



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY of WASHINGTON

Meeting Minutes

Date: Wednesday, October 21, 2020

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 3. Richard Grant, Washington National Primate Research Center
 4. Kevin Hybiske, Allergy and Infectious Diseases
 5. David Koelle, Allergy and Infectious Diseases
 6. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 7. Scott Meschke, Environmental & Occupational Health Sciences
 8. Susan Parazzoli (Community Member)
 9. Jason Smith, Microbiology (*IBC Vice Chair*)

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 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 September 16, 2020 meeting.
 - A member made a motion to approve the September 16, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the September 16, 2020 meeting minutes.
4. **OLD BUSINESS:**
 - At the March 18, 2020 meeting, Dr. Jerome's BUA was approved pending completion of the BUA application. This BUA is still pending.
 - At the March 18, 2020 meeting, Dr. Lagunoff's BUA was approved pending a successful lab inspection and training completion. 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. Gordon's BUA was approved pending a successful lab inspection.
 - At the August 19, 2020 meeting, Dr. Salipante's BUA was approved pending a successful lab inspection. This BUA is still pending.
 - At the August 19, 2020 meeting, Dr. Hyde's BUA was approved pending review of the IACUC submission. 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 September 16, 2020 meeting, Dr. Hellstrom's BUA was approved pending a successful lab inspection. This BUA has been sent out.
 - At the September 16, 2020 meeting, Dr. Kennedy's BUA was approved pending a successful lab inspection. This BUA has been sent out.
 - At the September 16, 2020 meeting, Dr. Servetnick's BUA was approved pending a successful lab inspection. This BUA is still pending.
 - At the September 16, 2020 meeting, Dr. Trapnell's BUA was approved pending a successful lab inspection. This BUA has been sent out.
 - At the September 16, 2020 meeting, Dr. Lee's BUA was approved pending an edit to the BUA letter. This BUA has been sent out.
 - At the September 16, 2020 meeting, Dr. West's BUA was held as a conditional approval. 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. Yeung renewed the BUA *Liver Tumor Research* working with human blood, tissue, body fluids, and cell lines.
- Dr. Hladik added in vitro use of non-recombinant Chlamydia trachomatis to the BUA *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*.
- Dr. Vojtech added in vitro use of non-recombinant Chlamydia trachomatis to the BUA *Mechanisms of sexual virus transmission*.
- Dr. Chiu renewed the BUA *Development of technologies for early detection and stratification of breast cancer* working with human blood, tissue, body fluids, and cell lines.
- Dr. Gao added use of a new facility for the BUA *Cryopreservation of Jurkat cells*.
- Dr. Tait Wonjo added use of Heligmosomoides polygyrus in vitro and in mice to the BUA *Regulation of immunity and inflammation at mucosal surfaces*.
- Dr. Fallas was approved for a new BUA called *Institute for Protein Design Translational Investigators*. Work includes in vitro use of Escherichia coli, non-pathogenic strains and human blood, tissue, body fluids, and cell lines.
- Dr. Van Voorhis added the use of fixed or inactivated SARS-CoV-2 samples or tissue to the BUA *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*.
- Dr. Campbell renewed the BUA *Chlamydia pneumonia antigens of biological significance*, working with various Chlamydia strains in vitro.
- Dr. King added a new lab space for work with previously approved agents.
- Dr. Pun added research involving clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the BUA *Biomaterials for Biomedical Applications*.
- Dr. Frevert added the use of fixed or inactivated SARS-CoV-2 samples or tissue to the BUA *Use of BSL2 agents in Histology and Imaging Core*.
- Dr. Akilesh added research involving clinical samples from patients known or suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the BUA *Kidney Disease Genomics*.
- Dr. Barria-Roman renewed the BUA *Regulation of Glutamatergic Synapses*. Work includes in vitro use of recombinant or synthetic DNA/RNA (non-viral) – enhanced gene delivery methods.
- Dr. Fujise added a new location to the BUA *Study of Fortilin*.
- 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

- One project received approval for UVC inactivation of SARS-CoV-2 Supernatant.
- The IBC Chair sought a motion to approve this month's BSL-3 Inactivation Approvals Report.
- A member made a motion to approve this month's BSL-3 Inactivation Approvals Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's BSL-3 Inactivation Approvals Report.

7. DURC REPORT

- One project received approval for continued use of Avian influenza virus. The 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.
- The Committee unanimously voted to approve this month's DURC Report.

