THE UNIVERSITY OF UTAH

INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES

March 19, 2026
Meeting was convened at 11:00 AM
Hybrid Meeting

Voting Members Present:
☒Cecilia Gerstner (IBC Chair)
☒Jeff Clifford (IBC Vice Chair)
☒Debbie Eckert (BSO)
☒Chris Hunter (ABSO)
☒Isaac Martineau (BS Specialist)
☒Ricky Bell (IBC Member)
☒Neil Bowles (IBC Member)
☐Jessica Brown (IBC Member)
☒Allison Carey (IBC Member)
☒Scott Cho (IBC Member)
☒David Gillespie (IBC Member)
☐Talia Karasov (Plant Expert)
☒John Kriesel (HGT Expert)
☒Karla McHale (IBC Member)
☒Bart Mickelsen (IBC Member)
☒Kate Modzelewska (IBC Member)
☒Andy Phillips (IBC Member)
☒Robert Sperling (IBC Member)
☒Alton Swennes (Animal Expert)
☐David Thomas (IBC Member)
☐Michael Voight (IBC Member)
☐Tom Wachter (IBC Member)
☒Zemin Zhou (IBC Member)
☒Wendy Zhu (IBC Member)

Quorum was present; 7 are required to conduct business.

Conflict of Interest Declaration

Chris Hunter for protocol #21-26.

Review of February 19, 2026 Minutes

Motion: **Approve**
Vote for Motion: 16 in favor of the motion
3 Abstain

Old Business

#16-26 Sankar Swaminathan. Role of EBV and KSHV in Carcinogenesis (Renewal of existing protocol #59-14).

Their research studies are aimed at understanding the mechanisms by which human cancer-causing herpesviruses interact with the host cell. They study Epstein-Barr virus (EBV) and Kaposi's sarcoma-associated virus (KSHV).

Outstanding issue to be resolved which was communicated to PI through post-review memo:

- **Biosafety Manual:**
  - PI needs to remove page 46 of the biosafety manual, wince these are not applicable to their lab.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 2/26/26.

#17-26 Conan Kinsey. Resistance Mechanisms and Immuno-Oncology with Combined MAP Kinase and Autophagy Inhibition in Gastrointestinal Malignancies.

The Kinsey Laboratory is interested in combining targeted therapies with autophagy inhibition in pancreatic and gastrointestinal cancers for rapid translation to patients. Dr. Kinsey published a manuscript describing the synergistic cytotoxicity of combining MEK1/2 and autophagy inhibition in RAS/RAF mutated cancers and is the primary investigator of two investigator-initiated clinical trials for pancreatic and gastrointestinal cancers resulting from this work.

Targeted therapies have been successful in some malignancies; however, a vast majority of cancers do not respond to predicted vulnerabilities. They have demonstrated that these non-responsive malignancies likely activate protective mechanisms such as autophagy, which result in primary resistance. Dr. Kinsey's laboratory works with cancer-derived cell lines, patient-derived organoids, and patient-derived xenograft models to evaluate the mechanistic, diagnostic, prognostic, and therapeutic potential of novel targeted combinations

Outstanding issues to be addressed which were communicated to PI through post-review memo:

- **SciShield:**
  - In the Viral Vector Form for pBABe-puro:
    - Step 5, Safety:
      - *Provide details for their method of disinfection or decontamination:* 80% ethanol is still referenced. PI needs to change this reference to 70%.
- **Biosafety Manual:**
  - In Appendix 5, Section D, PI needs to provide their SOP for performing the injections into animals.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 3/2/26.

#69-25.01 Martin Distel. Amendment to add Lentiviral vector.

The lab focus is on establishing pediatric cancer models in zebrafish (Danio rerio) through genetic approaches and xenotransplantation of human cancer cells, including patient-derived cancer cells. They will generate transgenic fish through integration of vectors/plasmids using Tol2 recombinase system. Their expression systems in zebrafish are typically Gal4 and Cre-based, which allows us to target (human) oncogenes to specific cell types in zebrafish. The goal of their projects is to better understand the origin of tumors and tumor development to ultimately identify novel and better therapeutic strategies to treat pediatric cancers. Genes and drugs identified in these studies are relevant to pediatric cancer due to the high degree of conservation of genetic and molecular pathways between zebrafish and humans. Therefore, findings in zebrafish can be translated to human patients.

