



# INSTITUTIONAL BIOSAFETY COMMITTEE

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## UNIVERSITY *of* WASHINGTON

### Meeting Minutes

**Date:** Wednesday, June 16, 2021

**Time:** 10:00 AM – 12:00 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. 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. 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 10:03 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 May 19, 2021 meeting.
  - A member made a motion to approve the May 19, 2021 minutes. Another member seconded the motion.
  - The committee voted to approve the May 19, 2021 meeting minutes. There was one voting abstention.
4. **OLD BUSINESS:**
  - At the April 21, 2021 meeting, Dr. Ladiges' BUA was approved pending review of the IACUC protocol. This BUA has been sent.
  - At the April 21, 2021 meeting, Dr. Wong's BUA was approved pending completion of a successful lab inspection. This BUA is still pending.
  - At the May 19, 2021 meeting, Dr. Wang's BUA was approved pending development and review of the ABSL-2 SOP. This BUA has been sent.
  - At the May 19, 2021 meeting, Dr. Carter's BUA was approved pending the addition of personnel to the BUA application. This BUA has been sent.
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. Dunham's BUA *Genome Evolution in Yeast* was renewed. Work includes use of various BSL-1 agents in vitro.
    - Dr. Soge's BUA *Surveillance of antimicrobial resistance in Neisseria gonorrhoeae and diagnostic test development for sexually transmitted infections* was renewed. Work includes use of *Neisseria* species and non-viral recombinant or synthetic DNA/RNA.
    - Dr. Palmiter added a new room for work with previously approved agents on the BUA *Genetics of Mouse Behavior*.
    - Dr. Reniere added use of non-human primate tissue to the BUA *Redox regulation and virulence in bacterial pathogens*.
    - Dr. Hawkins added new rooms to the BUA *Research, Development, and Manufacturing of Pluripotent Stem Cells and Differentiated Cells for the Treatment of Human Disease*.
    - Dr. Dale renewed the BUA *Severe Chronic Neutropenia International Registry*. Work includes use of human induced pluripotent stem (iPS) cells and non-viral recombinant or synthetic DNA/RNA.
    - Dr. Unadkat added a room to the BUA *Mechanisms of drug disposition*.
    - Dr. Bamshad renewed the BUA *Center for Clinical Genomics*. Work includes non-viral recombinant or synthetic DNA/RNA.

- Dr. Fink added SARS-CoV-2 nucleic acid to the BUA *Host-Pathogen Interactions During Viral Infection*.
- Dr. Altemeier added use of Influenza A virus A/CA/04/09, non-human primate cells, and new gene inserts for lentiviral vectors to the BUA *Inflammatory Response Modulation by Mechanical Ventilation*.
- Dr. Murry added work with nucleic acid from SARS-CoV-2 to the BUA *Myocardial Infarct Repair in Rats*.
- Dr. Winkler updated the agent for SARS-CoV-2 nucleic acids to the BUA *Winkler Lab - S. aureus and waste water SARS-CoV-2 testing*.
- Dr. McGuire renewed the BUA *Proof of Concept for an EBV Vaccine*. Work includes use of Rhesus lymphocryptovirus in macaques.
- Dr. Baker added use of a core facility to the BUA *Institute for Protein Design and Affiliate Investigators*.
- Dr. Scott added use of human cells in mice to the BUA *AKAP structure and Function*.
- Dr. Kim added a location for work with transgenic zebrafish on the BUA *ISCRM Aquatics Facility*.
- Dr. Cookson added a location for the BUA *Initiation and Regulation of Inflammation and Development of Protective Immunity*.
- Dr. Pun added a location for the BUA *Biomaterials for Biomedical Applications*.
- 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. 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. BSL-3 INACTIVATION REPORT

- Dr. Murry requested removal of SARS-CoV-2 samples treated with Thiourea or RIPA buffer.
- 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. Baker, David, renewal, *Institute for Protein Design and Affiliate Investigators*
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab in Biochemistry studies protein design.
  - Work includes in vitro use of lentiviral vectors, non-HIV pseudotyped, replication deficient.
  - A lab inspection is still required and scheduled for after this IBC meeting.
  - 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. Baker pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Baker pending completion of a successful lab inspection.
- b. Beliveau, Brian, renewal, *Probing the dynamics of chromosome organization in single cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this project is to understand how the 3D conformation of chromosomes affects nuclear processes such as transcription, replication, and repair utilizing advanced microscopy and molecular techniques.
  - Work includes in vitro use of lentiviral vectors, non-HIV pseudotyped, replication deficient.
  - A lab inspection has been performed but is pending follow-up by the lab.
  - 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. Beliveau.
  - The Committee voted unanimously to approve the draft BUA for Dr. Beliveau pending correction of lab inspection findings.
- c. Bumgarner, Roger, renewal, *Bumgarner Lab Genomic Research Projects*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall goal of the research is to characterize sequence variation that may be associated with phenotypic differences in bacteria.
  - Work includes in vitro use of *Cutibacterium acnes* and *avidum*.
  - A successful lab inspection has been completed. A few minor findings were identified and corrected by the lab.
  - 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. Bumgarner.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bumgarner.
- d. Crisa, Laura, renewal, *Immunobiology of bone marrow-derived endothelia and inflammatory cells in tissue repair*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall research goals are to investigate the cellular and molecular mechanisms by which vascular endothelial cells of different origin influence immune responses as well as pancreatic tissue progenitors regenerative events.
  - Work includes in vitro and mouse work with murine, human, and mouse cells transduced with various viral vectors including replication deficient amphotropic gammaretroviral vectors with oncogenic inserts at BSL-2 w/3 practices.
  - 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. Crisa.
  - The Committee voted unanimously to approve the draft BUA for Dr. Crisa.