8. INDIVIDUAL PROJECT REVIEWS

- a. Freedman, Benjamin, change, *Differentiation of Human Pluripotent Stem Cells into Kidney Cells*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab is adding lentiviral vectors, non-HIV pseudotyped, replication deficient for use in cell culture.
 - 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. Freedman.
 - The Committee voted unanimously to approve the draft BUA for Dr. Freedman.
- b. Fuller, Deborah, renewal, Prophylactic SHIV Vaccines in NHP
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The focus of this research is to study HIV infection biology using SHIV in NHPs that mimic human routes of infection.
 - Work includes use of Primate lentivirus in vitro and in macaques.
 - 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. Fuller pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Fuller pending a successful lab inspection.
- c. Loeb, Lawrence, renewal, *Loeb Lab Research Projects*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The Loeb lab studies cancer pathogenesis in the context of DNA damage and repair.
 - Work includes in vitro use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient, with oncogenic inserts.
 - 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. Loeb.
 - The Committee voted unanimously to approve the draft BUA for Dr. Loeb.

- d. Mack, David, new, *Gene Therapy for Neuromuscular Disorders*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab combines stem cell and gene therapies to develop new treatments for neuromuscular disease. This project uses a new model of Duchenne Muscular Dystrophy (DMD) in a rat for disease modeling and gene therapy studies. The goal is to use gene therapy to treat disease progression by delivering therapeutic genes to muscles via the bloodstream.
 - Work includes use of lentiviral vectors, third generation, non-HIV pseudotyped, replication deficient in vitro. It also includes use of adeno-associated viral vectors (adenovirus free) and murine cells transduced with adeno-associated viral vectors (adenovirus free) in rats.
 - 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. Mack.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mack.
- e. Mack, David, renewal, *Gene Therapy in Canine Myotubular Myopathy phase 2*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project is to develop and test viral vector-mediated gene therapy approaches to treat neuromuscular diseases in dog models.
 - Work includes use of adeno-associated viral vectors (adenovirus free) and canine cells transduced with adeno-associated viral vectors (adenovirus free) in dogs.
 - 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. Mack.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mack.
- f. Merz, Alexey, change, *Bacterial interactions with mammalian cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add in vitro use of *Pseudomonas aeruginosa* as well as recombinant strains of *Neisseria gonorrhoeae*.
 - 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. Merz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Merz.
- g. Neitz, Maureen, renewal, *Can gene therapy expand sensory capacity in the adult*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goals of this research is to study neural plasticity of the adult mammalian visual system by adding new sensory input and to develop adeno-associated viral vectors that efficiently transduce retinal cells.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in mice and in vitro.
 - 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.
- h. Pepper, Marion, renewal, *The Differentiation and Function of Memory T and B cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to understand how cells of the adaptive immune system develop to either prevent disease or cause allergic responses with the ultimate intent of developing novel vaccines and therapies for allergy and asthma.
 - Work includes use of *Plasmodium berghei* and *yoelli* in mice, as well as in vitro work with various other agents at BSL-2.
 - 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. Pepper pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pepper pending a successful lab inspection.
- i. Pillarisetty, Venu, new, *Immunotherapy for various solid tumors by tumor slice culture*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies tumorigenesis in the pancreas and liver, in the context of therapeutics and treatment regimens.
 - Work includes in vitro use of lentiviral vectors, non-HIV pseudotyped, replication deficient.
 - A successful lab inspection has been completed.
 - The required trainings have not yet been completed.
 - The committee asks that the PI include specific information to the BUA application regarding the generation of lentiviral vector being used, as well as the types of inserts.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Pillarisetty pending additional details to the BUA application and training completions.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pillarisetty pending the items above.
- j. Skerrett, Shawn, renewal, *Host Defense Against Bacterial Pneumonia*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall goals of this research are to understand essential mechanisms of resistance against bacterial infections of the lungs and to identify new ways to treat respiratory tract infections.
 - Work includes use of various agents in vitro and in mice at BSL-2/ABSL-2.
 - 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. Skerrett pending a successful lab inspection and a correction to the BUA letter.

- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett pending the items above.
- k. Sniadecki, Nathan, change, *Cell therapy in mice and rats*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds use of non-human primate cells transduced with lentiviral vectors, third generation, in mice and rats.
 - 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. Sniadecki.
 - The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.
- l. Stayton, Patrick, renewal, *Smart Proteins and Intracellular Delivery*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to develop new therapeutics for infectious disease, cancer, and inflammatory disease by engineering immune cell and polymer -based therapeutics that provide new immunomodulatory, antibacterial, and anti-malarial activities.
 - 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. Stayton pending a successful lab inspection.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stayton pending a successful lab inspection.
- m. Valdmanis, Paul, renewal, *Mitigating host responses for effective gene therapy*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to develop small RNA interference technologies for safe and efficient gene therapy use in repressing genes in liver and brain disorders.
 - Work includes use of lentiviral vectors, non-HIV pseudotyped, replication deficient in vitro as well as use of adeno-associated viral vectors (adenovirus free) in vitro and 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. Valdmanis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Valdmanis.