Outstanding issues to be addressed which were communicated to PI through a post-review memo:

- **In SciShield:**
  - Add lentivirus to the table titled "Viruses Used in Labs."
  - In the viral vector form, change the name to Lentiviral vsvg-pax2 to add clarity to the name.
  - In the viral vector form, Step 2, *Will another laboratory or a commercial supplier be involved in the production of the vector preparation?* Change answer to "yes"

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 2/24/26.

#15-24.01 Jessica Kramer. Amendment to add Candida albicans.

Synthesis of glycopolymers, polypeptides. Engineering of cell-surface proteins. Study of the epithelial glycocalyx.

Outstanding issues to be resolved which were communicated to PI through a post-screen memo.

- PI needs to edit the SOP for handling Candida albicans in appendix 5:
  - Because of the pathogenicity of Candida albicans, all manipulations need to take place in a biosafety cabinet.
  - Flames and/or intense heat is not allowed in a BSC as it can interfere with the function of the cabinet, as well as damage the HEPA filter. Alternatives to flame sterilized loops would be using disposable loops, or using a bead sterilizer. They can choose which is a better fit for their lab.
  - Secondary containment is necessary when the culture flask is on the orbital shaker, which can be as simple as a Ziploc bag

PI has not responded to post-review memo. Reminder email sent 3/11/26.

#84-24.05 Scott Hale. Amendment to add Lentiviral Vector

Their lab studies T cell responses to acute and chronic viral infections and in response to model vaccination in mice. Their goal is to understand how effective T cell responses are generated to induce long lasting protective immunity.

Outstanding issues to be resolved which were communicated to PI through post-review memo.

- **Biosafety Manual:**
  - Section B.1. The end of the lentivirus section says “no vaccines or post-exposure treatment options are available”. Remove “post-exposure treatment options” from this sentence.
  - Section B.3. says “post-exposure prophylaxis for occupational exposure with HIV-based viral vectors may include the use of antiretroviral drugs.” – Change ‘may include’ to ‘includes.’

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 2/26/26.

#35-23.03 Jennifer Weidhaas. Amendment to add project with sewer samples.

They conduct environmental engineering research with a particular focus on waterborne pathogens and the fate and transport of hazardous chemicals in the environment.

Outstanding issue to be addressed which was communicated to PI through post-review memo.
Biosafety Manual:

- In the ‘*Protocol for enriching Acinetobacter radioresistens on 13C media and flushing at NRH*’
  - In the ‘Preparations’ section. To avoid a possible horizontal drug resistance transfer, indicate only strains without antibiotic resistance will be utilized.
  - In step 7 indicate the toilet seat will remain covered for a minimum of 5 minutes to allow any aerosols to settle.

PI has not responded to post-review. Email sent 3/8/26, which the PI responded to saying they will make the changes.

Protocols for Review With 3 Year Approval

#21-26 Robin Shaw. A New Non-Canonical Role for an Alternatively Translated Ion Channel Protein.

Connexin 43 (Cx43) plays an important role in protecting the heart from ischemic injury and oxidative stress, but the underlying mechanisms behind its actions are still not well understood. Therefore, to further elucidate the cardioprotective effects of Cx43, they will use AAV9 viral vectors expressing either full length Cx43 (GJA1-43K) or one of its alternatively translated isoforms (GJA1-20K) to study their effects on cardiac injury.

All pre-screen comments were resolved and no additional concerns were raised during the meeting.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-D-4-b, III-E, III-E-3
Agent: AAV
Tissue Culture ☒ | Animal Work ☒ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☒| Antibiotic Resistance ☐
Transgenes and Sources: GST-GFP, GJA1-43K-GFP, GJA1-20K-GFP from human sources.

