dissecting the Transcriptional Network Governing Differentiation of Periderm*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies gene regulatory network of epithelial differentiation.
- Work includes *Danio rerio* (zebrafish), *E. coli*, and human blood, tissue, body fluids, and cell lines at BSL-2.
- A successful lab inspection has been completed with 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. Cornell.
- The Committee voted unanimously to approve the draft BUA for Dr. Cornell.

d. DeForest, Cole, Change, *Protein Engineering in E. coli*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies recombinant protein production to direct cell function in a polymer scaffold.
- This lab is adding the use of third generation lentiviral vectors and adenoviral vectors.
- 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. DeForest.
- The Committee voted unanimously to approve the draft BUA for Dr. DeForest.

e. Disteche, Christine, Renewal, *Molecular studies of sex chromosome aneuploidy*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies molecular consequences of an abnormal number of X or Y chromosome.
- This lab uses adeno-associated viral vectors administered to human cells.
- A successful lab inspection has been completed, and no deficiencies were found.
- 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. Disteche.
- The Committee voted unanimously to approve the draft BUA for Dr. Disteche.

f. Fang, Ferric, Renewal, *Salmonella Pathogenesis and Immunity*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies host-pathogen interactions, especially those between oxygen dependent antimicrobial mechanisms of phagocytic cells and microbes.
- This lab uses third generation lentiviral vectors and several recombinant Risk Group 2 bacteria in vitro and in mice.
- 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. Fang.
- The Committee voted unanimously to approve the draft BUA for Dr. Fang.

g. Giachelli, Cecilia, Renewal, *Engineering Osteoclasts to Prevent Medication Related Osteonecrosis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies cell and exosome-based therapy to prevent or treat medication-related death of the jawbone.
- This lab uses third generation lentiviral vectors in human cells and in mice.
- A lab inspection was performed with no deficiencies found.
- 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. Giachelli.
- The Committee voted unanimously to approve the draft BUA for Dr. Giachelli.

h. Gottlieb, Goeff, Renewal, *Antiretroviral Therapy for HIV-2 in Senegal, West Africa*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the efficacy of antiretroviral drugs in HIV-2 infected individuals and characterizes the methods of how HIV-2 evolves resistance to these inhibitors.
- This lab uses transfection of HIV, SIV, and HTLV genes in human cells and cell lines.
- A lab inspection was performed with no deficiencies found.
- 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. Gottlieb.
- The Committee voted unanimously to approve the draft BUA for Dr. Gottlieb pending clarification on conferring resistance to treatments in HIV strains.

i. Greenberg, E. Peter, Renewal, *Quorom sensing in Burkholderia mallei*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies a type of bacterial gene regulation known as quorum sensing and response as well as molecular mechanism and evolution of these systems.
- This lab uses several recombinant Risk Group 1 and 2 bacteria.
- A lab inspection was performed, and no deficiencies were found.
- 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. Greenberg.
- The Committee voted unanimously to approve the draft BUA for Dr. Greenberg pending confirmation if Risk Group 3 DNA is used in E. coli.

j. Harwood, Caroline, Renewal*, Harwood Research Projects.*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies molecular mechanisms of *Acinetobacter baumannii, Pseudomonas aeruginosa, Rhodopseudomonas palustris*, as well as plant-microbe and microbe-microbe interactions in bacteria associated with plants.
- This lab uses several recombinant Risk Group 1 and 2 bacteria.
- A successful lab inspection has been completed, and deficiencies have not yet 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. Harwood.
- The Committee voted unanimously to approve the draft BUA for Dr. Harwood pending successful completion of the lab inspection and clarification regarding bacterial strain antibiotic resistance.

k. Hladik, Florian, Change, *Elucidating the role and activation of M cells in the context of HIV infection in the gut Mucosa.*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies how HIV gains entrance into the host at the actual host-virus interface as well as latent HIV reservoir in blood and mucosal tissue.
- This BUA change adds SHIV infected NHP tissue. The lab submitted an SOP for using a cryostat to section the infected tissue. The biosafety officer also recommended a consultation with the occupational health nurse for this work.
- A lab inspection was not required for this change as the lab was inspected last month.
- 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. Hladik.
- The Committee voted to approve the draft BUA for Dr. Hladik with one abstention pending a correction to the BUA letter.

l. Horwitz, Gregory, Renewal, *Neurophysiology of Vision*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the relationship between vision and electrical activity in the brain.
- This lab uses AAV, lentiviral vectors, herpes simplex viral vectors, Sindbis viral vector, and G-deleted rabies viral vector in non-human primates.
- A successful lab inspection has been completed with no deficiencies found.
- 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. Horwitz.
- The Committee voted unanimously to approve the draft BUA for Dr. Horwitz pending BUA application edits for in vivo use of Sindbis viral vectors.

m. Kavanagh, Terrance, Renewal, *Predictive Toxicology Center for Organotypic Cultures and Assessment of AOPs for Engineered Nanomaterials*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies transduced culture outcomes/responses to reactive chemicals such as electronic cigarette vapor or other oxidative stress inducing chemicals.
- This lab uses 3rd gen lentiviral vectors and lipofectamine transduction into mouse cells.
- The lab inspection is scheduled for 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. Kavanagh.
- The Committee voted unanimously to approve the draft BUA for Dr. Kavanagh pending successful completion of the lab inspection.

n. Kojima, Yoshiko, Renewal, *A Neuronal Process of the Error Signal that Drives Saccade Adaption*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies optical manipulation of electrical activity in the brain by optimizing viral vectors and injection techniques in non-human primates.
- This lab uses AAV vectors in non-human primates.
- A successful lab inspection has been completed, and no deficiencies were found.
- 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. Kojima.
- The Committee voted unanimously to approve the draft BUA for Dr. Kojima.

