

## **Meeting Minutes**

**Date:** Wednesday, October 15, 2025

**Time:** 10:00 a.m. – 12:00 p.m.

**Location:** Zoom

Members

1. Lesley Colby, Comparative Medicine (Animal Containment Expert)

Present:

- Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
   Erin Heiniger, Department of Bioengineering (*Laboratory Specialist*)
- 4. Richard Grant, Washington National Primate Research Center
- 5. Kevin Hybiske, Allergy and Infectious Diseases (IBC Vice Chair)
- 6. Jennifer Iwamoto, Office of Animal Welfare (Animal Containment Expert)
- 7. David Koelle, Allergy and Infectious Diseases
- 8. Stephen Libby, Laboratory Medicine (Animal Containment Expert)
- 9. Susan Parazzoli (Community Member)
- 10. Jason Smith, Microbiology (IBC Chair)

## **Commonly Used Abbreviations**

<u>AAV</u>: adeno-associated viral vector BBP: bloodborne pathogens

BBF. Dioodborne patriogen

BSL: biosafety level

BSL-2w/3: BSL-2 with BSL-3 practices

**BSO**: biosafety officer

<u>BUA</u>: Biological Use Authorization <u>DURC</u>: Dual Use Research of Concern

IACUC: Institutional Animal Care and Use Committee

<u>IBC</u>: Institutional Biosafety Committee <u>iPSCs</u>: induced pluripotent stem cells

NHP: non-human primate

 $\underline{\text{NIH}}\text{:}$  National Institutes of Health

PI: Principal Investigator

rDNA: recombinant or synthetic DNA/RNA

RG: Risk Group

**SOP**: standard operating procedure

Source material: blood, tissue, body fluids, and cell lines

- 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. BIOSAFETY MONTH PRESENTATION

A biosafety officer presented on the 2025 Biosafety Month topic of "Get to Know Your Biosafety Cabinet" to share background information and best practices surrounding safe use, cleaning, and decontamination of biosafety cabinets.

### 4. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the September 17, 2025, meeting.
- A member made a motion to approve the September 17, 2025, meeting minutes. Another member seconded the motion.
- The committee voted unanimously to approve the September 17, 2025, meeting minutes, with one abstention.

#### 5. OLD BUSINESS:

- At the September 17, 2025 meeting, Dr. Ferguson's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
- At the September 17, 2025 meeting, Dr. Geng's BUA was approved pending successful
  completion of the lab inspection and submission and review of the IACUC protocol. This BUA
  is still pending.
- At the September 17, 2025 meeting, Dr. Hawkins's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
- At the September 17, 2025 meeting, Dr. Kong's BUA was approved pending successful completion of the lab inspection and edits to application. This BUA has been sent.
- At the September 17, 2025 meeting, Dr. Pepple's BUA was approved pending submission and review of the IACUC protocol. This BUA is still pending.
- At the September 17, 2025 meeting, Dr. Wakimoto's BUA was approved pending successful completion of the lab inspection. This BUA is still pending.
- At the September 17, 2025 meeting, Dr. Zagotta's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
- At the September 17, 2025 meeting, Dr. Seshadri's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
- 6. BIOSAFETY OFFICER (BSO) REPORT: The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under Sections III-E and III-F of the NIH Guidelines, (2) non-recombinant biological agents requiring BSL-2 with BSL-3 practices containment or lower, and (3) administrative updates, such as room additions.
  - a. Biosafety Officer Report
    - Dr. Disis added new rooms for work with previously approved agents on the BUA *Evaluation of Immunity to Cancer in a Rodent Model.*
    - Dr. Berndt added a new room for work with previously approved agents on the BUA *Screening and engineering of fluorescent biosensors.*

