



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, November 15, 2017

Time: 10:00 AM – 12:00 PM

Location: Foegen N-130A

- Members Present:**
1. Thea Brabb, Comparative Medicine (*Animal Containment Expert*)
 2. Richard Grant, Washington National Primate Research Center
 3. Garry Hamilton (*Community Member*)
 4. Kevin Hybiske, Allergy and Infectious Diseases
 5. Stephen Libby, Laboratory Medicine (*IBC Chair*)
 6. Scott Meschke, Environmental & Occupational Health Sciences
 7. David Scarsella, Pacific Northwest Diabetes Research Institute (*Community Member*)
 8. Jason Smith, Microbiology (*IBC Vice Chair*)

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 10:07 am. 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 October 18, 2017 meeting.
 - A member made a motion to approve the October 18, 2017 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the October 18, 2017 meeting minutes.
4. **OLD BUSINESS:**
 - At the April meeting, Dr. Hybiske's BUA was approved pending receipt of NIH approval for Chlamydia strains falling under section III-A of the NIH guidelines. The NIH approval was received. Dr. Hybiske needs to submit some SOPs and confirm that he has set up additional practices as required by the NIH.
 - At the August IBC meeting, Dr. Davis's project was approved pending the biosafety officer's review of the IACUC amendment. The IACUC amendment has not yet been submitted.
 - At the August IBC meeting, Dr. Hyde's project was approved pending the completion of the medical management plan, vaccine recommendations, and an occupational health consultation. All components of the medical management plan were completed and the BUA letter was sent out.
 - At the October IBC meeting, Dr. Keel's project was approved pending some questions about which autoclave will be used to disinfect waste. The investigator provided this information and the BUA letter was sent out.
 - At the October IBC meeting, Dr. Clark's project was approved pending the biosafety officer review of the IACUC protocol. The IACUC protocol was submitted and reviewed by the biosafety officer, and the BUA letter was sent out.
 - At the October IBC meeting, Dr. Curnow's project was approved pending the biosafety officer review of the IACUC protocol. The IACUC protocol was submitted and reviewed by the biosafety officer, and the BUA letter was sent out.
 - At the October IBC meeting, Dr. Fuller's project was approved pending removing references to historical non-circulating strains of influenza on the BUA application. The investigator clarified that they are not working with these strains and removed references to them on the BUA application. The BUA letter was sent out.
 - At the October IBC meeting, Dr. Pepper's project was approved pending the biosafety officer review of the IACUC protocol. The IACUC protocol was submitted and reviewed by the biosafety officer, and the BUA letter was sent out.
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. Coombs renewed a BUA involving human samples as well as non-recombinant human papillomavirus and *Plasmodium falciparum*.
- Dr. Neitz received a new BUA involving adeno-associated viral vectors used in Saimiri squirrel monkeys. These agents were already approved on one of Dr. Neitz's other BUAs.
- Dr. Gulsuner received a new BUA approval for human cells.
- The BUA for the project "Biology of the Artery Wall/ADAM-mediated Shedding" was transferred from Dr. Raines to Dr. Bornfeldt.
- The BUA for the project "Inflammatory Bowel Disease, Colon Cancer, Diet and the Microbiome" was transferred from Dr. Maggio-Price to Dr. Meeker.
- Dr. Miller and Dr. Zhu each added the cell analysis facility to their respective BUA letters.
- Dr. Patton added a new room to several of her BUA letters.
- The IBC Chair sought 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. CATEGORY III-D AMENDMENTS

1. Muster, Jeanot, change, *Wnt Genes and Signaling*
 - The biosafety officer presented the project.
 - At the August 16th IBC meeting, the committee temporarily approved this project through January 2018 until the School of Medicine appointed a permanent PI for the project. The School of Medicine has appointed Jeanot Muster to be the permanent PI. The letter has changed to reflect the extended expiration date for three years (concurrent with IACUC 3-year renewal date: September 7, 2020).
 - The assigned IBC member endorsed the biosafety officer's review.
 - The draft BUA letter was shown.
 - The assigned IBC member made a motion to approve the draft BUA for Jeanot Muster.
 - The Committee voted unanimously to approve the draft BUA for Jeanot Muster.

7. INDIVIDUAL PROJECT REVIEWS

2. Morrissey, Colm, renewal, *SRRM4 as a target to disrupt the transition to the neuroendocrine/neuronal phenotype in CRPC*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The goal of the project is to transduce established prostate cancer cell lines with a lentiviral vector to overexpress the SRRM4 gene and determine if this alters gene expression in the prostate cancer cell line.
 - Lentiviral vectors and human cell lines are used.
 - The lab inspection has been completed with no deficiencies remaining and 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. Morrissey.

