

# **Meeting Minutes**

**Date:** Wednesday, July 19, 2023 **Time:** 10:00 AM – 12:00 PM

**Location:** Zoom

Members

1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases

Present:

- 2. Lesley Decker, Environmental Health & Safety (Biosafety Officer)
- 3. Richard Grant, Washington National Primate Research Center
- 4. Erin Heiniger, Department of Bioengineering (Laboratory Specialist)
- 5. Kevin Hybiske, Allergy and Infectious Diseases (IBC Vice Chair)
- 6. Stephen Libby, Laboratory Medicine (Animal Containment Expert)
- 7. Scott Meschke, Environmental & Occupational Health Sciences
- 8. Jennifer Nemhauser, Department of Biology (Plant Expert)
- 9. Susan Parazzoli (Community Member)
- 10. Jason Smith, Microbiology (IBC Chair)
- 11. Paul Swenson, Seattle-King Co. Dept. of Public Health (Community Member)
- 12. Elyse Verstelle, Department of Immunology (Laboratory Specialist)

**Commonly Used Abbreviations** 

AAV: adeno-associated viral vector

**BSL: Biosafety level** 

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

BSO: Biosafety officer

BUA: Biological Use Authorization
DURC: Dual Use Research of Concern

IACUC: Institutional Animal Care and Use Committee

IBC: Institutional Biosafety Committee iPS: induced pluripotent stem cells

NHP: non-human primate

NIH: 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. AAALAC UPDATE: Zara Llewellyn gave a brief update about the recent AAALAC site visit.

#### 4. APPROVAL OF MINUTES:

- The IBC Chair sought a motion to approve the minutes from the June 21, 2023, meeting.
- A member made a motion to approve the June 21, 2023, minutes. Another member seconded the motion.
- The committee voted unanimously to approve the June 21, 2023, meeting minutes, with two abstentions.

## 5. OLD BUSINESS:

- At the June 21, 2023, meeting, Dr. Lam's BUA was approved pending an update to the IBC primary review. This BUA has been sent.
- At the June 21, 2023, meeting, Dr. Maly's BUA was approved pending successful completion of the lab inspection. This BUA has been sent.
- At the June 21, 2023, meeting, Dr. Mougous' BUA was approved pending successful
  completion of the lab inspection and follow up with the lab to clarify if there is potential for
  enzyme conferring resistance to gentamycin or other aminoglycoside antibiotics. This BUA
  has been sent out.
- At the June 21, 2023, meeting, Dr. Safyan's BUA was approved pending successful completion of the medical management plan. This BUA has been sent out.
- 6. BIOSAFETY OFFICER (BSO) REPORT: The Biosafety Officer Report includes projects involving: (1) recombinant or synthetic nucleic acids covered under section 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. Sniadecki added wildtype S. gordonii in rats to the BUA *Cell therapy in mice and rats*.
    - Dr. Bryant added a room for use of previously approved agents to the BUA *Thermosensation of parasitic nematodes*.
    - Dr. Sodora was approved for in vivo macaque work with simian immunodeficiency virus (SIV) on the BUA *SIV Immunopathology and therapies*.
    - Dr. Stetson added in vitro and in vivo mouse work with Coxsackie viruses to the BUA Mechanisms and Consequences of Innate Immune Detection of Nucleic Acids.
    - Dr. Valencia was approved for in vitro work with human source material and rDNA on the BUA *Mitochondrial adaptations to obesity and weight loss* (Section III-F).
    - Dr. Pravetoni added in vitro work with NHP source material to the BUA *Expression of recombinant monoclonal antibodies*.
    - Dr. Mitchell registered work with additional strains of Shigella flexneri in vitro and in mice on the BUA *Evolutionary, genetic, and molecular basis of host-pathogen interactions*.

- Dr. Derdeyn added a room for in vitro work with previously approved agents to the BUA *Virus neutralization, diversity, and B cell immunology*.
- 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. DURC REPORT

- One project received approval for use of Botulinum neurotoxin. It does not meet the DURC definition.
- The IBC Chair sought a motion to approve this month's DURC Report.
- A member made a motion to approve this month's DURC Report. Another member seconded the motion.
- The Committee unanimously voted to approve this month's DURC Report.

