



INSTITUTIONAL BIOSAFETY COMMITTEE

UNIVERSITY *of* WASHINGTON

Meeting Minutes

Date: Wednesday, May 18, 2022

Time: 10:00 AM – 12:00 PM

Location: Zoom

- Members Present:**
1. Jim Boonyaratanakornkit, Allergy and Infectious Diseases
 2. Jason Cantera (*Community Member*)
 3. Lesley Decker, Environmental Health & Safety (*Biosafety Officer*)
 4. Richard Grant, Washington National Primate Research Center
 5. Kevin Hybiske, Allergy and Infectious Diseases (*IBC Vice Chair*)
 6. David Koelle, Allergy and Infectious Diseases
 7. Stephen Libby, Laboratory Medicine
 8. Susan Parazzoli (*Community Member*)
 9. Jason Smith, Microbiology (*IBC Chair*)
 10. 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 10:00 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. **APPROVAL OF MINUTES:**
 - The IBC Chair sought a motion to approve the minutes from the April 20, 2022 meeting.
 - A member made a motion to approve the April 20, 2022 minutes. Another member seconded the motion.
 - The committee voted unanimously to approve the April 20, 2022 meeting minutes with two abstentions.
4. **OLD BUSINESS:**
 - At the April 20, 2022, meeting, the committee approved Dr. Carr's BUA pending completion of a successful lab inspection. The biosafety officer has sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Daggett's BUA pending clarification on the use of recombinant Risk Group 2 pathogens. The biosafety officer has sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Fuller's BUA pending updates to gene inserts used. The biosafety officer has not sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Gale's BUA pending preparation of information to share with labs. The biosafety officer has sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Heshmati's BUA pending revisions to BUAA, successful completion of inspection, and IACUC review. The biosafety officer has not sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Manicone's BUA pending third generation lentiviral information and revision of BUA application and IACUC review. The biosafety officer has sent out this BUA.
 - At the April 20, 2022, meeting, the committee approved Dr. Mitchell's BUA pending revisions to BUAA and IACUC submission. The biosafety officer has not sent out this BUA.
 - At the April 20, 2022, meeting, Dr. Murphy's BUA was approved pending submission of IACUC. The biosafety officer has not sent out this BUA.
 - At the April 20, 2022, meeting, Dr. Neumaier's BUA was approved pending IACUC protocol revisions. The biosafety officer has not sent out this BUA.
 - At the April 20, 2022, meeting, Dr. Van Voorhis' BUA was approved pending preparation of information to share with lab. The biosafety officer has out this BUA.
 - At the April 20, 2022, meeting, Dr. West's BUA was approved pending successful completion of an inspection, DURC, and IACUC. The biosafety officer has not sent out this BUA.
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. Greninger removed rooms and added rooms as well as new agents HIV-1 and HTLV-1 to the BUA *Laboratory Tests in Support of HIV and SARS-CoV-2 Research and Diagnostics*.
- Dr. Averkiou received approval for a new BUA *A novel paradigm of sensitization of the tumor microenvironment with image-guided ultrasound cavitation and mechanotherapeutics for targeted HCC treatment*.
- Dr. Barker-Haliski renewed the BUA *Evaluating the anticonvulsant and disease modifying potential of investigational anticonvulsant drugs in a mouse model of infection-induced seizures*.
- Dr. Eisenberg renewed the BUA *Eisenberg's Anthropological Genetics Lab*.
- Dr. Sparkman-Yager received approval for a new BUA *Aptamer-regulated RNA switches for use in microbial engineering*.
- Dr. von Moltke added wildtype *Ruminococcus gravus* in mice to the BUA *Initiation of Type 2 Immune Responses*.
- Dr. Babu registered adding vaccine boosters with no change in biological agents to their BUA *Phase 2 Clinical Trial to Expand and Optimize Immune Coverage of SARS-CoV-2 Existing and Emerging Antigenic Space*.
- 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.

6. BSL-3 INACTIVATION REPORT

- Dr. Gale requested EM fixative (4% glutaraldehyde, 5mM MgCL₂, 1% sucrose, 0.1M sodium cacodylate) inactivation of SARS-CoV-2 infected lung samples.
- The subcommittee reviewed procedure and inactivation data provided by the lab and approved the request.
- The IBC Chair sought a motion to approve this month's BSL-3 Inactivation Report.
- A member made a motion to approve this month's BSL-3 Inactivation Report. Another member seconded the motion.
- The committee voted to approve this month's BSL-3 Inactivation Report.

