



# INSTITUTIONAL BIOSAFETY COMMITTEE

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UNIVERSITY *of* WASHINGTON

## Meeting Minutes

**Date:** Wednesday, November 18, 2020

**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. Garry Hamilton (*Community Member*)
  6. Kevin Hybiske, Allergy and Infectious Diseases
  7. David Koelle, Allergy and Infectious Diseases
  8. Stephen Libby, Laboratory Medicine (*IBC Chair*)
  9. Scott Meschke, Environmental & Occupational Health Sciences
  10. Jason Smith, Microbiology (*IBC Vice Chair*)
  11. 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. **FY 2020 IBC METRICS:** EH&S presented a presentation to show IBC metrics for fiscal year 2020.
4. **APPROVAL OF MINUTES:**
  - The IBC Chair sought a motion to approve the minutes from the October 21, 2020 meeting.
  - A member made a motion to approve the October 21, 2020 minutes. Another member seconded the motion.
  - The committee voted to approve the October 21, 2020 meeting minutes. There were two abstentions.
5. **OLD BUSINESS:**
  - At the June 17, 2020 meeting, Dr. Altemeier's BUA was approved pending review of the IACUC protocol and required training. This BUA is still pending.
  - At the August 19, 2020 meeting, Dr. Hyde's BUA was approved pending review of the IACUC submission. This BUA is still pending.
  - At the August 19, 2020 meeting, Dr. Voigt's BUA was approved pending a medical management plan, Occupational Health consultations, training, and edits to the BUA application. This BUA is still pending.
  - At the October 21, 2020 meeting, Dr. Fuller's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the October 21, 2020 meeting, Dr. Pepper's BUA was approved pending a successful lab inspection. This BUA has been sent out.
  - At the October 21, 2020 meeting, Dr. Pillarisetty's BUA was approved pending additional details to the BUA application and training completions. This BUA has been sent out.
  - At the October 21, 2020 meeting, Dr. Skerrett's BUA was approved pending a successful lab inspection and a correction to the BUA letter. This BUA has been sent out.
  - At the October 21, 2020 meeting, Dr. Stayton's BUA was approved pending a successful lab inspection. This BUA has been sent out.
6. **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. Guttman renewed the BUA *Epitope mapping of neutralizing antibodies on staphylococcal enterotoxins* working with non-pathogenic strains of *Escherichia coli* and *Lysobacter enzymogenes* in vitro.
    - Dr. Roberts renewed the BUA *Environmental Microbiology*. Work includes use of various agents in vitro at BSL-2.
    - Dr. Bremner renewed the BUA *Bremner Research Lab*, working with human blood, tissue, body fluids, and cell lines.

- Dr. Vaughan renewed the BUA *Development and Application of Imaging Tools for Super-resolution Fluorescence Microscopy* working with non-human primate cells and human blood, tissue, body fluids, and cell lines in vitro.
- Dr. Lockwood was approved for the new BUA *Northwest Clinical Genomics Laboratory*, working with human blood, tissue, body fluids, and cell lines.
- Dr. Chung was approved for the new BUA *Highly sensitive and specific immuno-resistive sensor for point-of-care screening of COVID-19*. Work includes in vitro use of fixed or inactivated samples or tissue of MERS-CoV and SARS-CoV-2.
- Dr. Risques renewed the BUA *Molecular biomarkers for early cancer detection, prediction, and prognosis* working with human blood, tissue, body fluids, and cell lines.
- Dr. Dichek added a new room for work with previously approved agents to the BUA *Gene Transfer in Cardiovascular Disease (Mice)*.
- Dr. Murphy added use of enhanced gene delivery methods for a previously approved recDNA vaccine to the BUA *NHP Study*.
- Dr. Geisse added a new room and work with recombinant or synthetic nucleic acids with enhanced gene delivery methods to the BUA *Development of cultureware and devices for human cells in vitro research*.
- Dr. Adams Waldorf added new lab locations to her BUAs *Experimental Model of Viral-Induced Brain Injury*, *Experimental Model for Chorioamnionitis and Preterm Labor*, and *Influenza and Coronavirus Model of Immunity in Pregnancy*.
- Dr. Parsek changed lab locations for the BUA *Responses of Pseudomonas aeruginosa to other bacteria in the CF Lung*.
- Dr. Doty renewed the BUA *Microbiology Research Projects* working with bacterial endophyte isolates, non-pathogenic in vitro and in plants.
- Dr. Ladiges added vivarium use for previously approved agents to the BUA *Alzheimer's Disease Intervention*.
- 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:** The Dual Use Research of Concern Institutional Review Entity (DURC IRE) did not meet this month because there were no applications to review.

## **8. SECTION III-D AMENDMENT**

- a. Sniadecki, Nathan, change,
- The assigned IBC Primary Reviewer presented the Primary Review.
  - This change adds human cells transduced with lentiviral vectors administered to macaques.
  - 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. Sniadecki.

- The Committee voted unanimously to approve the draft BUA for Dr. Sniadecki.

## 9. INDIVIDUAL PROJECT REVIEWS

### b. Arnold, Samuel, new, *iNPG-pDox efficacy*

- The assigned IBC Primary Reviewer presented the Primary Review.
- The goal of this new research is to complete preclinical efficacy studies of the novel drug iNPG-pDox.
- Work includes use of human cells transduced with lentiviral vectors, non-HIV pseudotyped, replication deficient in vitro and in mice.
- Only the in vivo BUA approval will be issued so the IACUC can be approved. The in vitro portion of the BUA will be issued later as a change after the PI hires a lab technician so that a lab inspection can be performed. No in vitro work will be done before then.
- 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. Arnold.
- The Committee voted unanimously to approve the draft BUA for Dr. Arnold.

