

Meeting Minutes

Date: Wednesday, December 15, 2021

Time: 10:00 AM – 12:00 PM

Location: Zoom

Members

1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases

Present:

- 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. Kevin Hybiske, 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

<u>BSO</u>: Biological Safety Officer <u>BUA</u>: Biological Use Authorization

<u>BSL</u>: biosafety level <u>PI</u>: 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 November 17, 2021 meeting.
- A member made a motion to approve the November 17, 2021 minutes. Another member seconded the motion.
- The committee voted unanimously to approve the November 17, 2021 meeting minutes.

4. OLD BUSINESS:

- At the October 20, 2021 meeting, Dr. Gerner's BUA was approved pending additional information requested of the PI. This BUA has been sent out.
- At the November 17, 2021 meeting, Dr. Bosma's BUA was approved pending completion of a successful lab inspection. This BUA is still pending.
- 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 is still pending.
- At the November 17, 2021 meeting, Dr. Regnier's BUA was approved pending completion of a successful lab inspection, review of the IACUC protocol, and clarification of iPS cells. This BUA has been sent out.
- At the November 17, 2021 meeting, Dr. Starita's BUA was approved pending completion of a successful lab inspection and SOPs for BSL-2 with BSL-3 practices work. This BUA has been sent out
- At the November 17, 2021 meeting, Dr. Wang's BUA was approved pending additional information requested on the BUA application. 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. Baird renewed the BUA *Tissue Diagnostic Development*, working with non-viral recombinant or synthetic DNA/RNA.
 - Dr. Khaledi was approved for work with human blood, tissue, body fluids, and cell lines on the BUA Analysis of Human and Mammalian Tissue and Blood Samples for Lysosomal Storage Diseases.
 - Dr. Hsu renewed the BUA *Transgenic Resources Program*, creating transgenic mice.
 - Dr. Wei was approved for work with human blood, tissue, body fluids, and cell lines on the BUA *Transcription factor genes knock-out in human colon cancer cell line and human melanoma cell line by using CRISPR/CAS9 systems.*
 - Dr. Fuller added the use of SARS-CoV-2 nucleic acid to the BUA *DNA Vaccine Therapy*.
 - Dr. Gale added use the use of SARS-CoV-2 nucleic acid to the BUA *Host Response to BSL-3 Pathogens*.

- Dr. Seshadri added use of paraformaldehyde-fixed Mtb tissues from non-human primates on the BUA *Human Immunity to Mycobacterial Diseases*.
- Dr. Scatena added use of a core facility to the BUA *Endothelial cells for tissue* engineering and osteoprotegerin in atherosclerosis.
- Dr. Theberge added the use of non-recombinant Klebsiella aerogenes on the BUA Studying cell signaling and cell-microenvironment interactions with new analytical tools.
- Dr. Meschke added several non-recombinant Risk Group 2 agents, SARS-CoV-2 nucleic acid, and fixed/inactivated SARS-CoV-2 samples or tissue and renewed all other work on the BUA Detection and Characterization of Pathogens in Environmental Media.
- Dr. DeForest added a new room and use of a core facility to the BUA *Protein Engineering in E. coli*.
- Dr. Mitchell added non-recombinant adenoviruses and new human and non-human primate cell lines and tissues to the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions.*
- Dr. Fang added use of a new room and core facility to the BUA Salmonella Pathogenesis and Immunity.
- Dr. Wang renewed the BUA Enhanced chemotherapeutic drug delivery by High Intensity Focused Ultrasound, working with human blood, tissue, body fluids, and cell lines.
- Dr. Nemhauser renewed the BUA *Manipulation and Dissection of Growth Control Networks*, working with transgenic plants.
- Dr. Reed renewed the BUA Extracellular Matrix in Aging, working with human blood, tissue, body fluids, and cell lines.
- 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 voted to approve this month's Biosafety Officer Report. There was one voting abstention.

6. INDIVIDUAL PROJECT REVIEWS

- **a.** Basso, Michele, new, A miniature microscope for monitoring neuronal activity (NHPs)
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The objective of this research is to develop a wireless, miniature microscope to monitor the activity of multiple brain cells in alert and active macaques.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in macaques.
 - This BUA uses core facilities only, and does not require a separate lab inspection.
 - A toxin SOP and review are required.
 - Staff are still required to complete training.
 - The IACUC protocol requires review once submitted.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Basso pending submission of a toxin SOP and review, training completion, and IACUC review
 - The Committee voted unanimously to approve the draft BUA for Dr. Basso pending the items stated above.

- **b.** Basso, Michele, new, Brain circuits of perceptual decision-making in mice
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The objective of this research is to unravel neuronal circuits leading to decision making in the mouse brain by measuring neural activity in real time as mice accomplish cognitive tasks and directing some of the neuronal activity using chemicals and AAV with gene inserts injected into specific locations.
 - The lab still requires an inspection to be completed.
 - A toxin SOP and review are required.
 - Staff are still required to complete training.
 - The IACUC protocol requires review once submitted.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Basso pending submission of a toxin SOP and review, training completion, and IACUC review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Basso pending the items stated above.
- **c.** Basso, Michele, new, *Decision-making under uncertainty (NHPs)*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The objective of this research is to understand how the brain controls behavior.
 - Work includes use of adeno-associated viral vectors (adenovirus free) in macaques.
 - The lab still requires an inspection to be completed.
 - A toxin SOP and review are required.
 - Staff are still required to complete training.
 - The IACUC protocol requires review once submitted.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Basso pending submission of a toxin SOP and review, training completion, and IACUC
 - The Committee voted unanimously to approve the draft BUA for Dr. Basso pending the items stated above.
- **d.** Disis, Mary, renewal, Evaluation of Immunity to Cancer in a Rodent Model
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to develop diagnostic, preventative, and treatment strategies to combat cancer and modulate the immune system as it relates to cancer or inflammatory disease.
 - Work includes use of adenoviral vectors and lentiviral vectors in mice.
 - The Committee requests additional information regarding specific bacteria identities and requires investigation of room discrepancies between the BUA and IACUC protocol.
 - 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. Disis pending the additional information requested and room use clarification.