9. SUBCOMMITTEE REPORTS:

- n. Gale, Michael, renewal, *Host Response to BSL3 Pathogens*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab studies innate immune responses to viruses by working with several pathogenic human viruses that require BSL-3 containment, such as Hantavirus, Influenza, and SARS-CoV-2. Their goals are to: understand how viral and host factors impact innate immune defenses to determine the outcome of virus infection; develop antiviral therapeutics and vaccines to treat and prevent virus infection; and, provide quality control virus stocks to support these objectives.
 - A successful lab inspection has been completed.
 - All of the required trainings have been completed.
 - This BUA gives approval for work with agents of occupational health concern (Hantaviruses, HPAI, and SARS-CoV-2). The lab is to refer to the medical management plans for the BSL-3 program for occupational health requirements.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Gale. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Gale.
- o. Cassaday, Ryan, renewal, *A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) (ZUMA-3)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) has limited medical options. There is an FDA approved autologous CAR-T product for some B cell malignancies. Here, the manufacturer has changed the manufacturing process with the resultant product termed KTE-X19. Clinical trials are required to establish the safety and efficacy of KTE-X19.
 - Percutaneous exposure to pharmacy or nursing staff during preparation and administration is the greatest biosafety issue.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Cassaday. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cassaday.
- p. Chiorean, Elena, new, Phase I Study of Autologous Transgenic T-Cells Expressing High Affinity Mesothelin-Specific T-Cell Receptor (TCR) (FH-TCR TMSLN) in Patients with Metastatic Pancreatic Ductal Adenocarcinoma
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a first in humans use of this particular TCR. The investigators propose to treat patients with advanced pancreatic cancer with T cells that they hope will recognize the pancreatic cancer cells and exert an anti-tumor effect.
 - Percutaneous exposure to pharmacy or nursing staff during preparation and administration is the greatest biosafety issue.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Chiorean. Another member seconded the motion.

- The Committee voted unanimously to approve the draft BUA for Dr. Chiorean.
- q. Disis, Mary, renewal, *A Multicenter Phase II Study of Vaccines to Prevent Recurrence in Patients with HER-2 Positive Breast Cancer*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - Women with HER2+ breast cancer with any residual invasive disease at the time of surgical resection will be enrolled in a study of the safety and efficacy of two vaccines (multivalent anti-oncodriver DNA vaccine (WOKVAC) or HER-2-pulsed DC1 vaccine). Only the WOKVAC vaccine falls under the IBC criteria. Patients will be randomized to one of the vaccines and followed for recurrence.
 - Percutaneous exposure to pharmacy or nursing staff during preparation and administration is the greatest biosafety issue.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis.
- r. Wagner, Michael, new, *208467: Master Protocol to Assess the Safety and Antitumor Activity of Genetically Engineered NY-ESO-1-Specific (c259) T Cells, alone or in combination with other agents, in HLA-A2+ Participants with NY-ESO-1 and/or LAGE-1a Positive Solid Tumors*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a master protocol to assess safety and anti-tumor activity of T cells that have been genetically engineered ex vivo to express a NY-ESO-1 / LAGE-1a-Specific TCR, alone or in combination with other agents, in HLA-A2+ Participants with NY-ESO-1 and/or LAGE-1a Positive Solid Tumors. There are two non-randomized sub-studies to investigate the product in participants with advanced metastatic or unresectable synovial sarcomas.
 - Percutaneous exposure to pharmacy or nursing staff during preparation and administration is the greatest biosafety issue.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Wagner. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wagner.
- s. Inactivated Sample Policy
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The IBC requested that a subcommittee be formed to review if a policy should be drafted requiring UW researchers to have standard procedures and documentation for receiving and working with fixed or inactivated RG3 and RG4 samples at BSL-1 or BSL-2.
 - The subcommittee recommends that EH&S add fixed or inactivated RG3 or RG4 samples to BUA letters, update documents, and provide outreach and communication with recommendations to labs about information they should receive when obtaining fixed or inactivated RG3 or RG4 organism samples.

- A member made a motion to approve the subcommittee's recommendation. Another member seconded the motion.
- The Committee voted unanimously to approve the subcommittee's recommendation.

10. FOR YOUR INFORMATION:

- **National Biosafety Month:** A biosafety officer presented on National Biosafety Month. This year, EH&S is requesting that labs 'Update SOPs and Work Safely During COVID-19'.
- **NIH Incident Report:** A veterinary technician had a splash of buffer in the eye that had contained tissue from a non-human primate that had been infected with the recombinant virus SHIV-1157ipd3N4. The employee went to the Emergency Room for medical attention and is being monitored by the University Employee Health Clinic. This incident has been reported and is awaiting response from NIH.
- A new UW EH&S biosafety officer was introduced to the committee.

11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

- A subcommittee will be formed to review change of the current UW Biosafety Manual to make lab coats required (instead of recommended) for BSL-1 labs.
- There were no public comments.

12. MEETING ADJOURNED AT APPROXIMATELY 12:06 P.M.