Agent: Adenovirus
Tissue Culture ☒ | Animal Work ☒ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☒|

Antibiotic Resistance ☐
Transgenes and Sources: GJA1-20K-V5, GJA1-43K-V5

Risk Assessment: Sharps☒ | Vortexing ☒ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☒ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☐ | Treatment Available ☐ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 16 For Motion | 3 Abstain

#23-26 Gregory Hageman. Development of Complement Modulating Therapeutics for AMD.

Age-related macular degeneration (AMD) is an eye disease generally affecting people after the age of 60. Recent genetic research has shown a direct link between mutations in CFH, CFHT, HTRA1 and LOC105378525 proteins and increased risk of AMD. Their research project will examine several aspects of the genotype/phenotype connection. They will culture commonly used human cell lines purchased from the American Type Culture Collection (ATCC) that may contain partial viral sequences used for immortalization. These cells will be transfected with recombinant DNA encoding human cDNA sequences (CFH, CFHT, HTRA1 and LOC105378525) cloned into a pcDNA3 mammalian expression plasmid. Transfections of human cell lines will be performed using standard electroporation techniques. In addition, human cDNA sequences (CFH, CFHT, HTRA1 and LOC105378525) and shRNAs will be transduced into human cell lines using replication incompetent ViraPower Lentiviral expression system (Invitrogen) using pLenti plasmid. For some difficult to transduce cell lines they will use an adeno-associated virus (AAVpro) (Clontech) expression system with replication incompetent AAV2 plasmids. All viruses, viral particles and vector systems have an extremely low risk of causing human infection in accordance with U.S Public Health Service Guidelines for biosafety level 1 or 2. Over expression of these proteins in human cells will allow us to perform experiments to understand the role of these proteins in AMD biology.

All pre-screen comments were resolved and no additional concerns were raised during the meeting.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4-a, III-E-1
Agent: AAV
Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☒| Antibiotic Resistance ☐
Transgenes and Sources: CFH, CFHT, HTRA1, LOC from human sources

Agent: Lentivirus
Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☒ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Transgenes and Sources: CFH, CFHT, HTRA1, LOC from human sources.

Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☒ | Cell Sorting☒ | Centrifuging☐ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☒ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☐ | Treatment Available ☒ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 (BSL-2)
Vote for Motion: 17 For Motion | 2 Abstain

#24-26 Adrianne Dorrance. Crosstalk between leukemic blasts and the BM microenvironment contribute to leukemic transformation.

The major goal of their laboratory is to discover and dissect the functional role of novel genes involved in leukemia stem cells (LSCs) biology, as well as studying the role of these genes in normal hematopoietic stem cells (HSCs). They are mainly focused on determining the anti-leukemic effects of EGFL7 and miR-126 knock-down in murine primary AML blasts and leukemia stem cells (LSCs), and to characterize the interaction between the LSC and bone-marrow microenvironment in initiation, development and maintenance of leukemia.

All pre-screen comments were resolved and no additional concerns were raised during the meeting.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-D-4-b, III-D-4-c-(2), III-E-1, III-E-3
Agent: Murine Leukemia Virus
Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☒ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Transgenes and Sources: EGFL7, siRNA-EGFL7 from mouse sources.

Agent: Lentivirus
Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☒ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Transgenes and Sources: shEGFL7, shmiR-126 from mouse source

Agent: Diphtheria Toxin
Tissue Culture ☒ | Animal Work ☒ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☐ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☐ | Cell Sorting☒ | Centrifuging☒ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☒ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☒ | Treatment Available ☒ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 Enhanced (BSL-2+) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 18 For Motion | 1 Abstain

#25-26 Ramiro Garzon. Molecular Studies in Hematological Malignancies. Lentivirus. Renewal.

Their research program has an overall goal to discover novel players that are critical to the initiation and maintenance of hematological malignancies, dissect their functional role, develop novel strategies to use them as biomarkers and target them to improve treatment responses. To better understand the in vivo role of tumor suppressor genes and oncogenes they utilize animal models (knockout and transgenic mouse models, respectively) to study normal and malignant hematopoiesis. They are also investigating the microRNAs and other genes associated with Graft-Versus-Host Disease (GVHD) after hematopoietic stem cell transplant by using experimental murine bone marrow transplant models.