- The Committee voted unanimously to approve the draft BUA for Dr. Morrissey.
3. Trapnell, Cole, renewal, *Trapnell lab general operations*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab studies novel regulators that govern cellular transitions by utilizing single-cell genomics.
 - Third-generation lentiviral vectors both with and without oncogenic inserts are used on the project. Human cells are also used.
 - The lab inspection has been completed with no deficiencies remaining and 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. Trapnell.
 - The Committee voted unanimously to approve the draft BUA for Dr. Trapnell.
 4. Kennedy, Scott, new, *Somatic mutagenesis in aging and neurodegenerative diseases*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The goal of the research is to study the role of mutations in mitochondrial DNA and how that affects lifespan.
 - Transgenic fruit flies (*Drosophila*) are used.
 - The lab inspection has been completed with no deficiencies remaining and 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. Kennedy.
 - The Committee voted unanimously to approve the draft BUA for Dr. Kennedy.
 5. Koelle, David, change, *Immune response and pathogenesis of viral infections*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a change request to add non-recombinant *Plasmodium falciparum* and a recombinant herpes simplex 1 virus, T-VEC (Talimogene laherparepvec). The work will be conducted in vitro.
 - No inspection was required for this change, because the facilities have been recently inspected. 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. Koelle.
 - The Committee voted unanimously to approve the draft BUA for Dr. Koelle.
 6. Mougous, Joseph, renewal, *Type VI secretion-dependent interbacterial interactions*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - The lab studies the mechanisms and consequences of bacterial interactions.
 - Many different strains of Risk Group 1 and Risk Group 2 bacteria are used.
 - Three select agent exempt strains are used: *Bacillus anthracis* Sterne 34F2 strain, *Francisella tularensis* holarctica strain, and *Yersinia pestis* LCR- strain. The Sterne strain lacks the virulence plasmid PX02, the holarctica strain is an attenuated vaccine strain, and the LCR- strain lacks the virulence plasmid LCR. BSL-2 containment is appropriate for these strains.
 - First and second generation lentiviral vectors are also used.
 - This project previously involved animal work, but this part of the project will not be continued.

- The lab inspection is still pending. 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. Mougous.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mougous, pending completion of the lab inspection.
7. Neitz, Jay, renewal, *Expression and Function of Cone Pigment Genes*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The goal of the research is to develop gene therapy vectors for developing potentially therapeutic genes to cone photoreceptors by injection into the eye.
 - Adeno-associated viral vectors are used on the project, both in vitro and in mice.
 - The lab inspection is still pending. 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. Neitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neitz, pending completion of the lab inspection.
8. Neitz, Maureen, renewal, *Exploring plasticity of the adult visual system using viral gene delivery*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal of a project that studies genes involved in vision and agents with therapeutic potential for retinal degeneration.
 - Adeno-associated viral vectors (AAV) are used in vitro and in two primate models, macaques and Saimiri (squirrel monkeys).
 - Non-human primate and murine tissues are used.
 - AAV is used in squirrel monkeys at ABSL-1 because squirrel monkeys do not pose a herpes B virus risk to humans.
 - The lab inspection is still pending. 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. Neitz.
 - The Committee voted unanimously to approve the draft BUA for Dr. Neitz, pending the lab inspection.
9. Singh, Pradeep, renewal, *Determinants of virulence and antimicrobial tolerance in biofilm and acute infections*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This is a renewal. The investigator uses a wide variety of Risk Group 1 and Risk Group 2 organisms to study the genes needed for biofilm formation and the ability of these pathogens to become antibiotic tolerant.
 - *Burkholderia thailandensis* and *Klebsiella pneumoniae* are used in mice.
 - *Acinetobacter baumannii* and *Pseudomonas aeruginosa* are used in rats.
 - The lab inspection has been completed with no deficiencies remaining. The PI still needs to complete the biosafety training.
 - The IACUC renewal has not yet been submitted. The biosafety officer will review the IACUC protocol once it is submitted.
 - The draft BUA letter was shown.

- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Singh.
- The Committee voted unanimously to approve the draft BUA for Dr. Singh, pending completion of the biosafety training and submission of the IACUC protocol.

10. Skerrett, Shawn, change, *Host Defense Against Bacterial Pneumonia*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The goal of the research is to understand pulmonary mechanisms of resistance against bacterial infections and to aid the development of new treatment strategies.
- The lab uses an aerosol murine infection model. A discussion occurred regarding the decontamination of aerosol chambers. The Skerrett lab has SOPs in place that will be reviewed by the biosafety officer.
- The inspection is pending. 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. Skerrett.
- The Committee voted unanimously to approve the draft BUA for Dr. Skerrett, pending completion of the lab inspection.

11. Stayton, Patrick, renewal, *Smart Proteins and Intracellular Delivery*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The lab investigates methods to deliver drugs/therapeutics to increase effectiveness.
- *Burkholderia thailandensis* and *Francisella novicida* are used in vitro. Animal work is conducted on a collaborator's IACUC protocol, not Dr. Stayton's protocol.
- The inspection is pending. The required trainings are also pending.
- The draft BUA letter was shown.
- The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Stayton. The Committee voted unanimously to approve the draft BUA for Dr. Stayton, pending completion of the biosafety training and the lab inspection.

