THE UNIVERSITY OF UTAH

INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES

April 16, 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

Wendy for protocol #29-26.
Cecilia for protocol #34-26.

Review of March 19, 2026 Minutes

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

Old Business

#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 responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 4/1/26.

#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

PI responded to post-review memo, but response has not yet been verified for completion.

#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 responded to post-review memo. Response were evaluated by BSO and ABSO. Approval granted 4/13/26.

Protocols for Review With 3 Year Approval

#22-26 Niladri Sinha. Molecular mechanisms of ZAK- and GCN2-mediated signaling in response to ribotoxic stress; Molecular mechanisms of translational stress responses to cytosolic proteotoxicity; Translational control mechanisms underlying T cell activation and exhaustion.

They study key aspects of protein synthesis and translational control in healthy and diseased states. Their research explores the multifaceted roles of ribosomes as a central sensor and effector of cellular stress response. Specifically, they aim to elucidate how ribosomes detect and respond to ribotoxic stress, and identify and characterize ribosome-mediated quality control and signaling pathways that regulate cellular homeostasis and cell fate decisions in response to translational stress.

Outstanding issues to be addressed which were communicated to PI through email.

- In the Recombinant or Synthetic Nucleic Acid Molecules Survey, change Q5) to "No"
- As personnel are hired, add them to both SAM and SciShield registrations.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-E-1
Agent: Lentiviral Vector
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: sgRNA for MAP3K20, EIF2Ak1, EIF2AK2, EIF2AK3, EIF2AK4, EEF2K, ERN1, ERN2, DELE1 from synthetic 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: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve with contingencies at Biosafety Level 2 Enhanced (BSL-2+)
Vote for Motion: 18 For Motion | 2 Abstain

#28-26 Mei Yee Koh. Targeting iron metabolism in kidney cancer; Generation of HAF/SART1 Conditional Knockout Mice.

The Koh lab uses cell biology and molecular biology techniques to identify new treatment strategies for the treatment of cancer. Specifically, the lab focuses on the impact of low oxygen within the tumor micro-environment in promoting tumor progression and resistance to therapy.

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

- **In SciShield:**
  - Edit the project form for *Generation of HAF/SART1 Conditional Knockout Mice* to verify the IACUC number is provided is current. 1756 has been identified as applicable to their lab.
- **Biosafety Manual:**
  - In Section B. Training and Hepatitis B Vaccination Program, replace Animal Biosafety Level 2 Training with Viral Vector Training, which is repeated every 3 years.
  - In Section C. Agents Used in Lab,
    - Murine Leukemia Virus, PI needs to add the following medications to the Prophylaxis and Treatment Options section:
      - Dolutegravir 50 mg taken once a day for 7 days AND 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.

    - AAV8, PI needs to add theoretical risk of insertional mutagenesis in the Signs and Symptoms section.
- Add a note to Section F. Laboratory-Specific Standard Operating Procedures stating that all centrifugation will take place with sealed safety rotors or safety buckets and will be loaded/unloaded in a biosafety cabinet.

PI Cites NIH Guidelines: III-D-1, III-E, III-E-1
Agent: AAV Vector
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: Cre from mouse source

Agent: Lentiviral Vector
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: SART1/HAF, ISCA2 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 with contingencies at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 20 For Motion | 0 Abstain

#29-26 Shannon Odelberg. Identifying a nodal point for G alpha q signaling in eye disease; New Therapies to Restore Vascular Integrity During Sepsis; Targeting ARF6,AConvergence point for multiple pathways of Diabetic Retinopathy and age related Macular degeneration; The role of vasculature in MS.

Their lab studies basic vascular developmental biology (knockout and transgenic mice), to molecular relationships between inflammation and cancer via vascular endothelial cells, Cancer cells, and mice, with particular focus on small GTPase Arf6 and its effectors.

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-D-3, III-D-4, III-D-4-a, III-D-4-b, III-D-4-c-(2), III-E, III-E-1, 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: ARF6shRNA, GFP, Cre, Arf6 WT, Arf6Q67L, ARF6T27N from synthetic sources

Agent: Adenoviral Vector
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 ☐
Deletions:
Insertions:

Transgenes and Sources: Arf6, T27N, Q67L, GFP, CMV-null, CMV-GNAQ, ad-cinna1, ad Ras N17, ad Ras V12 from human sources.

Agent: Lentiviral Vector
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: NM001663.2shArf6#1, SHC002V, GPR 116, GPR 161, TRCN0000071453 SHCLNV-NM_011486 Stat3, 1 SHCLNV-NM_001663, GFP, Slit2 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 Enhanced (BSL-2+) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 19 For Motion | 1 Abstain

#30-26 Kelly Hughes. Coupling of flagellar gene expression to flagellar morphogensisi.

Genetic analysis of the biosynthesis of the bacterial flagellum and coupled gene regulatory mechanisms.