## 8. INDIVIDUAL PROJECT REVIEWS

- a. Fields, Stanley, renewal, Functional analysis of human genes
  - Sections III-D, IIIE, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Fields lab aims to understand how mutations in the human genome affect the functions of the encoded proteins.
  - This lab works with bacteriophage, Saccharomyces cerevisiae, lentiviral vectors, and rDNA in vitro.
  - 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. Fields.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fields.
- **b.** Gordon, Sharona, renewal, Mechanism of protein modulation.
  - Sections III-D, IIIE, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Gordon lab aims to understand the molecular basis for inflammatory painrelated hypersensitivity.
  - This lab works with baculoviral vectors, lentiviral vectors, and SARS-CoV-2 in vitro.
  - 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. Gordon.
  - The Committee voted unanimously to approve the draft BUA for Dr. Gordon, pending completion of the lab inspection response.
- **c.** Kwon, Ronald, renewal, *Genetic Regulation of Bone in Zebrafish* 
  - Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.

- The Kwon lab aims to identify new pathways underlying skeletal disease, development, and regeneration, as well as therapeutic strategies for intervention.
- This lab works with non-viral rDNA in vitro and transgenic zebrafish.
- 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. Kwon.
- The Committee voted unanimously to approve the draft BUA for Dr. Kwon, pending completion of the lab inspection response.
- **d.** Ladiges, Warren, renewal, Alzheimer's Disease Intervention
  - Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Ladiges lab aims to understand whether a combination of drugs with anti-aging effects can slow or halt the progression of Alzheimer's Disease pathology.
  - This lab works with AAV in vitro and in mice. They also work with rDNA and human source material in vitro.
  - The lab was inspected, and all deficiencies have been corrected.
  - 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. Ladiges.
  - The Committee voted unanimously to approve the draft BUA for Dr. Ladiges.
- **e.** Murry, Charles, renewal, *Contractile and non-contractile human pluripotent stem cell-derived cardiomyocyte grafts in non-human primates (NHPs)* 
  - Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Murry lab aims to understand whether non-contractile cardiomyocyte grafts in non-human primates (NHP) have the same therapeutical effect as the contractile counterpart through paracrine effects.
  - This lab works with human cells transfected with rDNA in NHP and in vitro.
  - 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. Murry.
  - The Committee voted unanimously to approve the draft BUA for Dr. Murry.
- f. Sakiyama-Elbert, Shelly, new, Ectopic Olfactory Receptor Guided Facial Nerve Regeneration
  - Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Sakiyama-Ebert lab aims to determine if odorants can be used to ectopically guide regeneration of other types of nerves, including the facial nerve after injury.
  - This lab works with AAV in vitro and in rats. They also work with rDNA and non-pathogenic strains of E. coli in vitro.
  - 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. Sakiyama-Ebert.
- The Committee voted unanimously to approve the draft BUA for Dr. Sakiyama-Ebert.
- g. Salipante, Stephen, renewal, Next-generation sequencing for clinical translation
  - Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Salipante lab aims to advance the capabilities of next generation sequencing and to use next generation sequencing to advance understanding of genetics in a variety of fields relevant to human health.
  - This lab works with several protozoan species, Chlamydia trachomatis,
     Staphylococcus aureus, Treponema pallidum, and rDNA in vitro.
  - The lab was inspected, and all deficiencies have been corrected.
  - All required trainings are complete.
  - There are occupational health requirements for work with Treponema pallidum.
  - The draft BUA letter was shown.
  - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Salipante.
  - The Committee voted unanimously to approve the draft BUA for Dr. Salipante.
- h. Schweppe, Devin, renewal, Chemical perturbation of bacterial and human cells
  - Sections III-D, III-E, and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Schweppe lab aims to determine the spatiotemporal protein interactions, proteome responses, and molecular characteristics of lung disease biology stemming from lung cancer and bacterial infection.
  - This lab works with several pathogenic bacteria species, non-pathogenic strains of E. coli, and rDNA in vitro.
  - 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. Schweppe.
  - The Committee voted unanimously to approve the draft BUA for Dr. Schweppe.
- i. Sniadecki, Nathan, change, Cell therapy in mice and rats
  - Section III-D
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Sniadecki lab is adding recombinant Streptococcus gordonii in rats.
  - A lab inspection was not required as the lab was recently inspected.
  - All required trainings are complete.
  - IACUC amendment has been approved.
  - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Sniadecki.
- The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.
- **j.** Zalatan, Jesse, renewal, *Physical organizing principles of biological signaling protein networks* 
  - Sections III-D, III-E and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Zalatan lab aims to understand the molecular mechanisms that allow living cells to process, integrate, and coordinate signals.
  - This lab works with several recombinant Risk Group 1 bacteria species, lentiviral vectors, and rDNA in vitro.
  - 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. Zalatan.
  - The Committee voted unanimously to approve the draft BUA for Dr. Zalatan.
- k. Zheng, Ying, renewal, Microfluidic control of vascular growth and remodeling
  - Sections III-D and III-F
  - The assigned IBC Primary Reviewer presented the Primary Review.
  - The Zheng lab aims to recreate microvascularized tissue in vitro for regenerative medicine and disease modeling.
  - This lab works with rDNA, replicant deficient gammaretroviral vectors with and without oncogenic inserts, human iPS cells, and lentiviral vectors in vitro.
  - 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. Zheng.
  - The Committee voted unanimously to approve the draft BUA for Dr. Zheng.