### c. Chu, Helen, change, *Hospitalized or Ambulatory Adults with Respiratory Virus Infections (HAARVI)*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This change is to add use of lentiviral vectors expressing GFP and luciferase.
- 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. Chu pending a change to the BUA letter.
- The Committee voted unanimously to approve the draft BUA for Dr. Chu pending a change to the BUA letter.

### d. Fowler, Douglas, change, *Pooled Tagging of Endogenous Loci Using AAV Delivered sgRNAs and Repair Template*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This change adds the in vitro use of adeno-associated viral vectors (adenovirus free) and gammaretroviral vectors, replication deficient, ecotropic.
- The committee discussed how ecotropic vs amphotropic would change the assigned biosafety level. AAV with oncogenes would be listed at BSL-2. The biosafety officer will verify use with the PI before approving the current BUA letter.
- 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. Fowler pending verification and any necessary edits to the BUA letter.
- The Committee voted unanimously to approve the draft BUA for Dr. Fowler pending the items above.

- e. Fuller, Deborah, renewal, *Prophylactic SIV Vaccines and Optimization of different Adjuvant combinations in NHP*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall research goal is to optimize a novel adjuvant for a HIV DNA vaccine to help combat the HIV epidemic.
  - Work includes use of recombinant or synthetic DNA/RNA (non-viral).
  - The lab was recently inspected and does not require an additional inspection for this renewal.
  - 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. Iritani, Brian, renewal, *Gene Function in Lymphopoiesis and Cancer*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goals of the project are to understand the roles and mechanisms of action of specific genes in the development, function, and transformation of immune cells.
  - Work includes use of murine and mouse cells transduced with gammaretroviral vectors, replication deficient, ecotropic, oncogenic inserts in vitro and in mice.
  - A successful 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. Iritani pending a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Iritani pending a successful lab inspection. There was one abstention.
- g. Lee, Donghoon, renewal, *MR Methods for Small Animal Imaging*
- The assigned IBC Secondary Reviewer presented the Primary Review.
  - The goal of this project renewal is to develop MRI methods to noninvasively monitor disease progression and therapy responses against AAV vector-mediated gene therapy for the mdx mouse model of Duchenne muscular dystrophy.
  - A successful lab inspection was 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. Lee.
  - The Committee voted unanimously to approve the draft BUA for Dr. Lee.
- h. Murphy, Sean, change, *Immunity to malaria infection*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The goal with this research is to utilize Plasmodium-infected mosquitoes to produce sporozoites for pre-erythrocytic vaccines, to test the ability of vaccines produced by the laboratory to block malaria transmission and to generate samples for diagnostic testing related to transmission blocking interventions.
  - This change adds new ACL-2 insectary locations for previously approved agents.
  - The biosafety officer will find out if recombinant DNA will be used in mosquitos.
  - A successful 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 a successful lab inspection and edits to the BUA application.
  - The Committee voted unanimously to approve the draft BUA for Dr. Murphy pending the items above.
- i. Soetedjo, Robijanto, renewal, *Saccade Motor Control*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The overall research goal is to implement optical manipulation of electrical activity in the brain by optimizing viral vectors and injection techniques in non-human primates.
  - Work includes use of adeno-associated viral vectors (adenovirus free) in vitro and in macaques.
  - A successful 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. Soetedjo pending edits to the BUA application and a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Soetedjo pending the items above.
- j. Zheng, Ning, change, *Protein Structural Biology - Dr. Ning Zheng Lab*
- The assigned IBC Primary Reviewer presented the Primary Review.
  - The lab is studying protein degradation promoted by a class of enzymes known as ubiquitin ligases, with the goal assessing the therapeutic potential of this biological process.
  - This change adds the in vitro use of lentiviral vectors, non-HIV pseudotyped, replication deficient.
  - A successful 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. Zheng pending a successful lab inspection.
  - The Committee voted unanimously to approve the draft BUA for Dr. Zheng pending a successful lab inspection.

## 10. SUBCOMMITTEE REPORTS:

- k. Disis, Mary, renewal, *A Phase 1 Trial of the Safety and Immunogenicity of a Multiple Antigen Vaccine (STEMVAC) in HER2 Negative Advanced Stage Breast Cancer Patients*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
  - This is a renewal of a protocol to treat breast cancer patients with a multiantigen vaccine encoding non-mutated human proteins associated with mesenchymal transformation.
  - The draft BUA letter was shown.

- A member made a motion to approve the draft BUA letter for Dr. Disis. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Disis.

I. Fuller, Deborah, change, *DNA Vaccine Therapy*

- Three members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a change to an existing BUA to request the addition of SARS-CoV-2 infection of mice in the ABSL-3. In vitro virus work at BSL-3 is already approved for this lab.
- All of the required trainings have been completed.
- The draft BUA letter was shown.
- A member made a motion to approve the draft BUA letter for Dr. Fuller. Another member seconded the motion.
- The Committee voted unanimously to approve the draft BUA for Dr. Fuller.

**10. FOR YOUR INFORMATION:**

- **COVID-19 Presentation:** A biosafety officer gave a presentation to the committee regarding COVID-19 work taking place at UW.

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

**12. MEETING ADJOURNED AT APPROXIMATELY 11:39 P.M.**