



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, May 20, 2020

Time: 10:00 AM – 12:00 PM

Location: Remote via Zoom

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. Lesley Colby, Comparative Medicine (*Animal Containment Expert*)
 3. Richard Grant, Washington National Primate Research Center
 4. Garry Hamilton (*Community Member*)
 5. Kevin Hybiske, Allergy and Infectious Diseases
 6. 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. Eric Stefansson, Environmental Health & Safety (*Biosafety Officer, Animal Containment Expert*)
 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 10:04 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:**
 - a. April 15, 2020
 - The IBC Chair sought a motion to approve the minutes from the April 15, 2020 meeting.
 - A member made a motion to approve the April 15, 2020 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the April 15, 2020 meeting minutes.
 - May 6, 2020
 - The IBC Chair sought a motion to approve the minutes from the May 6, 2020 meeting.
 - A member made a motion to approve the May 6, 2020 minutes. Another member seconded the motion.
 - The committee voted to approve the May 6, 2020 meeting minutes. There was one abstention.
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.
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. Koelle added a new location to the BUA *Koelle Laboratory at UW*.
 - Dr. West added use of clinical specimens from patients positive for COVID-19 to the BUA *Host genetics and response to infection*.
 - Dr. Byers renewed the BUA *Collagen Diagnostic Laboratory and Research Repository for Heritable Disorders of Bone, Blood Vessels and Skin*. Work includes in vitro use of human blood, tissue, body fluids, and cell lines.
 - Dr. Drury-Steward added a new location to the BUA *Silicon Photonic Blood Typing*.
 - Dr. Frevert renewed the BUA *Use of BSL2 agents in Histology and Imaging Core*.
 - Dr. Tian added non-recombinant E. coli administered to mice to the BUA *Energetics and Metabolism of the Heart*.
 - Dr. Wurfel added a new location the BUA *Human Innate Immune Variation*.
 - Dr. Veesler 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 *Expression of recombinant proteins using mammalian cell lines*. No viral isolation or culturing is permitted.

- Dr. Shi was approved for a new BUA, *The Shi Laboratory Animal Use and Other Research*. Work includes in vitro use of adeno-associated viral vectors (adenovirus free) and lentiviral vectors, non-HIV pseudotyped, replication deficient.
- Dr. Seshadri 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 *Human Immunity to Mycobacterial Diseases*. No viral isolation or culturing is permitted.
- Dr. Limaye 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 *Limaye Clinical Research*. No viral isolation or culturing is permitted.
- Dr. Shendure added non-recombinant H1N1 strain A/WSN/1933 influenza virus to the BUA *Shendure: General Research*.
- Dr. Lingappa 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 *International Clinical Research Center, Repository*. No viral isolation or culturing is permitted.
- Dr. Gu 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 *Study of small molecule-controlled CAR-T cell activation in mice*. No viral isolation or culturing is permitted.
- Dr. Grant added two human coronavirus strains, 229E and OC43, to the BUA *Primate Diagnostic Services Laboratories*.
- Dr. Lin 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 *Epigenomics of Heart Failure*. No viral isolation or culturing is permitted.
- Dr. Hallstrand 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 *Asthma and Translational Research Core*. No viral isolation or culturing is permitted.
- Dr. Murphy registered a new plasmid vaccine in mice to the BUA *Immunity to malaria infection*.
- Dr. Coombs renewed the BUA *Laboratory Tests in Support of HIV and SARS-COV-2 Research and Diagnostics*. Work includes use of clinical samples from patients suspected to be infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Dr. Van Voorhis added use of clinical specimens from patients positive for COVID-19 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. Adams Waldorf added use of clinical specimens from patients positive for COVID-19 to the BUA *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Starita added use of new rooms remodeled for testing clinical samples from COVID-19 patients to the BUA *Brotman Baty Advanced Technology Lab: General Research*.
- Dr. Sokurenko added use of clinical samples from COVID-19 patients to the BUA *Molecular Adaptation of Uropathogenic E. coli; Pathoadaptive Evolution of*

Salmonella; Properties of Bacterial Adhesins; Pathogenic Adaptation of Microbial Adhesins, New Statistical Methods for Neutral Phylogenetic Reconstruction; Detection and genotyping of viruses (belonging to coronaviridae, reoviridae, picornaviridae and togaviridae families) in clinical and environmental samples. Functional and structural analysis of coronaviridae proteins.

