



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, January 20, 2021

Time: 10:30 AM – 12:30 PM

Location: Zoom

Members Present:

1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
3. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
4. Richard Grant, Washington National Primate Research Center
5. Garry Hamilton (*Community Member*)
6. David Koelle, Allergy and Infectious Diseases
7. Stephen Libby, Laboratory Medicine (*IBC Chair*)
8. Scott Meschke, Environmental & Occupational Health Sciences
9. Susan Parazzoli (*Community Member*)
10. Jason Smith, Microbiology (*IBC Vice 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 10:34 a.m. A quorum was present. A new temporary biosafety officer for EH&S was introduced to the committee.
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. **2020 NIH PROGRAM REVIEW AND APS 12.7 UPDATE:** An update was given by EH&S regarding the annual completion of the internal IBC program review. The only changes to the program involved adapting to COVID-19 by way of conducting meetings remotely and by holding special meetings to meet the needs of timely COVID-19 research. UW Administrative Policy Statement 12.7 was also introduced regarding oversight of chemical and physical safety requirements in research and academic environments.
4. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the December 16, 2020 meeting.
 - A member made a motion to approve the December 16, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the December 16, 2020 meeting minutes.
5. **OLD BUSINESS:**
 - At the March 18, 2020 meeting, Dr. Lagunoff's BUA was approved pending training. This BUA is still pending.
 - At the June 17, 2020 meeting, Dr. Altemeier's BUA was approved pending review of the IACUC protocol and required training. This BUA is still pending.
 - At the August 19, 2020 meeting, Dr. Voigt's BUA was approved pending a medical management plan, Occupational Health consultations, training, and edits to the BUA application. This BUA is still pending.
 - At the December 16, 2020 meeting, Dr. Ceze's BUA was approved pending a successful lab inspection. This BUA is still pending.
6. **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. Johnstone renewed the BUA Factors Regulating Aqueous Outflow in Glaucoma. Work includes use of human and non-human primate blood, tissue, body fluids, and cell lines in vitro.
 - Dr. Varani renewed the BUA *RNA Structure/Function* for work with recombinant or synthetic DNA/RNA (non-viral) – enhanced gene delivery methods and human blood, tissue, body fluids, and cell lines.
 - Dr. Kaufman renewed the BUA *Clinical and Translational Studies of Air Pollution Toxicity* for work with human blood, tissue, body fluids, and cell lines.

- Dr. Giltyay renewed the BUA *B-cell and dendritic cell biology in inflammation and autoimmunity*. Work includes use of recombinant or synthetic DNA/RNA (non-viral) – enhanced gene delivery methods.
- Dr. Liu renewed the BUA *Prostate Cell Biology - Stromal Epithelial*. Work includes use of human induced pluripotent stem (iPS) cells and recombinant or synthetic DNA/RNA (non-viral).
- Dr. An added a new BSL-1 room to the BUA *Gingival-Periodontal Interface System*.
- Dr. Kim renewed the BUA *IKKBeta Mediated Impairment of Endothelial Nitric Oxide Production*. Work includes use of recombinant or synthetic DNA/RNA (non-viral).
- Dr. Xia added a new ABSL-1 room to the BUA *Neurogenesis*.
- Dr. Hawkins was approved for the BUA *Research, Development, and Manufacturing of Pluripotent Stem Cells and Differentiated Cells for the Treatment of Human Disease*. Work includes use of recombinant or synthetic DNA/RNA (non-viral) – enhanced gene delivery methods and use of human induced pluripotent stem (iPS) cells.
- Dr. Theberge added the use of non-recombinant *Streptococcus pyogenes* and *Streptococcus mutans* to the BUA *Studying cell signaling and cell-microenvironment interactions with new analytical tools*.
- 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.

7. 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.

8. INDIVIDUAL PROJECT REVIEWS

- a. Adams Waldorf, Kristina, renewal, *Experimental Model for Chorioamnionitis and Preterm Labor*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to determine the effects of various bacterial diseases on pregnancy and the fetus with the goal of understanding pathogenesis and developing vaccines and therapeutics to prevent injury.
 - Work includes use of *Streptococcus agalactiae* in macaques.
 - A successful lab inspection has been completed.
 - 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.
- b. Bothwell, Mark, renewal, *iPSC models of neuromuscular disease*
 - The assigned IBC Primary Reviewer presented the Primary Review.

