

# **Meeting Minutes**

Date: Wednesday, September 21, 2022

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. Erin Heiniger, Department of Bioengineering (Laboratory Specialist)
- 7. Richard Grant, Washington National Primate Research Center
- 8. Kevin Hybiske, Allergy and Infectious Diseases (IBC Vice Chair)
- 9. Stephen Libby, Laboratory Medicine (Animal Containment Expert)
- 10. Scott Meschke, Environmental & Occupational Health Sciences
- 11. Jason Smith, Microbiology (IBC 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 BUA: 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

NHP: Non-human Primate

**DURC**: Dual Use Research of Concern

- **1. CALL TO ORDER:** The Institutional Biosafety Committee (IBC) Chair called the meeting to order at 10:02 a.m. A quorum was present.
  - 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. Additionally, the IBC Chair reminded attendees that unsolicited written comments addressed to the IBC from members of the public shall be directly communicated to OSP.

#### 2. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the August 17, 2022, meeting.
- A member made a motion to approve the August 17, 2022, minutes. Another member seconded the motion.
- The committee voted unanimously to approve the August 17, 2022, meeting minutes.

#### 3. OLD BUSINESS:

- At the August 17, 2022, meeting, Dr. Chatterjee's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the August 17, 2022, meeting, Dr. Darveau's BUA was approved pending completion of a successful lab inspection. This BUA has been sent out.
- At the August 17, 2022, meeting, Dr. Ferreira's BUA was approved pending completion of the required trainings. This BUA is still pending.
- At the August 17, 2022, meeting, Dr. James' BUA was approved pending completion of a successful lab inspection. This has been sent out.
- At the August 17, 2022, meeting, Dr. Kublin's BUA was approved pending edits to the BUA and corrections to the BUA letter. This BUA is still pending.
- At the August 17, 2022, meeting, Dr. Ong's BUA was approved pending addition of HEK293 cells to the BUA application. This BUA has been sent out.
- At the August 17, 2022, meeting, Dr. Seshadri's BUA was approved for review of an updated draft BUA at the next IBC meeting. This BUA is still pending.
- At the August 17, 2022, meeting, Dr. Sniadecki's BUA was approved pending successful completion of the lab inspection. This BUA has been sent out.
- At the August 17, 2022, meeting, Dr. Sullivan's BUA was approved pending a BUA application edit. This BUA has been sent out.
- 4. 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. Mao added the use of human feces in mice to the BUA A Systems Pharmacology approach to predict the effects of pregnancy and infectious diseases on transporter-mediated drug disposition.
    - Dr. Vojtech renewed their project working with human and macaque tissues, blood, semen, and Zika virus to the BUA *Mechanisms of sexual virus transmission*.

- Dr. Isoherranen renewed their work using human derived cell lines, recombinant or synthetic DNA/RNA (non-viral), baculovirus and E. coli on the BUA Mechanisms of Regulation of Retinoic Acid Homeostasis.
- Dr. Dacey was approved for in vitro work with NHP blood, tissue, body fluids, and cell lines on the BUA *Neural Organization of Inner Retina*.
- Dr. Bundy was approved for in vitro work with a Photobacterium spp. on the BUA The fundamental role of heterotrophic bacteria in the ocean iron cycle.
- Dr. Tang added two new lab spaces and removed two spaces for work with previously approved agents to the BUA Mechanisms of Arteriogenesis in Mice and Rats.
- Dr. Unadkat renewed the BUA *Mechanisms of drug disposition* for in vitro work with human blood, tissue, body fluids, and cell lines.
- Dr. Kaufman added a new room working with previously approved agents to the BUA *Clinical and Translational Studies of Air Pollution Toxicity*.
- Dr. Ho renewed the BUA Mechanisms of Targeting Drugs to the Lymphatics for ABSL2 work with mice and work with human and NHP blood, tissue, body fluids, and cell lines.
- Dr. Samy renewed the BUA *Environmental Health Laboratory* for work with human blood, tissue, body fluids, cell lines.
- Dr. Hillhouse was approved for in vitro work with multiple fungal species on the BUA Kinetics of Mycelial Growth of Filamentous Fungi.
- Dr. Zagotta renewed their in vitro work on the BUA Gating Mechanisms of Ion Channels working with abculovirus, E. coli, yeast, and recDNA/RNA (non-viral) with enhanced gene delivery methods.
- Dr. Pravetoni was approved for in vitro work with human blood, tissue, body fluids, cell lines, and recDNA (non-viral) on the BUA Clinical Trials of Multivalent Opioid Vaccine Components.
- Dr. Pravetoni was approved for in vitro work with human blood, tissue, body fluids, cell lines, E. coli, and recDNA (non-viral) on the BUA Expression of recombinant monoclonal antibodies.
- Dr. Hotchkiss added two additional rooms for in vitro work with previously approved NHP blood, tissue, body fluids, and cell lines to the BUA Operation of Wanpac Animal Housing and Support Facilities.
- Dr. Theberge added contemporary circulating influenza strains, human coronavirus 229E, rhinovirus 16, respiratory syncytial virus and NHP blood, tissue, body fluids, and cell lines to the BUA Studying cell signaling and cellmicroenvironment interactions with new analytical tools.
- 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.