- Dr. DeForest renewed the BUA *Protein Engineering in E. coli*. Work includes in vitro use of non-pathogenic strains of E. coli.
- Dr. Sweet renewed the BUA *Tissue Characterization*. Work includes use of human blood, tissue, body fluids, and cell lines.
- Dr. Kreuzer renewed the BUA *Propagation of mammalian cells in tissue culture and preparation of frozen stocks*. Work includes use of human and non-human primate blood, tissue, body fluids, and cell lines.
- Dr. Wang renewed the BUA *Optical imaging of microstructures and microcirculations in tissue*. Work includes use of human blood, tissue, body fluids, and cell lines.
- Dr. Scott renewed the BUA *Molecular Development Laboratory for the Identification of Genetic Mutations of Inborn Errors of Metabolism*. Work includes use of human blood, tissue, body fluids, and cell lines.
- Dr. Wang was approved for a new BUA, *Ultrasound treatment of Abscesses*. Work includes in vitro use of Bacteroides fragilis, Enterobacter cloacae, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and human blood, tissue, body fluids, and cell lines.
- Dr. Armbrust was approved for a new BUA, *Thalassiosira flavodoxin*. Work includes in vitro use of Thalassiosira oceanica and non-pathogenic strains of Escherichia coli.
- Dr. Doty added use of wild type plant pathogens for in vitro studies to the BUA *Microbiology Research Projects*.
- The IBC Chair sought a motion to approve this month's Biosafety Officer Report.
- A member made a motion to approve this month's Biosafety Officer Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's Biosafety Officer Report.

6. 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.

7. INDIVIDUAL PROJECT REVIEWS

- a. Campos, Carlos, change, *Viscerosensory contributions to behavior*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this project change is to add the use of replication deficient HSV-1 H129 in mice. The protocol is identical to the pseudotyped rabies virus procedure they are already approve for.
 - A lab inspection is not required for this change.
 - 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. Campos.
 - The Committee voted unanimously to approve the draft BUA for Dr. Campos.
- b. Chamberlain, Jeffrey, renewal, *Gene Therapy for Neuromuscular Disorders in Canines*

- The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to find a treatment or cure for muscular dystrophy utilizing gene therapy.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in vitro and in dogs.
 - The lab was inspected and no deficiencies were identified.
 - 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. Chamberlain.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain.
- c. Duthie, Malcolm, new, *Novel immunization strategies to protect against infectious diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a new project that seeks to develop improved vaccines and immune therapies through the development of improved deliver platforms such as non-replicating RNA replicons and formulations.
 - Work includes use of Influenza virus-like particles (not containing genetic material) and recombinant or synthetic DNA/RNA (non-viral) in mice.
 - A lab inspection is not required for this project. All work takes place within a core facility approved on a separate BUA.
 - 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. Duthie pending additions to the BUA application.
 - The Committee voted unanimously to approve the draft BUA for Dr. Duthie pending additions to the BUA application.
- d. Hu, Shiu-lok, renewal, *HIVRAD: Core B: Virology/Immunology*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal to continue work on recombinant HIV and SHIV to make better HIV models in macaques.
 - Work includes use of primate lentivirus and plasmid DNA containing full length supercoiled primate lentivirus genome in macaques.
 - This approval did not require a new lab inspection. The lab was recently inspected and found no deficiencies.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hu.
- e. Palmiter, Richard, renewal, *Genetics of Mouse Behavior*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project uses mouse genetics and viral transduction to understand neural circuits controlling behavior.
 - Work includes use of adeno-associated viral vectors (adenovirus free) and canine adenoviral vector (E1a deleted), replication deficient in vitro and in mice.

