INSTITUTIONAL BIOSAFETY COMMITTEE UNIVERSITY of WASHINGTON

Meeting Minutes

Date:	Wednesday, January 19, 2022
Time:	10:00 AM - 12:00 PM

Location: Zoom

Members Present:

- Members 1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 - 2. Thea Brabb, Comparative Medicine (Animal Containment Expert)
 - 3. Jason Cantera (Community Member)
 - 4. Lesley Colby, Comparative Medicine (Animal Containment Expert)
 - 5. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 - 6. Richard Grant, Washington National Primate Research Center
 - 7. David Koelle, Allergy and Infectious Diseases
 - 8. Stephen Libby, Laboratory Medicine (IBC Chair)
 - 9. Scott Meschke, Environmental & Occupational Health Sciences
 - 10. Susan Parazzoli (Community Member)
 - 11. Jason Smith, Microbiology (IBC Vice Chair)
 - 12. Paul Swenson, Seattle-King Co. Dept. of Public Health (Community Member)

Commonly Used Abbreviations IBC: Institutional Biosafety Committee BSO: Biological Safety Officer BUA: Biological Use Authorization BSL: biosafety level PI: Principal Investigator IACUC: Institutional Animal Care and Use Committee NIH: National Institutes of Health DURC: Dual Use Research of Concern SOP: standard operating procedure

- **1. CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:01 a.m. A quorum was present.
- 2. **REMINDER:** The IBC Chair reminded attendees that any notes that they retain are subject to public disclosure. A statement was also made about conflict of interest and voting on research proposals as described in the IBC Charter. This includes sharing a grant or a familial relationship.
- **3. OCCUPATIONAL HEALTH PRESENTATION:** This presentation is deferred to a future meeting in the interest of allotting more time to today's project reviews.

4. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the December 15, 2021, meeting.
- A member made a motion to approve the December 15, 2021, minutes. Another member seconded the motion.
- The committee voted unanimously to approve the December 15, 2021, meeting minutes.

5. OLD BUSINESS:

- At the November 17, 2021 meeting, Dr. Bosma's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the November 17, 2021 meeting, Dr. Pun's BUA was approved pending completion of a successful lab inspection and review of the IACUC protocol. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Basso's BUA A miniature microscope for monitoring neuronal activity (NHPs) was approved pending submission of a toxin SOP and review, training completion, and IACUC review. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Basso's BUA *Brain circuits of perceptual decision-making in mice* was approved pending submission of a toxin SOP and review, training completion, and IACUC review. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Basso's BUA *Decision-making under uncertainty* (*NHPs*) was approved pending submission of a toxin SOP and review, training completion, and IACUC review. This BUA is still pending.
- At the December 15, 2021 meeting, Dr. Disis's BUA *Evaluation of Immunity to Cancer in a Rodent Model* was approved pending additional information requested and room use clarification. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Disis's BUA *Vaccination in a modified microbiome* was approved pending additional information requested and room use clarification. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Seshadri's BUA was approved pending Occupational Health review. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Simpson's BUA was approved pending review of the biotoxin SOP. This BUA has been sent out.
- At the December 15, 2021 meeting, it was decided that Dr. Van Voorhis's BUA come back to the January 2022 IBC meeting once additional information and action from the lab is complete.
- At the December 15, 2021 meeting, Dr. Bender Ignacio's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the December 15, 2021 meeting, Dr. Freedman's BUA was approved pending submission of the BSL-3 BBPECP. This BUA has been sent out.