12. Xu, Libin, renewal, *7-Dehydrocholesterol-derived oxysterols in SLOS: role and therapy*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request to add *Staphylococcus aureus* and *Enterococcus faecalis* for in vitro use.
- No inspection was required for this change, because the facilities have been recently inspected. 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. Xu.
- The Committee voted unanimously to approve the draft BUA for Dr. Xu.

13. Bryers, James, renewal, *Periodontal Biomaterials with BITE (NIDCR) GRANT 1 Now Adding Biomaterials that Promote Infection Immunity (NIAID) GRANT 2*

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a renewal. The investigator will use wild-type strains of *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Staphylococcus epidermidis* in vitro. Plasmid DNA and RNA will be used in mice.
- The investigator has confirmed that he will not be doing involving bacteria administered to mice.

- The lab inspection has been completed with no deficiencies remaining and 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. Bryers.
- The Committee voted unanimously to approve the draft BUA for Dr. Bryers, pending updating the BUA application and IACUC protocol to remove references to administering bacteria to mice.

14. Murry, Charles, change, AAV Gene Therapy for Heart Failure in Pigs

- The assigned IBC Primary Reviewer presented the Primary Review.
- This is a change request to use previously approved transduced human cells in a pig model under ABSL-1 housing conditions.
- The human cells have been tested and shown to be negative for bloodborne pathogens and LCMV.
- The cells will be transduced with adeno-associated viral vectors, foamy viral vectors, amphotropic gammaretroviral vectors, and/or lentiviral vectors. The adeno-associated viral vectors are adenovirus-free. The foamy viral vectors have a replication-competent virus (RCV) free packaging system. The gammaretroviral vectors have been tested and confirmed to be RCV-negative. The lentiviral vectors are third-generation.
- The standard operating procedure for administration of the cells to pigs has been reviewed and approved by a biosafety officer.
- No inspection was required for this change, because the facilities have been recently inspected. The required trainings have been completed.
- The IACUC amendment has not yet been submitted.
- 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, pending completion of the IACUC protocol.

SUBCOMMITTEE REPORTS:

15. Cassaday, Ryan, new, A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Adult Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia (r/r ALL) (ZUMA-3)

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a new clinical trial involving a previously approved cellular therapy product, genetically modified autologous cells called CAR-T cells. The investigator wants to give this to participants with acute lymphoblastic leukemia.
- The consent forms were reviewed, and the subcommittee felt that they are clearly worded and present the possible risks of the treatment in a straightforward manner.
- The required trainings have been completed. The facility where the plasmid will be administered has been inspected by a biosafety officer.
- 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.

16. Disis, Mary, new, *A Multicenter Phase II Study of Vaccines to Prevent Recurrence in Patients with HER-2 Positive Breast Cancer*

- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
- This is a new application for a clinical trial of a previously approved plasmid vaccine (WOKVAC) , a tri-antigen plasmid DNA vaccine targeting Insulin like growth factor binding protein 2 (IGFBP-2), human epidermal growth factor receptor 2 (HER2), and insulin like growth factor receptor-1 (IGF-1R) in participants with breast cancer.
- The consent forms were reviewed, and the subcommittee felt that they are clearly worded and present the possible risks of the treatment in a straightforward manner.
- The required trainings have been completed. The facility where the plasmid will be administered has been inspected by a biosafety officer.
- 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.

OTHER VOTING ITEMS:

17. Unadkat lab inspection cycle

- The Unadkat BUA for human blood, cells, tissues, and body fluids was renewed and approved in July 2016. At that time, there were many deficiencies found on the first lab inspection, and the biosafety officer visited the lab three times to help them correct the deficiencies. In September 2017, the Lab Safety Survey Team surveyed the Unadkat lab and found many deficiencies, including poor housekeeping and overfilled biohazard waste containers. In response to this inspection, the biosafety officer visited the Unadkat lab again to conduct a biosafety lab inspection. Several deficiencies were identified involving sharps not being disposed of properly and biohazard waste that was improperly packaged. The biosafety officer worked with the lab to correct these issues.
- Normally labs receive a biosafety lab inspection once every three years, or when a BUA change application is submitted. The IBC discussed these findings and decided that a more frequent lab inspection cycle is appropriate for this lab. The committee discussed the possibility of inspecting the lab every six months or every year. The committee would like the biosafety officer to inspect the lab in early January and report back to them at the January IBC meeting. At that time, they will determine the next steps.
- The Committee voted unanimously for the Unadkat lab to be inspected in January with the findings reported at the January IBC meeting.

ISSUES FROM THE FLOOR & PUBLIC COMMENTS:

There were no issues from the floor, and no public comments.

MEETING ADJOURNED AT APPROXIMATELY 12:01 p.m.