- Dr. Sabo initiated work with human source material in vitro on the BUA *The impact of vaginal washing on cervicovaginal inflammation*.
- Dr. Samy renewed work with human and NHP source material on the BUA Environmental Health Laboratory.
- Dr. Ferreira added a new room for work with previously approved agents on the BUA Tissue Bank for the Investigation of the Genetics and Basic Biology of Human Vascular Malformations and Skull base tumors.
- Dr. O'Connor updated agents used in previously approved rooms on the BUA Emerging infectious diseases and SIV co-infections.
- Dr. Gerner added work with fixed Mycobacterium tuberculosis samples on the BUA
   Organization of Immunity.
- Dr. Pravetoni initiated a new project with previously approved agents on the BUA mRNA in vaccine formulations. This work was previously approved by the IBC on another project. (Section III-D, III-E, and III-F)
- Dr. Unadkat renewed work with rDNA and human source material in vitro on the BUA *Mechanism of drug disposition*. (Section III-E and III-F)
- Dr. Paik renewed work with human feces, Blautia producta, Blautia wexlerae, and rDNA on the BUA *GNAC facility*. (Section III-F)
- Dr. Cao added work with human source material and murine cells infected with wildtype murine leukemia virus on the BUA Mucosal Immunoengineering and Microbiome Pharmaceutics.
- Dr. Soge added new rooms and work with bacterial clinical isolates on the BUA Surveillance of antimicrobial resistance in Neisseria gonorrhoeae and diagnostic test development for sexually transmitted infections.
- Dr. Bundy renewed work with Photobacterium phosphoreum, Pseudoalteromonas sp. BB2-AT2, and Vibrio cyclitrophicus on the BUA The dark side of the biological pump.
- Dr. McLean took over work previously overseen by Dr. Mougous on the BUA Microbial Interactions and Microbiome Center.
- 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.

# 7. BSL-3 INACTIVATION REPORT

- Dr. Seshadri requested approval for 1% (v/v) formaldehyde fixation for single cell suspensions and approval for supernatant filtration through two 0.22-micron filters to inactivate Mycobacterium tuberculosis.
- The subcommittee reviewed the procedures and inactivation data provided by the lab and approved their requests.
- The IBC Chair made a motion to approve this month's BSL-3 Inactivation Report.
- The committee voted to approve this month's BSL-3 Inactivation Report.

#### 8. INDIVIDUAL PROJECT REVIEWS

- **a.** Bammler, Theodor, change, Generating data for large-scale molecular epidemiology studies using genotyping capabilities, gene expression profiling, and immunoassays using magnetic beads
  - NIH Guidelines Sections III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Bammler lab is adding work to process NHP samples from animals that were previously exposed to recombinant Toxoplasma gondii and Streptococcus agalactiae and to wildtype influenza viruses, RSV, and Zika virus.
  - The lab was inspected and all deficiencies have been corrected.
  - All required trainings are complete.
  - There are occupational health requirements for work with influenza viruses and Zika virus.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Bammler.
  - The Committee voted unanimously to approve the draft BUA for Dr. Bammler.
- **b.** Cabernard, Clemens C, renewal, *Invertebrate Asymmetry* 
  - NIH Guidelines Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Cabernard lab investigates asymmetric cell division in marine mollusk embryos and transgenic Drosophila.
  - The lab works with transgenic Drosophila, rDNA in Drosophila and in snails, and E. coli at BSL-1.
  - The lab was inspected and no deficiencies were noted.
  - 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. Cabernard.
  - The Committee voted unanimously to approve the draft BUA for Dr. Cabernard.
- **c.** Dhodapkar, Madhav, new, Role of commensal microbiota on multiple myeloma (MM) progression and therapy
  - NIH Guidelines Sections III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Dhodapkar researches the role of gut microbiota may play in multiple myeloma.
  - The lab works with human source material and human cells transduced with first/second/unknown generation lentiviral vectors in mice at BSL-2.
  - A lab inspection was not required as all work takes place inside a vivarium.
  - 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. Dhodapkar.
  - The Committee voted unanimously to approve the draft BUA for Dr. Dhodapkar.