o. Kwon, Young, Renewal, *Regulation of growth and wasting*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies organ growth and wasting regulation using drosophila genetics and biochemistry.
- This lab uses 1st/2nd generation lentiviral vectors grown in humans.
- A successful lab inspection has been completed, and deficiencies have not yet 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. Kwon.
- The Committee voted unanimously to approve the draft BUA for Dr. Kwon pending successful completion of the lab inspection.

p. Merz, Alex, Renewal, *Bacterial interactions with mammalian cells*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies how bacterial cells adhere to human cells as a part of the infection process, and how human cells respond to bacterial attachment.
- This lab uses 3rd generation lentiviral vectors in vitro and recombinant *Neisseria* species.
- The lab inspection is scheduled for 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. Merz.
- The Committee voted unanimously to approve the draft BUA for Dr. Merz pending successful completion of the lab inspection.

q. Morrissey, Colm, Renewal, *SLFN11 May be the Key to Identifying New Combination Treatments to Treat CRPC*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies if the response to chemotherapeutic drugs given knockdown expression by lentiviral vector.
- This lab uses lentiviral vectors in human prostate cancer cell lines.
- The lab inspection is scheduled for 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. Morrissey.
- The Committee voted unanimously to approve the draft BUA for Dr. Morrisey pending successful completion of the lab inspection and an edit to the BUA letter.

r. Nahmani, Marc, Renewal, *Structure and Function of Neuronal Microcircuits*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the mechanisms behind initiating and ending critical periods in human brains when neurons are in a phase of plasticity.
- This lab uses AAV vectors in human cell lines as well as transgenic *Drosophila* and *C. elegans.*
- A successful lab inspection has been completed, and no deficiencies were found.
- 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. Nahmani.
- The Committee voted unanimously to approve the draft BUA for Dr. Nahmani.

s. Sweet, Ian, Renewal, *Islet Cell and Functional Analysis*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies pancreatic islet and tissue isolation techniques.

- This lab uses adenoviral vectors in vitro and in human and murine cell cultures.
- 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. Sweet.
- The Committee voted unanimously to approve the draft BUA for Dr. Sweet.

t. Van Voorhis, Wesley, Renewal, *1. Immune Response: Chagas 2. Biochemistry of Protein Prenylation 3. Plasmodium falciparum Protein Farnesyltransferase Inhibitors 4. Drugs for Toxoplasma and Cryptosporidium 5. Giardia 6. Shigella Inhibitors 7. EE*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies development and discovery of new therapeutic drugs needed for infections, especially parasitic infections.
- This lab uses several recombinant microorganisms in vitro and in mice.
- A lab inspection has been completed, but deficiencies have not yet 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. Van Voorhis .
- The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis pending resolution of the remaining lab inspection items.

u. Veesler, David, Change, *Understanding evolution in SARS-CoV-2 spike protein*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This lab studies the production of highly pure recombinant proteins for structural characterization.
- This change adds use of recombinant vaccinia virus and Vesicular stomatitis virus (VSV) pseudotyped with SARS CoV-2 spike protein.
- An inspection was not required as the lab was recently inspected.
- 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. Veesler.
- The Committee voted unanimously to approve the draft BUA for Dr. Veesler.

9. SUBCOMMITTEE REPORTS:

v. Babu, Tia, New, *Phase 2 Clinical Trial to Expand and Optimize Immune Coverage of SARS-CoV-2 Existing and Emerging Antigenic Space*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This lab studies the safety and immunogenicity of additional doses of COVID-19 vaccines.
- This study involves administration of a SARS CoV-2 nucleic acid vaccine in humans.
- 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. Babu. Another member seconded the motion.
- The Committee voted to approve the draft BUA for Dr. Babu with one abstention.

w. Gauthier, Jordan, New, *A Phase 3 Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy and Safety of AB-205 plus Standard of Care versus Placebo plus Standard of Care in Adults with Lymphoma Undergoing High-Dose Therapy and Autologous Hematopoietic Cell Transplantation (HDT-AHCT*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This lab studies the efficiency and safety of AB-205-301 to treat damaged organ vascular stem cell niches caused by off target cytotoxicity of high dose therapy for non-Hodgkin and Hodgkin lymphomas.
- This lab will use human cells transduced with gammaretroviral vectors.
- 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. Gauthier. Another member seconded the motion.
- The Committee voted to approve the draft BUA with for Dr. Gauthier.

x. Maloney, David, New, *A Phase 1, Multicenter, Open-label Study of BMS-986403 in Subjects with Relapsed and/or Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This lab studies safety and tolerability of BMS-986403 in subjects with R/R CLL/SLL as well as maximum tolerated dose and/or RP2D of BMS-986403 in subjects with R/R CLL or SLL.
- This study involves human cells transduced with third generation lentiviral vectors in humans.
- 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. Gauthier. Another member seconded the motion.
- The Committee voted to approve the draft BUA with for Dr. Gauthier.

y. Skerrett, Shawn, Change, *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.
- This lab studies interactions of *Francisella tularensis* with human alveolar macrophages compared to mouse alveolar and bone marrow derived macrophages.
- This change adds a new recombinant strain of *Francisella tularensis* to existing BSL-3 research.
- An inspection of the site is not required. 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. Skerrett. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett pending clarification on if strain has antibiotic resistance marker.

10. FOR YOUR INFORMATION:

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

12. MEETING ADJOURNED AT APPROXIMATELY 11:55 A.M.