- The Committee voted unanimously to approve the draft BUA for Dr. Disis pending the items stated above.
- e. Disis, Mary, renewal, Vaccination in a modified microbiome
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of this research is to develop diagnostic, preventative, and treatment strategies to combat cancer.
 - Work includes non-viral recombinant or synthetic DNA/RNA in mice.
 - The Committee requests additional information regarding specific bacteria identities and requires investigation of room discrepancies between the BUA and IACUC protocol.
 - 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. Disis pending the additional information requested and room use clarification.
 - The Committee voted unanimously to approve the draft BUA for Dr. Disis pending the items stated above.
- f. Queitsch, Christine, renewal, Tandem Repeats as a source of phenotypic variation
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab studies the role of repetitive DNA elements for their potential in causing human diseases, and uses established model organisms to conduct these studies.
 - Work includes use, breeding, and/or creation of transgenic Caenorhabditis elegans.
 - 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. Queitsch.
 - The Committee voted unanimously to approve the draft BUA for Dr. Queitsch.
- g. Seshadri, Chetan, change, Immune Profiling in Infectious Diseases
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds the use of attenuated Mycobacterium tuberculosis H37Rv strains.
 - An official ruling was received from the NIH to allow lowering containment of these tuberculosis strains from BSL-3 to BSL-2.
 - The lab was recently inspected and does not require an additional inspection for this change.
 - All of the required trainings have been completed.
 - Occupational Health review is still required to confirm that there are no requirements for this work.
 - The draft BUA letter was shown.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Seshadri pending Occupational Health review.
 - The Committee voted unanimously to approve the draft BUA for Dr. Seshadri pending Occupational Health review.
- **h.** Simpson, Cory, new, *Skin cell differentiation, regeneration, and disease models*
 - The assigned IBC Primary Reviewer presented the Primary Review.

- This lab studies skin and skin diseases.
- Work includes in vitro use of gammaretroviral vectors, replication deficient, amphotropic and lentiviral vectors, HIV pseudotyped, replication deficient.
- The lab still requires an inspection to be completed.
- A biotoxin SOP is required for work with cholera.
- 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. Simpson pending review of the biotoxin SOP.
- The Committee voted unanimously to approve the draft BUA for Dr. Simpson pending review of the biotoxin SOP.
- i. Ting, Jonathan, new, Gene Therapy Vectors in NHP
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This study aims to advance novel therapeutics toward clinical applications to treat a host of debilitating brain disorders.
 - Work includes use of adeno-associated viral vectors (adenovirus free) 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. Ting.
 - The Committee voted unanimously to approve the draft BUA for Dr. Ting.
- j. 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.
 - The lab is seeking approval to use a replication-defective, single-round SARS-CoV-2 vector at BSL-2 in cell culture.
 - After discussion, the Committee had a number of questions and concerns that require additional information and action from the lab.
 - The Committee agreed to bring this application for Dr. Van Voorhis back for review at the January 2022 meeting.
- k. Xu, Haodong, change, Regulation of Cardiac Na+ Channel
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This change adds the use of human induced pluripotent stem (iPS) cells that were created with plasmids in vitro and in mice.
 - The lab was recently inspected and does not require an additional 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. Xu.
 - The Committee voted unanimously to approve the draft BUA for Dr. Xu.

7. SUBCOMMITTEE REPORTS:

- I. Bender Ignacio, Rachel, new, Phase II, Double-Blind, Randomized, Placebo-Controlled Trial to Evaluate the Safety and Immunogenicity of a Modified Vaccinia Ankara (MVA)-based anti-Cytomegalovirus (CMV) Vaccine (Triplex®), in Adults with Both Human Immunodeficiency Virus (HIV)-1 and CMV Who Are on Potent Combination ART with Conserved Immune Function
 - Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - The overall goal of the research is to see if improving CMV immune control in people living with HIV leads to improvements in inflammation and residual immune deficits.
 - A lab inspection is required and scheduled to take place today.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Bender Ignacio pending completion of a successful lab inspection. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Bender Ignacio pending completion of a successful lab inspection.
- **m.** Freedman, Benjamin, change, *Differentiation of Human Pluripotent Stem Cells into Kidney Cells*
 - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This change adds the use of adeno-associated viral vectors (adenovirus free) in mice as well as human induced pluripotent stem (iPS) cells in vitro.
 - All work takes place in the UW BSL-3 facility.
 - All of the required trainings have been completed.
 - BSL-3 BBPECP is required.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Freedman pending submission of the BSL-3 BBPECP. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Freedman pending submission of the BSL-3 BBPECP.

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 11:51 A.M.