## 5. INDIVIDUAL PROJECT REVIEWS

- a. Altemeier, William, change, Inflammatory response modulation by mechanical ventilation
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Altemeier lab is adding a new room, work with human tissue to previously approved rooms, and recombinant yeast in mice.
- The lab was inspected, and no deficiencies were noted.
- All required trainings are complete.
- The IACUC protocol is still pending.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Altemeier.
- The Committee voted unanimously to approve the draft BUA for Dr. Altemeier.
- **b.** Dichek, David, change, *Gene Transfer in Cardiovascular Disease (Rabbits)* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Dichek lab is adding in vivo rabbit experiments with previously approved agents, and new gene inserts to their BUA.
  - A discussion occurred regarding the hold time in ABSL-2 for rabbits after injection of adenoviral vectors with >2/3 adenovirus genome. A group of IBC reviewers will meet with the investigator and review existing data from literature sources to determine the appropriate hold time before moving to ABSL-1.
  - The lab was inspected, and no deficiencies were noted.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Dichek.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dichek pending clarification of ABSL-2 hold time for rabbits.
- **c.** Duthie, Malcolm, new, Evaluation of treatments to interrupt tumor development
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Duthie lab is doing research evaluating various immune intervention strategies for the disruption of tumor development.
  - The project includes use of human and murine cells transduced with lentiviral vectors in mice and recDNA vaccines in mice.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Duthie.
  - The Committee voted unanimously to approve the draft BUA for Dr. Duthie
- **d.** Ferguson, Sarah, new, *Brain circuits that regulate drug use and addiction* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Ferguson lab aims to separate the changes in the brain that occur as a function of pharmacological exposure to a drug from the changes that occur that underlie addiction.
  - This work includes administering various viral vectors to rats at ABSL-2.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - All required trainings are complete.
  - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Ferguson.
- The Committee voted unanimously to approve the draft BUA for Dr. Ferguson pending confirmation of ABSL-2 locations in the vivarium for use.
- e. Gerner, Michael, change, Organization of Immunity
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gerner lab is adding recombinant mouse-adapted influenza A viral strains for in vitro and in vivo work in mice.
  - A lab inspection was not required for this change.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Gerner.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gerner
- **f.** Greninger, Alex, change, *Discovery and Characterization of Virus-Host Interactions and Determination of Antiviral Drug Resistance* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Greninger lab is adding Vaccinia virus for in vitro work in a previously approved room.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Greninger.
  - The Committee voted unanimously to approve the draft BUA for Dr. Greninger.
- **g.** Hawkins, R. David, renewal, *Epigenomics of various stem cells* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Hawkins lab aims to determine how epigenetic modifications define cell types and how these patterns change with cell fate.
  - This research includes transfecting human cell lines and primary cells with plasmid DNA or lentivirus, and oligonucleotides. Additionally, it includes work with E. coli K-12 strains.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Hawkins.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hawkins pending a successful response to their lab inspection.
- **h.** McLean, Jeff, new, General Lab Operations for Center for Microbiome Sciences and Therapeutics
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The McLean lab are investigating microbiome communities with an emphasis on the oral cavity.
  - The research includes handling 10 different bacterial cultures.
  - The lab inspection is scheduled for after the IBC meeting.

- All required trainings are complete.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. McLean.
- The Committee voted unanimously to approve the draft BUA for Dr. McLean pending successful lab inspection.
- i. Mitchell, Patrick, change, Evolutionary, genetic, and molecular basis of host-pathogen interactions
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Mitchell lab added the use of recombinant Vibrio parahaemolyticus in vitro and in mice in previously approved rooms.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - This project has an IACUC protocol in review.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Mitchell.
  - The Committee voted unanimously to approve the draft BUA for Dr. Mitchell.
- j. Seshadri, Chetan, renewal, Immune Profiling in Infectious Diseases
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Seshadri lab aims to understand why people have varying susceptibility to infections like tuberculosis for improved treatment strategies.
  - The lab's research involves working with human and non-human primate blood samples and lentiviral vectors.
  - The lab was inspected, and no deficiencies were noted.
  - All required trainings are complete.
  - Personnel working with SARS-CoV-2 clinical samples from COVID patients and/or fixed or inactivated samples or tissue must call the UW Employee Health Center for counseling prior to work.
  - For use of attenuated Mycobacterium tuberculosis H37Rv strains, the PI or supervisor must offer a baseline IGRA to personnel with direct contact to the agent, infected animals, or contaminated items prior to, annually, and at the end of work.
     Personnel working with these strains must contact the Employee Health Center immediately following an exposure.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Seshadri.
  - The Committee voted unanimously to approve the draft BUA for Dr. Seshadri.
- **k.** Shears, Melanie J., new, *Shears NHP studies* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Shears lab aims to develop NHP models for evaluating malaria infections and test promising vaccination strategies in NHPs.
  - This work includes administering agents to non-human primates.
  - There was a discussion about the recombinant nature of the plasmodium species used in NHP and mosquitoes and whether resistance to first line drugs for the treatment of malaria would be introduced. Updated information from the PI was requested.
  - The lab was inspected, and no deficiencies were noted.