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

SciShield

- In the Pathogen Registration Form 'Salmonella Typhimurium'
    - Indicate a Biological Safety Cabinet (BSC) is used for all aerosol generating actions (e.g., vortexing and opening of tubes, centrifugation, etc.). This practice is institutional policy (see U of U Institutional Biosafety Manual) and recommended guidance from the CDC and NIH (Biosafety in Microbiological and Biomedical Laboratories, 6th addition) for BSL-2 containment.

Biosafety Manual:

- Section I. Experimental Procedures:
    - Indicate a Biological Safety Cabinet (BSC) is used for all aerosol generating actions (e.g. vortexing and opening of tubes, centrifugation, etc.). This practice is institutional policy (see U of U Institutional Biosafety Manual) and recommended guidance from the CDC and NIH (Biosafety in Microbiological and Biomedical Laboratories, 6th addition) for BSL-2 containment.

PI Cites NIH Guidelines: III-D-1, III-D-2
Agent: Salmonella typhimurium LT2 strain
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: 20 For Motion | 0 Abstain

#32-26 Natalia Harasymowicz. The role of immune cells in pathogenesis of osteoarthritis.

Dr. Harasymowicz's laboratory studies Osteoarthritis (OA), a family of diseases characterized by the degradation of articular cartilage, joint inflammation, fibrosis of the synovium and joint fat pad, as well as alterations in bone structure. Tissue inflammation driven by immune cells is suggested to play an important role in exacerbating the pathogenesis of OA. Dr. Harasymowicz's lab focuses on investigating the role of immune cells in the progression of OA and aging. They use interdisciplinary approaches including molecular, genetic, and cellular techniques to understand the precise role of the immune system in OA.

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

- **In SciShield:**
  - On the viral vector forms, safety sections for disinfection, if bleach is to be followed by 70% ETOH then a water rinse between is required to avoid chemical incompatibility.
- **Biosafety Manual:**
  - Provide an ECP. They can use Section D of the attached BSL-2 Manual Template and incorporate into section C (C.8)
  - In Section C.1 Training, the biosafety manual at the given link is out of date. For updated training information, PI needs to see the IBC training website, here: https://ibc.utah.edu/training.php
  - In Section C.3, Step 20, change the NOTE to "No untreated or non-disinfected biological agent-containing material, including recombinant and synthetic nucleic acids, should be allowed into any drain connected to the sanitary sewer system (e.g. from a sink)
  - For AAV, indicate "Yes" for 'Could the agent integrate into the genome.' Although it is unlikely, it is theoretically possible.
  - Appendix 5 SOP for Lentiviral Infection and Selection

Note: For any downstream assays that require removal of the cells from the BSC, describe how the cells will remain under containment, or indicate that the cells are lentivirus-free (have been passaged for 72 hours or longer and have undergone 5 or more media changes and/or washes) and pathogen free using the attached SOP

PI Cites NIH Guidelines: III-D-1, III-D-4-a, III-D-4-c-(2), III-E-1, 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: Lyve1 and GFP from mus musculus

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: Lyve1 from mus musculus

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) and Animal Biosafety Level 1 Stepdown (ABSL-1+)
Vote for Motion: 20 For Motion | 0 Abstain

#34-26 Katherine Ullman. Coordination of cell division: nuclear assembly and cytokinesis.

Their research projects focus on fundamental aspects of cell biology, including nuclear formation, cytokinesis, and the DNA damage response.