- 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. Jayadev added new locations to the BUA *Inflammatory Mediators of Neurodegeneration.*
 - Dr. Cangelosi renewed the BUA *Novel Detection of Bacterial, Viral, and Parasitic Pathogens in Clinical and Environmental Samples.* Work includes various Risk Group 1 and 2 agents in vitro.
 - Dr. Yazdan-Shahmorad added a new room to the BUA Understanding the underlying mechanisms of neural simulation.
 - Dr. Samy added a new room to the BUA *Environmental Health Laboratory*.
 - Dr. Regnier added use of human iPS cells in rats and in vitro at ABSL-1 to the BUA *Rodent Striated Muscle*. The cells were tested and shown to be free of bloodborne pathogens and LCMV.
 - The IBC Chair made 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</u> <u>Report.</u>

7. BSL-3 INACTIVATION REPORT

- Dr. Kreuzer requested MPLEx (chloroform methanol) inactivation of SARS-CoV-1.
- The subcommittee reviewed procedure and inactivation data provided by the lab and approved the request.
- The IBC Chair a motion to approve this month's BSL-3 Inactivation Report.
- A member made a motion to approve this month's BSL-3 Inactivation Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's BSL-3 Inactivation Report.

8. INDIVIDUAL PROJECT REVIEWS

- **a.** Adair, Jennifer, new, *In vivo CRISPR engineering ofB cells to produce anti-HIV broadly neutralizing antibodies using novel nanoparticle*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goals of this project are to induce the production of broadly neutralizing antibodies (bNAb) in nonhuman primates and to test if those antibodies can suppress SHIV infection.
 - Work includes use of primate lentivirus at BSL/ABSL-2 w/3 practices and the use of nanoparticles to deliver recDNA.
 - The Committee requests additional information regarding nanoparticle use and whether or not the animals may excrete SHIV.
 - A lab inspection is not required since only vivarium space in WaNPRC is being used.
 - 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. Adair pending additional information regarding nanoparticle use.
- <u>The Committee voted unanimously to approve the draft BUA for Dr. Adair pending</u> <u>the items stated above.</u>
- b. Gale, Michael, renewal, The Host Response to Virus Infection
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how viral and host factors impact innate immune defenses to determine the outcome of virus infection.
 - Work includes virus use in mice at BSL/ABSL-2 w/3 practices.
 - The Committee requests clarification of recombinant SIV and avian influenza virus types being used.
 - A lab inspection is scheduled for later today and requires successful completion for BUA approval.
 - 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. Gale pending clarification of recombinant SIV, gammaretroviral vector work, and avian influenza virus types being used and completion of a successful lab inspection.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Gale pending</u> the items stated above.
- c. Grant, Richard, change, Primate Diagnostic Laboratories
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds non-human primate samples collected from animals that may have been previously exposed to infectious agents or recombinant DNA. All animals are already covered under investigator BUAs. The samples are collected as part of the primate center's animal behavioral management program.
 - The lab was inspected recently so 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. Grant.
 - <u>The Committee voted to approve the draft BUA for Dr. Grant. There was one voting</u> <u>abstention.</u>
- **d.** Orsborn, Amy, renewal, Adaptive neural interfaces for treating neurological disorders and probing neural function
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab develops neural interfaces to study and restore sensorimotor function using a non-human primate animal model.
 - Work includes use of adeno-associated viral vectors (adenovirus free) and lentiviral vectors, non-HIV pseudotyped, replication deficient in macaques.
 - A successful lab inspection has been completed with no deficiencies 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. Orsborn.
 - The Committee voted unanimously to approve the draft BUA for Dr. Orsborn.

- e. Stella, Nephi, new, Neuroinflammation in Mouse Model
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The overall research goal is to study the function of the enzyme ABHD6 in human and mouse cell model systems in order to discover its role in neuronal endocannabinoid signaling and to characterize novel ABHD6 inhibitors (ABHD6 is overexpressed in certain tumors).
 - Work includes in vitro use of adeno-associated viral vectors (adenovirus free).
 - A successful lab inspection has been completed with no deficiencies 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. Stella.
 - The Committee voted unanimously to approve the draft BUA for Dr. Stella.
- **f.** Van Voorhis, Wes, change, 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 change adds the use of a single-round infection SARS-CoV-2 transcomplementation system, which includes non-human primate cells and SARS-CoV-2 nucleic acid.
 - The SARS-CoV-2 trans-complementation system has been approved by the NIH for use at BSL-2.
 - The lab was recently inspected, and no additional inspection is 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. Van Voorhis.
 - The Committee voted unanimously to approve the draft BUA for Dr. Van Voorhis.
- g. Veesler, David, change, Visualization of recombinant Cedar virus using Cryo-ET
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds recombinant Cedar virus for electron microscopy.
 - A discussion occurred about whether NIH approval is needed for this recombinant virus that may contain sequences from Risk Group 4 agents.
 - The lab was recently inspected, and no additional inspection is required for this change.
 - The PI has required trainings to complete before approval can be given.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Veesler pending training completion.
 - <u>The Committee voted unanimously to approve the draft BUA for Dr. Veesler</u> pending training completion and clarification of NIH requirements.
- **h.** Woodward, Joshua, renewal, *Staphylococcus aureus and Pseudomonas aeruginosa pathogenesis and host response*
 - The assigned IBC Primary Reviewer presented the Primary Review.