- This group works with human induced pluripotent stem cell lines originally transduced in other labs via Sendai or lentiviral vectors to introduce reprogramming genes. They differentiate the stem cells into motor neurons or skeletal muscles and study their biochemical properties.
 - A successful lab inspection is still required.
 - 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. Bothwell pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bothwell pending completion of a successful lab inspection.
- c. Geisse, Nicholas, change, *Development of cultureware and devices for human cells in vitro research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds use of adeno-associated viral vectors (adenovirus free) in vitro.
 - A successful lab inspection is still required.
 - 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. Geisse pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Geisse pending completion of a successful lab inspection.
- d. Jerome, Keith, renewal, *Understanding viral antibody resistance*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab seeks to understand mechanisms of viral escape from antibody neutralization.
 - Work includes in vitro use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient.
 - A successful lab inspection has been completed.
 - 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. Jerome.
 - The Committee voted unanimously to approve the draft BUA for Dr. Jerome.
- e. Kawasumi, Masaoki, renewal, *Skin Cancer Research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to gain a better understanding of the mechanisms of skin carcinogenesis (including UV-induced squamous cell carcinoma, melanoma, and Merkel cell carcinoma) and develop methods of prevention and/or treatment.
 - Work includes work with adenoviral vector (E1a deleted), >2/3 adenovirus genome, gammaretroviral vectors, replication deficient, amphotropic, and lentiviral vectors, non-HIV pseudotyped, replication deficient. Mice are also injected with human cells transduced with lentiviral vectors.
 - A successful lab inspection is still required.
 - 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 pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kawasumi pending completion of a successful lab inspection.
- f. Kimelman, David, renewal, *Early Fish Development*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab uses early zebrafish embryo development as a model for human development.
 - Work includes breeding, creation, and/or use of transgenic zebrafish and in vitro use of escherichia coli, exempt K-12 non-pathogenic strains.
 - A successful lab inspection is still required.
 - 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. Kimelman pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kimelman pending completion of a successful lab inspection.
- g. Levy, Karen, new, *Levy Research Group: ChEEP ChEEP, EcoMiD, EcoZUR, PAASIM*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The purpose of this project is to detect and quantify pathogenic and indicator microorganisms in environmental media (e.g., water, food, dust, soil) and clinical samples (e.g., stool, blood spots).
 - Work includes use of Salmonella typhimurium in vitro.
 - This lab is currently working in an approved lab space under another PI. Once the Levy lab is set up they will be required to pass a lab inspection in order to work in that location.
 - 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. Levy.
 - The Committee voted to approve the draft BUA for Dr. Levy. There was one voting abstention.
- h. MacLellan, W. Robb, renewal, *Cardiac Development, Growth and Regeneration*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The verall research goal is to dissect cellular and molecular mechanisms underlying the development of congestive heart failure (CHF) and to develop cell and molecular based therapies for the disease.
 - Work includes in vitro use of adeno-associated viral vectors (adenovirus free) with oncogenic inserts.
 - A successful lab inspection is still required.
 - 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. MacLellan pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. MacLellan pending completion of a successful lab inspection.

- i. Mizumori, Sheri, renewal, *Neuromodulatory Control of Reward Neurocircuitry and Memory*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to discover the mechanisms by which neural circuits of the brain change their function as a result of and to influence future learning, memory and decisions.
 - Work includes use of adeno-associated viral vectors (adenovirus free) and canine adenovirus 2 in rats.
 - A successful lab inspection is still required.
 - 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 pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mizumori pending completion of a successful lab inspection.
- j. Moritz, Chet, renewal, *Combined Stem Cell Transplantation and Targeted Microstimulation to Direct the Formation of Functional Connections and Neural Repair in Mice*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project aims to develop a treatment for damage to the brain, spinal cord, or bladder.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in mice.
 - A successful lab inspection has been completed.
 - 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. Moritz pending an edit to the BUA letter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Moritz pending an edit to the BUA letter.
- k. Neitz, Maureen, renewal, *Opsin gene splicing assay using viral mediated gene delivery in gerbils*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goals of this project are to use adeno-associated viral vectors to deliver opsin minigenes to retinas of gerbils to assess mutations that cause a defect in splicing, as well as to use human blood cells to induce pluripotent stem cells to devise a gene therapy that will force correct splicing of opsin mutations that cause a splicing defect.
 - A successful lab inspection has been completed.
 - 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.
- l. Oda, Shannon, new, *Engineering novel immunotherapeutic strategies*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The Oda lab at Seattle Children's focuses on developing immunotherapies for cancer.