- e. Fuller, Deborah, renewal, *Evaluation of SIV Co-Infection on ZIKV Pathogenesis in Pigtail Macaques*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab works on an HIV-ZIKV co-infection model in non-human primates to determine whether HIV infection enhances ZIKV pathogenesis.
  - Work includes use of primate lentivirus and zika virus 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. Fuller.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fuller.
- f. Kelly, Edward, renewal, *In Vivo Function of CYP4BI; Generation of Induced Pluripotent Stem Cells*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal of this project renewal is to analyze human organ function in normal and diseased states using primary cells derived from anonymized tissue donors.
  - Work includes in vitro use of lentiviral vectors, 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. Kelly.
  - The Committee voted unanimously to approve the draft BUA for Dr. Kelly.
- g. Lee, Kelly, renewal, *Structural studies of enveloped viruses and plasmodia*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab uses biophysical and structural approaches to study the mechanisms of viral dynamics and biology.
  - Work includes in vitro use of: Influenza A virus strains; Plasmodium falciparum; gammaretroviral vectors, replication deficient, amphotropic; and, lentiviral vectors, non-HIV pseudotyped, replication deficient.
  - A 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. Lee pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lee pending completion of a successful lab inspection.
- h. Murphy, Sean, renewal, *NHP Study*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall research goals are to develop non-human primate models for evaluating malaria infections and to test promising vaccination strategies in non-human primates.
  - Work includes use of non-viral recombinant or synthetic DNA/RNA in macaques.
  - A 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. Murphy pending completion of a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Murphy pending completion of a successful lab inspection.
- i. Paragas, Neal, renewal, *Pathophysiology of Kidney Disease*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies the biology and cell biology of urinary tract infections in mice as a model for human bladder and kidney infection.
  - Work includes use of pathogenic *Escherichia coli* 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. Paragas.
  - The Committee voted unanimously to approve the draft BUA for Dr. Paragas.
- j. Raskind, Wendy, renewal, *Genetic Contributions to Dyslexia Gene Discovery in Neurogenetic Disorders; Spinocerebellar-Ataxia Type 14: Animal Models of Human Disease; Genetics of Autism; Genetics of Human Diseases*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This lab studies inherited human diseases to identify the genes that cause them and the effects of mutations on the function of the genes.
  - A lab inspection is still required.
  - All of the required trainings have been completed.
  - IACUC submission is still pending, and will require review by the biosafety officer.
  - The reviewer wants the PI to submit a revised application to include clarification of oncogene use.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Raskind pending a successful lab inspection, IACUC review, and a revised application to include clarification of oncogene use.
  - The Committee voted unanimously to approve the draft BUA for Dr. Raskind pending the conditions stated above.
- k. von Moltke, Jakob, change, *Initiation of Type 2 Immune Responses*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This change adds use of gammaretroviral vectors, replication deficient, amphotropic in vitro and mice.
  - The lab was recently inspected, satisfying the requirements 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. von Moltke.
  - The Committee voted unanimously to approve the draft BUA for Dr. von Moltke.
- l. Woodward, Josh, new, *Targeted bacterial eradication using designed chimeric molecules*
- The assigned IBC Primary Reviewer presented the Primary Review.

- This lab uses rational design methods to create and test macrocycles and miniproteins to target bacterial pathogens for degradation by the host immune response. They propose to use several bacteria, all of which will be made to express fluorescent proteins (GFP and RFP).
- Bacteria used include *Acinetobacter baumannii*, *Francisella novicida*, *Listeria monocytogenes*, and *Pseudomonas aeruginosa*.
- The lab was recently inspected, satisfying the requirements for this application.
- 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:

- m. Walter, Roland, new, *A Phase 1 Open-label, Multicenter Study Evaluating the Safety of KITE-222, an Autologous Anti-CLL-1 CAR T-cell Therapy, in Subjects With Relapsed/Refractory Acute Myeloid Leukemia*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a new, first in humans trial. Acute myeloid leukemia (AML) remains difficult to cure. This CAR-T trial is conceptually similar to the FDA-approved CD19-directed CAR-T therapies, but targets another cell surface molecule that is overexpressed on the target tumor cells. The cell product will be administered to patients at UWMC.
  - The greatest biohazardous risk to study personnel is percutaneous exposure to CAR-T cell product.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Walter. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Walter.
- n. Wong, Kit, renewal, *A PHASE I OPEN LABEL, CLINICAL TRIAL EVALUATING THE SAFETY AND ANTI-TUMOR ACTIVITY OF AUTOLOGOUS T CELLS EXPRESSING ENHANCED TCRS SPECIFIC FOR ALPHA-FETOPROTEIN (AFPC332T) IN HLA-A2 POSITIVE SUBJECTS WITH ADVANCED HEPATOCELLULAR CARCINOMA (HCC)*
- 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 adoptive T cell therapy attempt to treat hepatocellular carcinoma (HCC). The cell product will be infused in patients at UWMC.
  - The greatest biohazardous risk to study personnel is percutaneous exposure to CAR-T cell product.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Wong. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Wong.

**10. FOR YOUR INFORMATION:**

- **Foege Compactor:** A report regarding biohazardous waste missing from the Foege facility was reviewed by the NIH. The NIH OSP stated that the University's response was appropriate, and that no further action was required.
- **NIH Incident Report:** The incident report of the research assistant who poked their thumb with a pair of precision tweezers used to transfer a coverslip that contained human induced pluripotent cardiomyocytes transfected with recombinant DNA (reported out at the May 19 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.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:35 A.M.**