- The lab inspection checklist was completed by the PI and no deficiencies were identified. An in-person lab inspection is postponed due to COVID-19.
 - 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. Palmiter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Palmiter.
- f. Pepper, Marion, change, *The Differentiation and Function of Memory T and B cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This change is to add the use of *Anopheles* spp. mosquitoes in studies of immune responses to *Plasmodium* spp. They will use these vector mosquitoes to complete the life cycle of murine and human malaria parasites and to deliver murine parasites to experimental mice by mosquito bite.
 - Work includes use of *Plasmodium berghei*, *chabaudii*, *falciparum*, and *yoelli* in *Anopheles* mosquitos.
 - A self-inspection of the lab has been completed, and photos and videos of the facility have been submitted, allowing work at BSL-1 to begin. An in-person lab inspection is required for the approval of BSL-2 work.
 - 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 in-person lab inspection for BSL-2 work to begin.
 - The Committee voted unanimously to approve the draft BUA for Dr. Pepper pending a successful in-person lab inspection for BSL-2 work to begin.
- g. Perlmutter, Steve, renewal, *Neural Plasticity for Learning and Rehabilitation*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project is studying neural mechanisms underlying motor learning and the recovery of motor function after injury to the central nervous system, as well as developing therapies to improve recovery through exogenous activation of neural pathways.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in rats.
 - An in-person lab inspection is postponed due to COVID-19.
 - 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. Perlmutter.
 - The Committee voted unanimously to approve the draft BUA for Dr. Perlmutter.
- h. Rabinovitch, Peter, renewal, *Biology of Aging*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This project studies the effects of aging by using adenoviral vector (E1a deleted), >2/3 adenovirus genome and human blood, tissue, body fluids, and cell lines in vitro.
 - An in-person lab inspection is postponed due to COVID-19.
 - 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. Rabinovitch.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rabinovitch.
- i. Rathod, Pradipsinh, renewal, *Genomic Tools to Characterize Hypermutating Plasmodium falciparum*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research aim of the lab is to understand the mechanisms of malarial drug resistance and to test new antimalarial compounds developed in the laboratory.
 - Work includes in vitro use of Plasmodium falciparum.
 - An in-person lab inspection is postponed due to COVID-19.
 - Required trainings have yet to be completed.
 - Occupational health will address personnel working with open wounds in the lab.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Rathod pending training completion and occupational health concerns.
 - The Committee voted unanimously to approve the draft BUA for Dr. Rathod pending training and occupational health concerns.
- j. Scott, John, renewal, *AKAP structure and Function*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies A kinase anchoring proteins (AKAPs) for their functional roles in a variety of human diseases such as heart disease, diabetes, etc.
 - Work includes in vitro use of various viral vectors at BSL-2 and -1 as well as non-human primate cells and human blood, tissue, body fluids, and cell lines.
 - The lab inspection checklist was completed by the PI and no deficiencies were identified. An in-person lab inspection is postponed due to COVID-19.
 - 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. Scott.
 - The Committee voted unanimously to approve the draft BUA for Dr. Scott.
- k. Stewart, Tessandra, new, *The Stewart Laboratory Animal Use and Other Research*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to elucidate the cellular and molecular mechanisms underlying neurodegeneration such as in Parkinson's and Alzheimer's disease.
 - Work includes use of lentiviral vectors, non-HIV pseudotyped, replication deficient, adeno-associated viral vectors (adenovirus free), non-pathogenic strains of Escherichia coli, and human and non-human primate blood, tissue, body fluids, and cell lines.
 - An in-person lab inspection is postponed due to COVID-19.
 - 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. Stewart.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stewart.
- l. Wood, Gwen, change, *Multiple projects involving sexually transmitted bacterial pathogens*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is an amendment to research involving the study of reproductive tract bacterial
- Pathogens, adding a macaque model to the study of Mycoplasma genitalium.
- The lab was recently inspected and did not require an inspection for this change.
- 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. Wood.
- The Committee voted unanimously to approve the draft BUA for Dr. Wood.