## 9. SUBCOMMITTEE REPORTS:

- I. Fisher (001), Cynthia, new, A Phase 2, Observer-Blind, Placebo-Controlled, Proof-of-concept Trial to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1647 Cytomegalovirus Vaccine in Liver Transplant Candidates and Recipients
  - Section III-C
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The is a new, company sponsored, phase 2, multicenter, non-first-in-humans, clinical trial of a 6-valent mRNA vaccine to reduce cytomegalovirus (CMV) disease in persons with liver disease who are awaiting possible liver transplant.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Fisher. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fisher.

- **m.** Fisher (002), Cynthia, new, Cytomegalovirus (CMV) Vaccine in Orthotopic Liver Transplant Candidates
  - Section III-C
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a new, multi-center, NIH-funded, randomized, double blind, placebo-controlled phase II clinical trial of a modified vaccinia Ankara-cytomegalovirus (MVA-CMV) vaccine in seronegative pre-liver transplant recipients to examine safety, immunogenicity, and efficacy before and after transplant.
  - All required trainings are complete.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Fisher. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Fisher.
- **n.** Seshadri, Chetan, change, *Immune Profiling in Infectious Diseases* 
  - Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - The Seshadri lab is adding wild type strains of Mycobacterium tuberculosis (Mtb) and Mtb-infected NHP and murine samples.
  - All required trainings are complete.
  - A medical management plan is in place for M. tuberculosis.
  - The draft BUA letter was shown.
  - A member made a motion to approve the draft BUA letter for Dr. Seshadri. Another member seconded the motion.
  - The Committee voted unanimously to approve the draft BUA for Dr. Seshadri, pending revision of the BUAL to list samples from mice and NHPs exposed to Mtb.

# **10. FOR YOUR INFORMATION:**

- NIH Incident Report: A research assistant experienced a needlestick from a needle that
  was contaminated with Pseudomonas aeruginosa PA01 strain with a wspF gene
  deletion. The employee contacted the University Employee Health Clinic for medical
  guidance and was advised that no medical treatment was needed but to monitor the
  wound for signs of infection. EH&S is investigating the incident.
- **11. ISSUES FROM THE FLOOR & PUBLIC COMMENTS:** There were no issues from the floor, and no public comments.
- 12. MEETING ADJOURNED AT APPROXIMATELY 11:26 A.M.