7. DURC REPORT

- Dr. West received approval for use of *Burkholderia pseudomallei* and *Francisella tularensis*. This work 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 REVIEW

- a. Buckner, Frederick, renewal, *Buckner antiparasitic and antibacterial drug discovery*
 - The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies drug discovery related to pathogenic protozoan parasites and Risk Group 2 bacteria.
 - This lab works with recombinant Risk Group 2 pathogens in vitro and in mice.

- The lab was inspected with no deficiencies found.
 - 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. Buckner.
 - The Committee voted unanimously to approve the draft BUA for Dr. Buckner pending review of the IACUC protocol.
- b. Buffalo, Elizabeth, renewal, *Neurobiology of Memory***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies anatomical pathways between memory structures and ultimate manipulation of electrical activity in the brain.
 - This lab works with adeno-associated viral vectors (AAV) and lentiviral vectors in macaques.
 - A lab inspection was not required.
 - 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. Buffalo.
 - The Committee voted unanimously to approve the draft BUA for Dr. Buffalo pending review of the IACUC protocol.
- c. Bryers, James, new, *Injectable Hydrogel Depots for Self-replicating mRNA Vaccine Deliver***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the creation of injectable vaccine depots centered on patients infected with staphylococcus aureus bacterium.
 - This lab works with Risk Group 2 bacteria and self-replicating mRNA in a mouse model.
 - A discussion occurred regarding the NIH classification of the use of vaccine depots in mouse models.
 - The lab was inspected, and all deficiencies have been corrected.
 - 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. Bryers.
 - The Committee voted unanimously to approve the draft BUA for Dr. Byers with one member abstaining from the vote.
- d. Cai, Shanshan, renewal, *Innate immunity in pneumonic sepsis***
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how immune mechanisms are integrated into successful host resistance in pulmonary organs.
 - This lab works with recombinant Risk group 2 bacteria.
 - A discussion occurred regarding outstanding questions about the nature of the recombinant bacteria used by the lab.
 - The lab was inspected with minor deficiencies still pending correction.
 - 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. Cai.
 - The Committee voted unanimously to approve the draft BUA for Dr. Cai pending a response to the lab inspection findings and clarification on the nature of the recombinant bacteria.
- e. Chamberlain, Jeffery, renewal, *Gene Therapy for Neuromuscular Disorders*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies methods to treat and cure muscular dystrophy.
 - This lab works with recombinant E. coli, human cell lines, plasmid vectors and in mice and in vitro work with adeno-associated viral vectors (AAV) and lentiviral vectors.
 - The lab was inspected, and all deficiencies have been corrected.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - The IACUC protocol is still pending.
 - The IBC Primary Reviewer made a motion to approve the draft BUA for Dr. Chamberlain.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chamberlain pending review of the IACUC protocol.
- f. Chavkin, Charles, renewal, *Chavkin-Mice*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the effects of stress on motivated behavior as well as the molecular basis of addictive drug action to develop novel strategies to treat drug addiction, mood disorders and pain.
 - This lab works with human blood tissue, body fluids and cell lines, plasmids, and viral vectors including adeno-associated viral vectors (AAV) and gutless canine adenovirus in mice models.
 - The lab was inspected, and all deficiencies have been corrected.
 - 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. Chavkin.
 - The Committee voted unanimously to approve the draft BUA for Dr. Chavkin.
- g. Golden, Sam, renewal, *Functional connectomics of maladaptive social motivation and neuropsychiatric disease.*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies circuit specific mechanisms in maladaptive social motivation and their interaction with disorders like addiction and depression.
 - This lab works with adeno-associated viral vectors (AAV) in mice and in vitro as well as recombinant DNA/RNA and human blood, tissues and cell lines in vitro.
 - The lab was inspected with minor deficiencies corrected.
 - 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. Golden.