All pre-screen comments were resolved and no additional concerns were raised during the meeting.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-D-4-b, III-D-4-c-(2), III-E-1, III-E-3
Agent: Lentivirus
Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☒ | Narrowed Tropism ☐ | Wild Type Tropism ☐|

Antibiotic Resistance ☐
Transgenes and Sources: Dancr

Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☐ | Cell Sorting☒ | Centrifuging☒ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☐ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☒ | Treatment Available ☒ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 Enhanced (BSL-2+) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 18 For Motion | 1 Abstain

#26-26 Erik Jorgensen. Synaptic vesicle recycling in rat hippocampal synapses; Genome engineering in Nematode C. elegans.

The Jorgensen laboratory is identifying the proteins that function at the synapse to release and recycle synaptic vesicles. To identify these molecules, they have undertaken a genetic analysis of neurotransmission in the nematode Caenorhabditis elegans. C. elegans is particularly advantageous for such studies for several reasons: First, mutants with defective synapses are viable and can be studied as adults. Second, they can select for mutants with defective neurotransmission using drug resistance screens. Third, they can characterize mutant synapses at the ultrastructural and electrophysiological levels. So far, the lab has identified over 30 genes that are required for normal synaptic transmission. Some of these genes are required for synaptic vesicle exocytosis and some are required for synaptic vesicle endocytosis. The precise function of these proteins is being determined using electrophysiological, biochemical, fluorescence and electron microscopic techniques.

Outstanding issues to be resolved which were communicated to PI through post-review memo.

- **SciShield:**
  - A reference to Tetrodotoxin (TTX) was found in the biosafety manual. If TTX is included with this registration, contact the biosafety office for assistance updating SciShield.
  - Update the 'Table of Cell Lines Used in Lab' to include all cell lines used in the laboratory, including primary neuronal cell lines.
  - In the Project Form 'Synaptic vesicle recycling in rat hippocampal synapses'.
    - Update the IACUC number to reflect the current protocol number.
  - On the Viral Vector Forms for AAV and Lentivirus:
    - Step 5: Safety; After disinfecting with bleach, perform a water rinse instead of, or before, rinsing with 70% ethanol to avoid bleach/ethanol incompatibility
    - Replace all references to bleach to say “a freshly prepared 1:10 dilution of bleach.”
  - In the Viral Vector Form for AAV, Step 2: Vector Production; Line 4, should read “5% CO2” instead of 5% CO.
- **Biosafety Manual:**
  - Update all references to bleach to say “a freshly prepared 1:10 dilution of bleach”
  - For any occurrences that describe disinfection with bleach followed by 70% ethanol, indicate a water rinse instead of, or before, rinsing with 70% ethanol to avoid bleach/ethanol incompatibility.
  - There are updated recommendations for post-exposure prophylaxis for lentiviral vectors. PI needs to update Section B, Background, and Section C.6.:
    - Dolutegravir 50 mg taken once a day for 7 days
    - Tenofovir disoproxil fumarate 300 mg taken once a day for 7 days.
      Important Notes:
    - These recommendations are for replication-deficient vectors.
    - Replication-competent vectors would require 28 days of treatment as with HIV.
  - Section C.1. Required Training:
    - Add EHS Viral Vector Training Course to be taken at initial assignment and every third year thereafter.
    - The link to the Institutional Biosafety Manual referenced in the final paragraph references a legacy volume of the manual. An updated link is https://ibc.utah.edu/biosafety-policies.php
  - Section C.3. General BSL-2 Laboratory Safety
    - Verify ASB 461 is a correct location for laboratory work.