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

- **SciShield:**
  - In the Viral Vector Registration Form-SMART vector Inducible Lentiviral shRNAs
    - Step 1, '*Have any changes been made to the natural host range or tropism?'* Change the answer to 'Yes' due to VSV-g pseudotyping.
- **Biosafety Manual:**
  - The manual specifies a risk of HPV exposure for work with HeLa cells (Section B and Appendix 6). PI needs to note that HeLa cells have a partial HPV-18 genome integrated into chromosome 8, leading to the expression of some of the HPV-18 proteins. However, there is not any evidence for the production of HPV particles. The IBC does not require warnings of HPV exposure from HeLa cells. As with all human cells, it is possible that cultures could have any range of human pathogenic viruses due to accidental contamination.
  - The biosafety manual provided requires multiple administrative updates. The IBC suggests adopting the newest template manual to capture these updates. The current BSL2 Biosafety Manual Template is located https://ibc.utah.edu/_resources/documents/templates/biosafety_level_2__manual_template2024.docx
    - In the new manual, provide the Lentiviral Post-Exposure prophylaxis directives in the appropriate section (Section C), include lab-specific SOPs, and viral vectors maps. Contact the Biosafety Office for assistance as required.
    - If they choose not to adopt the current template, PI needs to make all of the below changes to their current manual:
  - When working with human source material (e.g. human cell lines), an Exposure Control Plan (ECP) must be included into the biosafety manual. Incorporate Section D and Appendix 10 of the template biosafety manual into their current biosafety manual. This can be included as an appendix or by creating section C.8.
  - Section B. Background.
    - Expand the background section to include a Risk Assessment, Signs and Symptoms of Infection, Prophylaxis and Treatment Options, and Methods of Disinfection and Inactivation for biologicals used in the laboratory.
    - Refer to Section C of the referenced template biosafety manual.
    - Include information relating to the Lentiviral vectors used in the laboratory.
  - Appendix 2 Post-exposure Standard Operating Procedures:
    - Provide information relative to Lentivirus and Lentiviral Vectors.
    - Incorporate the following information for lentivirus post-exposure prophylaxis:
      - Visit the Occupational Medicine Clinic. Managing occupational exposure to HIV-based viral vectors relies on the use of antivirals targeting the pre-integration steps, in order to prevent insertional mutagenesis. Post-exposure prophylaxis (PEP) should be administered as soon as possible, within 72 hours following any exposure. The following post-exposure prophylaxis are available:
        - 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. Training.
    - Update the statement in paragraph 4, 'Documentation of training will be uploaded to the laboratory registration in BioRAFT' to indicate training records are maintained in the SAM system.
  - Section E.4 Autoclave.
    - Clarify the statement 'They have lab services pick up their contaminated materials to be autoclave.'
    - Is 'lab services' a contracting service provider?
      - 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."

- Section I: Experimental Procedures:
  - This section is included with the table of contents, however, is labeled incorrectly in the provided manual.
  - Provide laboratory SOPs for work with human cell lines and the production and use of lentiviral vectors.
    - For any downstream assays, such as imaging, that require removal of the cells from the BSC, describe how the cells will remain under containment, or indicate that the cells are lentivirus-free (have been passaged for 72 hours or longer and have undergone 5 or more media changes and/or washes) and pathogen-free
  - SOPs for Lentiviral production and transduction are attached to SciShield. Include these within the biosafety manual.
- Provide vector maps for the lentiviral plasmids (including packaging and envelope plasmids) as an appendix to the biosafety manual.

- **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 with 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 individuals listed below are listed as active personnel on the Project Form(s) in SciShield. Provide the applicable training certificates:
    - Only personnel listed in the table and who have provided complete all required training requirements will be approved for work under this registration.
    - To update active personnel, PI needs to log in to SciShield and revise the personnel listed on the Project Form(s).
    - Information on training can be found at: https://ibc.utah.edu/training.php

PI Cites NIH Guidelines: III-D-1, III-D-3, III-E, 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: CHMP4C, Nup153, LaminA, LEM2, ATF6, SF3B1, SRRM2, SRRM1, SRSF2, SF2/ASF from human source

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: 20 For Motion | 0 Abstain

#36-26 Shannon Buckley-McKeown. Posttranslational regulation of normal and malignant hematopoiesis. Lentivirus, Retrovirus. BSL-2+/ABSL-1. Renewal.

Molecular mechanisms regulating leukemia and lymphoma

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

- **SciShield:**

- In the Recombinant or Synthetic Nucleic Acid Molecules Survey:
    - Question 6: Update to be 'Yes'. This will prompt additional questions 6a-6c. Likely these will be 'Yes' as well.
    - Question 7 D-i indicates the creation of transgenic animals. PI needs to clarify. If transgenic animals are created, contact the biosafety office for next steps.
- In the Table of Bacteria Used in Lab. Provide the details of the E.coli strain(s) used.
    - If these are K-12 strains update the Recombinant or Synthetic Nucleic Acid Molecules Survey, Exempt Q8 to 'Yes' and cite Appendix C-II of the NIH Guidelines
    - If these are non-K12 strains, update Q11 of the Recombinant or Synthetic Nucleic Acid Molecules Survey to 'Yes'.
- In the Table of Viruses Used in Lab, include Lentivirus in the table.
- In the Viral Vector Registration Form-Retrovirus:
    - Step 1 Vector Information: *Does their vector system include a helper virus?* Update the answer to 'Yes', as packaging cell lines provide this function.
    - Step 5 Safety: Update the PPE listed to include BSL2+ PPE consisting of Solid Front/Rear Closing lab coat, double nitrile gloves and safety glasses.
- In the Viral Vector Registration Form-Lentivirus:
    - Step 1 Vector Information: *Does their vector system include a helper virus?* Update the answer to 'Yes', as packaging cell lines provide this function.