- The Committee voted unanimously to approve the draft BUA for Dr. Golden.
- h. Hotchkiss, Charlotte, new, *Umoja: Lentiviral Vectors in NHP*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies technology designed to engineer modified human T-cells inside patient bodies capable of recognizing attack cancer cells.
 - This lab works with third generation replication deficient lentiviral vectors in macaques.
 - 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. Hotchkiss.
 - The Committee voted unanimously to approve the draft BUA for Dr. Hotchkiss.
- i. King, Neil, renewal, *Institute for Protein Design: King Lab*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies computational protein design for use in recombinant expression vector systems to produce purified recombinant proteins in E. coli or mammalian expression systems.
 - This lab works with synthetic genes that encode proteins that are ultimately transformed into expression hosts such as yeast, bacteria, in vitro translation systems, and third generation lentiviral vectors which are used to produce recombinant proteins.
 - A discussion occurred regarding the use of an oncogenic insert in human cells that will be administered to mice. The biosafety officer needs to confirm with the lab if they want to do this work at BSL-2 with BSL-3 practices, get the vector tested for RCV to lower to BSL-2, or use a different vector system at BSL-2.
 - The lab inspection is scheduled for after the IBC meeting.
 - The IACUC protocol is still pending.
 - 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. King.
 - The Committee voted unanimously to approve the draft BUA for Dr. King pending clarification on the use of an oncogenic insert in lentiviral vectors, completion of a successful lab inspection, and review of the IACUC protocol.
- j. Moreno, Claudia, renewal, *Calcium signaling in the aging pacemaker*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how aging affects the function of pacemakers using cell lines and mice models.
 - This lab works with viral vectors including adeno-associated viral vectors (AAV) and 1st/2nd generation lentiviral vectors in vitro and in vivo.
 - A lab inspection has been performed and there are still open items.
 - 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. Moreno.
 - The Committee voted unanimously to approve the draft BUA for Dr. Moreno pending a response to the lab inspection items and review of the IACUC protocol.
- k. Murry, Charles, renewal, *Gene and Stem Cell Therapy in Swine*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies the development of a new therapeutic treatment of heart failure and scar triggered arrhythmias in a swine model.
 - This lab works with human embryonic stem cell culturing, use of human cells and AAV in pigs, and gene modification using CRISPR-Cas9. The human cell lines administered to pigs are tested and shown to be free of human bloodborne pathogens and lymphocytic choriomeningitis virus (LCMV).
 - The lab inspection is complete with no findings.
 - All required trainings are complete.
 - The 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. Murry.
 - The Committee voted unanimously to approve the draft BUA for Dr. Murry.
- l. Zweifel, Larry, renewal, *Genetic Dissection of the Emotional Basis of Learning*
- The assigned IBC Primary Reviewer presented the Primary Review.
 - This lab studies how genes affect brain function and behavior to better understand neurological and psychiatric disorders.
 - This lab works with adeno-associated viral vectors and replication deficient canine adenoviral vectors in vitro and in mice.
 - The lab inspection is scheduled for after the IBC meeting.
 - The required trainings are still pending.
 - The 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. Zweifel.
 - The Committee voted unanimously to approve the draft BUA for Dr. Zweifel pending completion of a successful lab inspection and completion of required trainings.

9. SUBCOMMITTEE REPORTS:

- m. Green, Damian, new, *A Safety and Efficacy Study of JNJ-68284528 (ciltacabtagene autoleucl) Out-of-Specification (OOS) for Commercial Release in Patients with Multiple Myeloma*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This study seeks to assess using an autologous chimeric antigen receptor T-cell therapy as a treatment for myeloma.
 - Human cells transduced with third generation non-HIV pseudotyped, replication deficient lentiviral vectors will be administered to humans.
 - 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.

- n. Mallhi, Kanwaldee, renewal, *A Phase 3 Study Evaluating Gene Therapy by Transplantation of Autologous CD34+ Stem Cells Transduced Ex Vivo with the BB305 Lentiviral Vector in Subjects with Sickle Cell Disease*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This study seeks to assess the efficiency of a recombinant third generation lentiviral vector expressing an anti-sickling variant of beta-globin.
 - Human cells transduced with third generation non-HIV pseudotyped, replication deficient lentiviral vectors will be administered to humans.
 - A discussion occurred about replication competent lentivirus (RCL) testing for the study product. RCL testing of the exposed patients has been done with no RCL identified.
 - All required trainings are complete.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Mallhi. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Mallhi.
- o. Wagner, Michael, renewal, *A Phase 2 Single Arm Open-Label Clinical Trial of ADP-A2M4 SPEARTM T cells in subjects with Advanced Synovial Sarcoma or Myxoid/Round Cell Liposarcoma (SPEARHEAD 1 Study)*
- Two members of the IBC served as the Subcommittee Reviewers. One of the Subcommittee Reviewers presented the Subcommittee Report.
 - This study studies genetically engineered T cell therapy as a treatment for advanced synovial sarcoma or myxoid/round cell liposarcoma.
 - Human cells transduced with third generation non-HIV pseudotyped, replication deficient lentiviral vectors will be administered to humans.
 - Completion of required trainings is still pending.
 - The draft BUA letter was shown.
 - A member made a motion to approve the draft BUA letter for Dr. Wagner. Another member seconded the motion.
 - The Committee voted unanimously to approve the draft BUA for Dr. Wagner.

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

11. MEETING ADJOURNED AT APPROXIMATELY 11:32 A.M.