- Section C.8. Work with human source materials requires an Exposure Control Plan within the biosafety manual. Incorporate Section D. Exposure Control Plan, from the attached BSL2 Biosafety Manual Template as section C.8 in the current laboratory biosafety manual.
- Section I. Experimental Procedures
  - Adeno-Associated Virus Production Protocol:
    - Rename the 'Adenovirus Production Protocol' to reference 'Adeno-Associated Virus' as Adenovirus is not included with this registration.
    - In the statement *'BSL-2 techniques are employed when generating and utilizing lentiviruses in this protocol.'* Replace 'Lentiviruses' with *'viral vectors'*
    - Update the AAV production protocol to indicate capped rotors will be used at all centrifugation steps involving viral vectors and/or human cell lines.
  - Lentivirus Production Protocol:
    - Day 5, Step 5 indicates 'primary neurons'. Clarify if the neurons are human source material.
  - Provide an SOP for the use of Tetrodotoxin (TTX) referenced in the Biological Toxin SOP referenced in Appendix 4. If TTX is not used in laboratory, delete Appendix 4
  - Provide an SOP for the experiments using C. elegans.
- Complete the Gene Editing Questionnaire located in Appendix 7 of the attached BSL 2 Biosafety Manual Template and include in the questionnaire the laboratory biosafety manual as an appendix.

- **Documentation:**
  - To comply with NIH regulations, the IBC is required to publish minutes from convened meetings, which they provide on the IBC website https://ibc.utah.edu/meeting-minutes.php . PI needs to inform us if their IBC registration contains proprietary information that cannot be included in the minutes.
  - PI needs to verify laboratory signage (BSL2/ABSL2 Warning sign) is up to date. Updated signage can be requested on SAM https://sam.ehs.utah.edu/ehsa/
  - Due to the risks of the agents used in their lab, enrollment in Occupational Medicine's Hepatitis B and Immunocompetence programs is required, regardless of vaccination status.
    - Contact Dr. Andy Phillips at Occupational Medicine for access to the health screening questionnaire in Open Range.
    - In the email, provide the lab name and all lab personnel uNIDs to Dr. Phillips.
    - Once contact with Dr. Phillips has been obtained this item is considered complete by the IBC.
  - The personnel listed below are identified as active with this registration. Provide the applicable training certificates:

Provide documentation that all personnel have completed lab-specific training within the past year. This can be accomplished by review and signing the Biosafety manual and SOPs.

  - Provide documentation that personnel have completed the EHS BSL-2/BBP training course within the past year, as determined by their job duties.
  - Provide documentation that personnel have completed the EHS Viral Vector class within the past three (3) years, as determined by their job duties.
  - As shipping is indicated in the registration. PI needs to provide documentation that personnel involved with shipping samples have completed the Shipping Category B Infectious Substances and Dry Ice Training within the past two years.
  - Information on training can be found at: https://ibc.utah.edu/training.php

Training courses can be registered on LearningHub

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-E-1

Agent: Lentivirus

Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐

Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☒ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐

Transgenes and Sources: VAMP1, SYP from rat sources

Agent: AAV

Tissue Culture ☒ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐

Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☒| Antibiotic Resistance ☐
Transgenes and Sources: NcSyt1, NbvGlut1, NbStx1a, NbMunc13A3, NbMunc13B2 from alpaca sources

Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☒ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☐ | Treatment Available ☒ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve with contingencies at Biosafety Level 2 (BSL-2)
Vote for Motion: 17 For Motion | 2 Abstain

#29-24.09 Allison Carey. Amendment to add Mycobacterium tuberculosis H37Ra.

Their lab is focused on the genetics and genomics of pathogenic mycobacteria. They are currently focused on a group of environmental mycobacteria called 'non-tuberculous mycobacteria' (NTM). NTM cause chronic and treatment-recalcitrant lung and soft tissue infections in vulnerable populations (the immune compromised, the elderly, and those with underlying lung disease). They use advanced genetic tools including transposon mutagenesis and CRISPR to interrogate the roles of bacterial genes in antibiotic resistance and virulence. They use in vitro models as well as mouse and cell culture models of infection to address these questions. One question they are interested in is how bacterial strain diversity impacts antibiotic resistance and virulence, and to address this question they work with clinically-derived isolates of mycobacteria from ARUP laboratories, lab-adapted reference strains, and environmental isolates obtained from domestic water supplies, where NTM are frequently reported to be present.