- All required trainings are complete
- This project has an IACUC protocol in review.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Shears.
- The Committee voted unanimously to approve the draft BUA for Dr. Shears pending clarification of the recombinant malaria information.
- I. Wakimoto, Barbara, renewal, *Developmental Genetic Analysis of Fertilization Pathways in Drosophila* 
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Wakimoto lab aims to identify the pathways and molecules essential for sperm development and sperm function during fertilization in the model insect species, Drosophila melanogaster.
  - The work includes the creation and use of transgenic flies.
  - The lab inspection is scheduled for after the IBC meeting.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Wakimoto.
  - The Committee voted unanimously to approve the draft BUA for Dr. Wakimoto pending completion of a successful lab inspection.
- m. Waterston, Robert, renewal, Single Cell Gene Expression in C. elegans
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Waterson lab aims to identify when and where individual transcription factors are expressed during embryonic development of C. elegans and how they control gene expression.
  - This work includes generation and maintenance of transgenic C. elegans worms and manipulation of recombinant nucleic acid.
  - A lab inspection has been performed and is still pending a response.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Waterston.
  - The Committee voted unanimously to approve the draft BUA for Dr. Waterston pending completion of a successful lab inspection.

### 6. SUBCOMMITTEE REPORTS:

- **n.** Gale, Michael, change, The Host Response to BSL-3 Pathogens
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Gale lab added the use of Monkeypox virus, nucleic acid, and clinical isolates in vitro. The change also adds the use of WT SARS-CoV in vitro and in hamsters.
     Additionally, they added WT SARS-CoV-2 in hamsters and new recombinant SARS-CoV-2 strains in mice in previously approved room.
  - This work includes administering agents to animals.

- All required trainings are complete.
- Medical management plan revision is in progress for SARS-CoV.
- This project has an IACUC protocol in review.
- A lab inspection was not required.
- 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 pending updated medical management plan.
- **o.** Green, Damian, renewal, A Phase 2, Multicohort Open-Label Study of JNJ-68284528, a Chimeric Antigen Receptor Tcell (CAR-T) Therapy Directed Against BCMA in Subjects with Multiple Myeloma
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Green lab renewed their clinical study to evaluate the overall minimal residual disease (MRD) negative rate of subjects who receive the trial drug product, human cells transduced with third generation lentiviral vectors.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Green. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Green.
- p. Hyde, Jennifer, change, Pathogenesis studies of alphaviruses and +ssRNA viruses
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Hyde lab added the use of WT and recombinant select agent Venezuelan equine encephalitis virus (VEEV) strains and Sindbis virus in mice.
  - This work includes administering agents to animals.
  - All required trainings are complete.
  - Medical management plan is in place for Venezuelan Equine Encephalitis virus.
  - This project has an IACUC protocol in review.
  - A lab inspection was not required as the lab was recently inspected.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Hyde. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Hyde.
- **q.** Veesler, David, renewal, Expression of recombinant proteins using mammalian cell lines
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Veesler lab renewed their work studying emerging and re-emerging viruses.
  - The research includes the handling of pathogens.
  - There was a discussion that the description of the monkeypox research in the BUA application was unclear. The committee determined that more information on the proposed monkeypox research is needed to perform a risk assessment.

- The lab was inspected, and all deficiencies have been corrected.
- The required trainings are still pending.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Veesler. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Veesler pending removal of monkeypox work.

### 10. FOR YOUR INFORMATION:

- NIH Incident Report: A research assistant working with recombinant Risk Group 1 E. coli BL21 at BSL-1 had a splash to the eye while they were decontaminating a centrifuge bottle. The research assistant was being trained in a new procedure at the time of the exposure. The research assistant used the emergency eyewash and then received medical consultation from the Employee Health Center. The root cause was determined to be the use of pressurized water from the faucet causing splash back to the eye. EH&S asked the lab to revise their SOP for this procedure to pour diluted bleach into bottles rather than use the pressurized water faucet and to include PPE for eye/face protection. This incident has been reported and is awaiting response from NIH.
- **Break:** A 5-minute break has been added to the IBC agenda going forward.
- **Training:** Public Meetings Act (PMA) training video was viewed at the beginning of the meeting to fulfill the 4-year PMA training requirement.
- **11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 12. MEETING ADJOURNED AT APPROXIMATELY 12:07 P.M.