8. SUBCOMMITTEE REPORTS:

- m. Kreuzer, Helen, new, *Evaluation of multi-omics data in SARS-CoV-2-infected cells*
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The overall goals of the project are to understand the host response to the highly pathogenic human coronavirus strain severe acute respiratory distress syndrome coronavirus 2 (SARS-CoV 2). The host signatures (RNA, protein, metabolites, or lipids) will be used to determine host pathways that are critical for CoV infection and to identify novel targets for therapeutic interventions.
 - Work includes use of human and non-human primate cells.
 - The greatest biosafety issue is the culture of SARS-CoV-2.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Kreuzer. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kreuzer.
- n. Lee, Sylvia, new, *A PHASE 1A/1B, OPEN-LABEL FIRST-IN-HUMAN STUDY OF THE SAFETY, TOLERABILITY AND FEASIBILITY OF GENE-EDITED AUTOLOGOUS NeoTCR T CELLS (NeoTCR-P1) ADMINISTERED AS A SINGLE AGENT OR IN COMBINATION WITH ANTI-PD-1 TO PATIENTS WITH LOCALLY ADVANCED OR METASTATIC SOLID TUMORS*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - Therapy of T cells targeting tumors is central to many modern immunotherapy concepts. Unlike FDA approved CAR-T, this trial uses a TCR as the targeting molecule and uses gene editing with CRISPR-Cas9 to both silence endogenous TCR expression and introduce the TCR of interest.
 - Cells will be reinfused in patients at the University of Washington Medical Center.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Lee. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Lee.
- o. Schweizer, Michaela, new, *ATTAMAGE-A1.: Phase I/II study of Autologous CD8+ and CD4+ Transgenic T cells expressing high affinity MAG-E-A1-specific T-Cell Receptor (TCR) combined with Atezolizumab in patients with metastatic MAG-E-A1 expressing cancer*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.

- This is an autologous transgenic TCR adoptive T cell therapy protocol in which patients with advanced solid tumors are treated with their own T cells that are lentivirally transduced to express a putative tumor-specific TCR. It is hoped that these T cells will recognize cancer cells and either kill them or secrete anti-tumor cytokines to coordinate an anti tumor response.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Schweizer. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Schweizer.
- p. Gale Inactivation Validation**
- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The IBC reviewed and approved several validation procedures by Dr. Gale at the April IBC for removing SARS-CoV-2 samples out of the BSL-3 facility to be worked on at BSL-2. The Gale lab initially provided a verification step that included batch testing of samples from future experiments to confirm inactivation prior to removing from BSL-3. The Gale lab is requesting to waive the verification process for confirmation of inactivation.
 - The subcommittee is aware of the limited knowledge about the SARS-CoV-2 characteristics and lack of available data for inactivation procedures. Although the Gale lab provided a validation protocol, the subcommittee finds the power of replicates to be low for a newly emerged virus and recommends that verification of inactivation continue until more data is generated. The verification data can then be reevaluated by the IBC in 2021 or when sufficient data is generated.
 - A member made a motion to approve the subcommittee recommendation for Dr. Gale. Another member seconded the motion.
 - The Committee voted unanimously to approve the subcommittee recommendation for Dr. Gale.

10. FOR YOUR INFORMATION:

- **NIH Incident Report:** The incident report of the veterinary specialist bitten by a macaque experimentally infected with SHIV (reported out at the April 15 IBC meeting) was reviewed by the NIH. The NIH OSP stated that the University's response was appropriate, and that no further action was required.
- **EHSA Inspection Update:** EH&S provided an update on the new EHSA online process currently being used by biosafety officers to perform and record lab inspections.

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.