All pre-screen comments were resolved and no additional concerns were raised during the meeting.

PI Cites NIH Guidelines: III-D-1, III-D-2, III-E
Agent: Mycobacterium tuberculosis H37Ra
Tissue Culture ☒ | Animal Work ☒ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☒ | Replication Incompetent ☐ | Replication Competent ☒ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☒ | Treatment Available ☒ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 Enhanced (BSL-2+) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 18 For Motion | 1 Abstain

<u>Protocols for Review, Requiring IBC Approval Before Initiation, Transfer of rsNA into Humans</u>

#35-26 Douglas Sborov. AstraZeneca D8311C00001 (WCG) >> A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4).

Outstanding issues to be resolved which were communicated to PI through post-review memo.
Agent Administration:

- Question 5: Expand the description of sharps usage to include devices specifically used with this study. From the current description, it is unclear what sharps are used in the preparation of AZD0120.
- Question 14: Expand the description of disposal of unused doses. Indicate the use of a biohazardous waste container or directives given by the Sponsor. The Investigator Brochure indicates disposal instructions are provided in a Cell Therapy IMP Manual, which was not provided. Please indicate in the answer to this question what those disposal instructions are.

Other:

- Due to the risks of the agents used in your study, enrollment in Occupational Medicine's Hepatitis B and Immunocompetence programs is required, regardless of vaccination status.
    - Contact Dr. Andy Phillips with Occupational Medicine for access to the health screening questionnaire in Open Range.
    - In the email, provide the uNIDs of all lab personnel with potential exposure to AZD0120 to Dr. Phillips.
    - Once contact with Dr. Phillips has been obtained this item is considered complete by the IBC.

PI Cites NIH Guidelines: III-C
Agent: AZD0120 (CAR-T)
Tissue Culture ☐ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☒ | Environment Samples ☐
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☐ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☐| Antibiotic Resistance ☐
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anesthetization☐ | Restraints ☐ | Safer Sharps☐ | Enhanced PPE ☐ | Treatment Available ☐ | Vaccine Available ☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve with contingencies at Biosafety Level 2 (BSL-2)
Vote for Motion: 18 For Motion | 1 Abstain

Pending Protocols

#01-26 Ayako Yamaguchi. Functional analyses of the neural circuits underlying vocal production in Xenopus laevis.

The focus of their research is to understand how the motor programs are generated by the nervous system using frog vocalizations as a model. They have used behavioral, histological, and electrophysiological technique to analyze the vocal pathways. In addition, they are starting to use optogenetics technique by expressing optogenetics sensors/actuators in the nervous system of the frog to monitor and control the activity of neurons.

Outstanding issues to be addressed which were communicated to PI through post-review memo:

- **SciShield:**
    - In the Animal Source Survey:
        - Remove the checkbox 'Carrying no pathogens and no recombinant DNA into laboratory animals'
        - Add 'Carrying recombinant DNA into laboratory animals'
        - Save changes when complete.
    - In the Recombinant or Synthetic Nucleic Acid Molecules Survey
        - Update the chart in Q7-D-i) to reflect the work being done.
        - Update Q7-E-iii) to “No” since it doesn’t seem like Their lab is propagating the animals.
        - Update Q7-F-i) to include the work in Their lab.
    - In the Table of Cells Used in Lab:
        - Include all cell lines used in the laboratory.
    - In the Table of Tissues Used in Lab:

        - Include all tissues used in the lab.
    - In the Viral Vector Registration Form *'AAV with fluorophores'*
        - Step 5 Safety: Remove vinyl gloves from the table of PPE
        - Step 4: Change answer to “Will Their laboratory be producing transgenic or knockout animals using this vector system?” to “Yes”
    - Viral Vector Registration – G-deleted VSV encoding ArchT-GFP
        - Step 4, change answer to “Will Their laboratory be producing transgenic or knockout animals using this vector system?” to “Yes”
        - Update 'Surgical Mask' to be 'N-95 respirator'
    - Viral Vector Registration – G-deleted VSV encoding GtACR2-EYFP
        - Step 4, change answer to “Will Their laboratory be producing transgenic or knockout animals using this vector system?” to “Yes”
        - Update 'Surgical Mask' to be 'N-95 respirator'
    - Viral Vector Registration – G-deleted VSV encoding GCamp6f
        - Step 4, change answer to “Will Their laboratory be producing transgenic or knockout animals using this vector system?” to “Yes”
        - Update 'Surgical Mask' to be 'N-95 respirator'
- **Biosafety Manual:**
    - Section I, experimental procedures
        - Step I: “No personnel will be allowed to enter the BSL-2 room without the appropriate N-95 respirator during viral vector injection procedure” - the door should ideally not be opened at all during this procedure. People should not be coming in and out
        - Steps IV and VI: Change times listed so that the disinfection time is consistent (listed as 10 minutes one place and 20 minutes in the other for the same disinfectant and the same virus)
        - Step XII: Rinse centrifuge tube with water between bleach and ethanol
        - Clarify if it is the brain or the frog being transferred to the electrophysiological recording room and if the frog is being moved live but anaesthetized, clarify the container type.
        - Room 315 does not seem appropriate for live infected frogs or unfixed brains.
        - Not fixing the brains with paraformaldehyde doesn’t match the registration answers given earlier
        - Section i.5 is referenced but there is no i.5, only two i.4 sections.
        - Step XIII: Change to include a water rinse between bleach and ethanol
        - Step XIV: Since the water of the pre-injection tank was in the room where the virus was manipulated, it should still be disinfected prior to disposal down the sink.
    - In Section F.2 Laundry:
        - The address for the Hospital Laundry and Linen Services has changed from the School of Medicine. PI needs to update the address in Their biosafety manual with the following:
            - “The University of Utah Hospital can be used to clean contaminated clothing and other articles that require laundering. Linen Services can be found in the lower level of the Acute Care Building in the University Hospital, 801-581-2200.”
- **Documentation:**
    - To comply with NIH regulations, the IBC is required to publish minutes from convened meetings, which They provide on the IBC website https://ibc.utah.edu/meeting-minutes.php . PI needs to inform us if Their IBC registration contains proprietary information that cannot be included in the minutes.
    - PI needs to verify laboratory signage (BSL2/ABSL2 Warning sign) is up to date. Updated signage can be requested on SAM https://sam.ehs.utah.edu/ehsa/
    - The OSHA Bloodborne Pathogen Standards requires enrollment in the Hepatitis B program when working with human source materials, regardless of vaccination status. Contact Dr. Andy Phillips at Occupational Medicine for access to the health screening questionnaire in Open Range. In the email, provide the lab name and all lab personnel uNIDs to Dr. Phillips. Once contact with Dr. Phillips has been obtained this item is considered complete by the IBC.
    - Laboratory work with VSV requires enrollment in Occupational Medicine's Immunocompetence program. Contact Dr. Andy Phillips at Occupational Medicine at Occupational Medicine for instructions to access the program. Provide the lab name and uNIDs for all lab personnel.

    - Provide documentation that all personnel have completed lab-specific training within the past year. This can be accomplished by review and signing the Biosafety manual and SOPs.
    - Provide documentation that personnel have completed the EHS BSL-2/BBP classes within the past year, as determined by their job duties.
  - Information on training can be found at: https://ibc.utah.edu/training.php
  - Training courses can be registered on LearningHub
- **General Questions:**
  - Clarify if viral vectors (AAV, VSV) are used with this registration.
    - If viral vectors are no longer in use, contact biosafety@ehs.utah.edu for next steps directives, including a revised memorandum of corrections.
  - Clarify the locations of animal procedure and housing locations.

Lab/Protocol Closures

None

Spills and Incidents

None

Other Business

IBC Meetings from January to April will be held in HSEB 2958.

Next IBC meeting will be held April 16, 2026 in HSEB 2958.