- This group studies the molecular mechanisms that allow Staphylococcus aureus and Pseudomonas aeruginosa to infect and cause tissue damage to eukaryotic hosts, utilizing standard molecular biology techniques, infections in vitro (variety of cell lines including human) and infections in mice.
- The lab was recently inspected for another project so an inspection was not 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. Woodward.
- The Committee voted unanimously to approve the draft BUA for Dr. Woodward.

9. SUBCOMMITTEE REPORTS:

- i. Disis, Mary, new, A Phase II Trial of the Immunogenicity of a DNA Plasmid Based Vaccine (STEMVAC)Encoding Th1 Selective Epitopes from Five Antigens Associated with Breast Cancer Stem Cells (MDM2, YB1, SOX2, CDH3, CD105) in Patients with Triple Negative Breast Cancer
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This is a multi-center, single arm, non-randomized phase II clinical trial of a DNA vaccine encoding Th1 epitopes from five antigens found in breast cancer stem cells.
 - The phase II study is designed to determine immunogenicity in triple negative breast cancer patients who are in complete remission after completing chemotherapy.
 - Percutaneous exposure of the plasmid to staff is the greatest biosafety issue.
 - All of the required trainings have been completed.
 - 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.
- **j.** Hyde, Jennifer, renewal, *Contribution of virus-host interactions to viral pathogenesis (BSL3, non-select)*
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This lab is interested in virus-host interactions focusing on alphaviruses and sarbecoviruses (SARS-CoV-2). The overall aim is to find points of intersection between host interferon stimulated genes (ISG) and virally encoded proteins.
 - The PI was present at this meeting to discuss their research and address questions and concerns of the Committee.
 - The Committee requests clarification on VEEV and SARS mutations from the NIH before granting approval for this BUA.
 - A lab inspection is not required for this project as all work is completed in the BSL-3 facility that is already inspected.
 - All of the required trainings have been completed.
 - Occupational Health review is still required.
 - The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Hyde pending clarification on VEEV and SARS mutations from the NIH and Occupational Health review. Another member seconded the motion.
- <u>The Committee voted to approve the draft BUA for Dr. Hyde pending the items stated</u> <u>above. There was one voting abstention.</u>
- **k.** Riolobos, Laura, new, A Phase II Randomized Study of Safety and Efficacy of a Multiple Antigen Vaccine (STEMVAC)in Non-Squamous Non-Small-Cell Lung Cancer Patients
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This research is to treat lung cancer patients with a multiantigen vaccine encoding nonmutated human proteins associated with EMT. EMT (Epithelial Mesenchymal Transition) is a biological process by which anchorage dependent cancer cells acquire the ability to migrate, metastasize, and develop a chemo-resistant stem cell-like phenotype.
 - Percutaneous exposure of the plasmid to staff is the greatest biosafety issue.
 - All of the required trainings have been completed.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Riolobos. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Riolobos.

10. FOR YOUR INFORMATION:

- NIH Incident Report: Recombinant Agrobacterium tumefaciens (disarmed strain GV3101) in a BSL-1 laboratory squirted into a research assistant's eye while inoculating plants. Recommendations have been made by EH&S including installation of an eye wash station and immediate reporting of future incidents. The NIH has reviewed the information provided, and no further action is required.
- **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.**