- The lab will bring human and mouse cells transduced with third generation lentiviral vectors (potentially with oncogenes) and ecotropic gammaretroviral vectors (potentially with oncogenes) to do flow cytometry/cell sorting at a UW facility. No other laboratory work will be conducted on the UW campus.
 - A successful lab inspection has been completed.
 - 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. Oda.
 - The Committee voted unanimously to approve the draft BUA for Dr. Oda.
- m. Pillarisetty, Venu, change, *Immunotherapy for various solid tumors by tumor slice culture***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change application is to add gutless adenovirus vectors to transduce human cells and tissues and run PCR.
 - The gutless adenovirus vectors are made in a collaborator's lab. None of the inserts identified are oncogenes.
 - A successful lab inspection has been completed.
 - 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. Pillarisetty.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pillarisetty.
- n. Spain, William, renewal, *Pilot collaboration with Neurophysiology of Vision***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project performs electrical recordings of neurons within slices of fresh or cultured macaque cortical tissue.
 - The macaque tissue is from a primate that has been experimentally exposed to adeno-associated viral vectors (adenovirus free).
 - A successful lab inspection has been completed.
 - 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. Spain.
 - The Committee voted unanimously to approve the draft BUA for Dr. Spain.
- o. Tian, Rong, renewal, *Energetics and Metabolism of the Heart***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goal of the research is to study the regulation of cardiac function and myocardial energy metabolism in fetal, neonatal, normal adult, senescent, and diseased hearts in order to gain knowledge about the roles of altered energy metabolism in the development of cardiac hypertrophy and heart failure.
 - Work includes in vitro use of various viral vectors as well as use of adeno-associated viral vectors (adenovirus free) and Escherichia coli, exempt K-12 non-pathogenic strains in mice.
 - A successful lab inspection is still required.
 - 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 pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Tian pending completion of a successful lab inspection.
- p. Wong, Rachel, renewal, *Development of the retina (mouse)*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The major goal of this project is to understand how neural circuits in the vertebrate retina are assembled correctly during development and during regeneration. This research uses mouse models to study retinal neural connectivity using multiple experimental approaches such as live imaging of mouse retinal tissue explants.
 - Work includes use of adeno-associated viral vectors (adenovirus free) and recombinant or synthetic DNA/RNA (non-viral) in mice.
 - A successful lab inspection is still required.
 - 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. Wong pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wong pending completion of a successful lab inspection.
- q. Yadav, Smita, renewal, *Signaling in neuronal development and disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project aims to identify kinase signaling pathways that are involved in neuronal development and to understand how dysfunction of these pathways contributes to neurodevelopmental and psychiatric disorders such as autism and schizophrenia.
 - Work includes in vitro use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient.
 - A successful lab inspection is still required.
 - 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 pending completion of a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Yadav pending completion of a successful lab inspection.

9. SUBCOMMITTEE REPORTS:

- r. Nakamura, Kenta, new, *A Phase 1/2 Trial of Direct Administration of AdVEGF-AIIGA+, a Replication Deficient Adenovirus Vector Expressing a cDNA/Genomic Hybrid of Human Vascular Endothelial Growth Factor, to the Ischemic Myocardium of Subjects with Angina Pectoria Secondary to Coronary Artery Disease that is Refractory to Drug Therapy and Unsuitable for Revascularization*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The trial proposes direct cardiac injection of a replication incompetent adenovirus, termed XC001, that encodes a biologically active form of vascular endothelial growth

factor (VEGF) into persons with severe coronary artery disease (CAD) with no other therapy options.

- The drug will be readied for injection at UWMC. In the CT surgery operating rooms the heart muscle will be surgically exposed. There will be up to 15 direct injections into the left ventricle wall using A 1 ml syringe and 6.5 inch long needle.
 - Percutaneous administration of drug substance to pharmacy or operating room staff is the greatest biohazardous risk. The long needles and operating room environment may add risk compared to standard IM vaccination-like administration. There is also the possibility of shedding of VEGF-expressing rep-incomp Ad5.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Nakamura. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Nakamura.
- s. Shinoha, Michi, new, *A phase 1, open-label, safety and dosing study of autologous desmoglein 3 chimeric autoantibody receptor T cells (DSG3-CAART) in subjects with active, anti-DSG3, mucosal-dominant pemphigus vulgaris*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a multicenter trial of adoptive T cell therapy for mucosal dominant pemphigus vulgaris. The research investigates dose and dose fractionation schedules of DSG3-CAART cells. The main objectives are to establish safety and determine dose and fractionation, with secondary objectives including cell persistence, immune biomarkers and clinical endpoints.
 - Percutaneous exposure of pharmacy or clinical/nursing staff during cell thaw, preparation, and administration is the greatest biohazardous risk.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Shinoha. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Shinoha.
- t. West, Timothy, change, *Host genetics and response to infection*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is an ongoing project that involves work with *Burkholderia pseudomallei* in the BSL3 lab. The PI inadvertently received some antibiotic resistant strains of *Burkholderia pseudomallei* in a shipment of other approved strains sent from Thailand. Since the strains are here, the PI wishes to store them for potential future use.
 - The strains were sent as stabs so they must be grown up to create glycerol freezer stocks. This approval is only for the growth and storage of the antibiotic resistant strains. No further research with these strains is approved at this time. IBC review and approval are required for any further research with these strains.
 - The medical management plan does not need to be updated at this time. If the lab wishes to work with these strains in the future then it will need to be updated.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. West. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. West.

10. FOR YOUR INFORMATION: There were no items to report.

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

12. MEETING ADJOURNED AT APPROXIMATELY 12:31 P.M.