- d. Fink, Susan L, renewal, Host-Pathogen Interactions
  - NIH Guidelines Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Fink lab studies the host cell biology of infection and immune responses to multiple viral and bacterial pathogens.
  - The lab's in vitro work at BSL-2 includes recombinant Salmonella Typhiurium and Yersinia pseudotuberculosis and several wildtype RG 2 viruses, including human coronaviruses, Mayaro virus, Ross River virus, Sindbis virus, and the TC-83 strain of Venezuelan equine encephalitis virus. They also work with alpha-, corona-, and flaviviral replicons as well as corona-, flavi-, and lentiviral vectors. SARS-CoV-2 is administered to mice at BSL-2. They also work with human and NHP source material at BSL-2.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - A medical management plan is in place for Zika virus, and there are occupational health requirements for work with SARS-CoV-2.
  - 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. Fink.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fink.
- e. Isoherranen, Nina, renewal, Mechanisms of Retinoic Acid Homeostasis
  - NIH Guidelines Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Isoherranen lab studies the biology of vitamin A homeostasis and metabolism in the context of liver tissues.
  - The lab works with human source material in vitro at BSL-2 and with baculoviral vectors, E. coli, and rDNA in vitro at BSL-1.
  - 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. Isoherranen.
  - The Committee voted unanimously to approve the draft BUA for Dr. Isoherranen.
- f. Pravetoni, Marco, renewal, Expression of recombinant monoclonal antibodies
  - NIH Guidelines Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Pravetoni lab develops monoclonal antibodies against opioids and other drugs of abuse to investigate their binding properties in vivo and in vitro to support vaccine development.
  - The lab works with human and NHP source material in vitro at BSL-2 and with rDNA in mice and rats at BSL-1.
  - A lab inspection has been performed and is still pending a response.
  - 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. Pravetoni.
- The Committee voted unanimously to approve the draft BUA for Dr. Pravetoni, pending responses to inspection.
- **g.** Sakiyama-Elbert, Shelly, renewal, *Developing New Tools to Understand the Role of Interneurons in Rewiring After SCI* 
  - NIH Guidelines Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Sakiyama-Elbert lab studies the role of specific types of neurons in rewiring and recovery of function following spinal cord injury.
  - The lab works with AAV, E. coli, and rDNA in vitro at BSL-1.
  - 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. Sakiyama-Elbert.
  - The Committee voted unanimously to approve the draft BUA for Dr. Sakiyama-Elbert.
- h. Veesler, David J, renewal, Expression of recombinant proteins using mammalian cell lines
  - NIH Guidelines Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Veesler lab studies the structure of enveloped viruses, discovering neutralizing antibodies to those viruses, and designing vaccines.
  - The lab works with Cedar virus, RG 2 human coronaviruses including SARS-CoV-2, vaccinia virus, human source material, NHP source material, Varicella zoster virus, and Vesicular stomatitis virus strains in vitro at BSL-2, and with third generation lentiviral vectors, E. coli, and rDNA in vitro at BSL-1.
  - A committee member asked if the bat cell lines have been tested or screened for pathogens. The biosafety officer confirmed they would ask the lab for clarification.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - There are occupational health requirements for work with SARS-CoV-2 and vaccinia virus.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Veesler.
  - The Committee voted unanimously to approve the draft BUA for Dr. Veesler, pending clarification of bat cell line testing/screening.

## 9. SUBCOMMITTEE REPORTS:

- i. Cassaday, Ryan, new, A Single-Arm, Open-Label, Multi-Center, Phase 1b/ 2 Study to Evaluate the Safety, Efficacy, and Cellular Pharmacokinetic Profile of CTD402 in Participants with Relapsed/Refractory T-cell Acute Lymphoblastic Leukemia (T-ALL) and Lymphoblastic Lymphoma (TLBL) (TENACITY-01)
  - NIH Guidelines Sections III-C

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a company-sponsored, multi-site, non-first-in-humans cell therapy trial for T cell leukemia and lymphoma.
- A CAR-T cell study product will be administered to human study participants.
- All required trainings are complete.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Cassaday. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Cassaday.

## **10. FOR YOUR INFORMATION:**

- NIH Listening Sessions. The Biosafety Manager notified the committee that the NIH held
  the first listening session for modernizing and strengthening oversight for biosafety. The
  NIH plans to accept thoughts in writing, though the process is on hold due to the
  government shut down. Once more information is available, EH&S will send out
  communications.
- **11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 12. MEETING ADJOURNED AT APPROXIMATELY 11:00 a.m.