- **Biosafety Manual:**
    - Section B. Background:
        - Step 2. Update this section to include the major risks associated with lentiviral vectors are insertional mutagenesis and local inflammation.
        - Step 3. Incorporate the following information for lentivirus post-exposure prophylaxis:
            - Visit the Occupational Medicine Clinic. Managing occupational exposure to HIV-based viral vectors relies on the use of antivirals targeting the pre-integration steps, in order to prevent insertional mutagenesis. Post-exposure prophylaxis (PEP) should be administered as soon as possible, within 72 hours following any exposure. The following post-exposure prophylaxis are available:
                - 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 B.3. Training:
        - Remove #3 as Animal Biosafety Level 2 procedures are not included with this registration.
        - Remove 'through RATS' from the second paragraph as the RATS program is no longer used for training modules.
        - Update the statement in paragraph 4, 'Documentation of training will be uploaded to the laboratory registration in BioRAFT' to indicate training records are maintained in the SAM system.
    - Section I. Experimental Procedures:
        - In Step B: 'Preparation of Concentrated Lentiviral Particles' and Step C: 'Retrovirus Transfection/Viral Collection Protocol'
            - In 'Day 5' (pg27, 28), indicate plates are disposed of in a biowaste container.
        - PI needs to provide the SOP used for tail vein injections and bone marrow studies.
    - Appendix 2: Post-exposure Standard Operating Procedure:
        - This appendix is largely redundant with Section B. Background. To avoid duplication of information, remove/archive the vector specific information contained in this appendix (pg 37, 38 of the manual).
        - Retain the Appendix title.
        - Retain all Occupational Medicine Clinic information. This information begins on page 39 and begins with 'Actions in the Event of an Exposure'.
        - Contact the biosafety office for additional clarification if necessary.
    - Delete Appendix 4. Vaccination attestation/declination forms are managed by the Occupational Medicine team.
    - Delete the Gene Editing Questionnaire, Appendix 7.

- Appendix 10: The statement relating to face shield usage is made *'If they fit, wear goggles underneath the face shield.'* (pg 63 of Biosafety Manual)
    - Remove this statement or *modify* to indicated the use of eye protection in conjunction with a faceshield is required.

- **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 with 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 individuals listed below are listed as active personnel on the Project Form(s) in SciShield. Complete the applicable training modules:
    - Only personnel listed in the table and who have provided complete all required training requirements will be approved for work under this registration.
    - To update active personnel, PI needs to log in to SciShield and revise the personnel listed on the Project Form(s).
    - Information on training can be found at: https://ibc.utah.edu/training.php

PI Cites NIH Guidelines: III-D-1, III-D-4-a, III-D-4-c-(2), 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: N-SF, GFP, MycT58A, from human sources

Agent:
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: mCherry, N-SF 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: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Table
Vote for Motion: 20 For Motion | 0 Abstain

#39-26 Jill Shea. Patient Derived Xenografts; RNA-guided CRISPR/Cas9 system to target malignant cells; Determining the Efficacy of a Novel Apatite-Based Antimicrobial Bone Scaffold for Craniofacial Surgical Applications.

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

- **In SciShield:**

- In the Recombinant or Synthetic Nucleic Acid Molecules Survey, change Q11) to “Yes”

- **Biosafety Manual:**
  - Section F: Laboratory Specific Standard Operating Procedures
    - For 'In Vivo Osteomyelitis Model and Scaffold Implantation' add the SOP for the preparation of the bacterial inoculum (Staphylococcus aureus).
- **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 program 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 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 individuals listed below are listed as active personnel on the Project Form(s) in SciShield.
    - Only personnel listed in the table and who have provided complete all required training requirements will be approved for work under this registration.
    - To update active personnel, PI needs to log in to SciShield and revise the personnel listed on the Project Form(s).

Information on training can be found at: https://ibc.utah.edu/training.php

PI Cites NIH Guidelines: III-D-4, III-D-4-b, III-E
Agent: Staphylococcus aureus (MSSA)
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 ☐
Agent: PDX
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) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 19 For Motion | 1 Abstain

#40-26 Clement Chow. NGLY1 deficiency, Characterizing ATF4 pseudogenes, PIGA deficiency, characterization of stress reponses in the context of other stresses, Genetic architecture of the in vivo ER stress response.

Their lab is focused on understanding the role of genetic variation on disease outcomes. They employ quantitative and functional tools, in a variety of model organisms, to study how genetic variation impacts basic cellular traits important to human health. Their work in model organisms will help to model and inform studies of genetic variation in the human

population. They hope to identify variation that can lead to more precise, personalized therapies, especially for rare disease.

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

- **SciShield:**
  - In the Human Source Material Survey: Edit the survey to indicate human cell lines are used for packaging viral vectors and are infected with viral vectors.
  - In the Recombinant or Synthetic Nucleic Acid Molecules Survey:
    - Q6-A Update to 'Yes' (Lentiviral vector in culture)
    - Q11 Update to 'Yes' and complete the updated question regarding Gene Drive.
  - In the Project Form *'Genetic architecture of the in vivo ER stress response'.*
    - Edit to provide the current IACUC protocol number.
    - Alternatively, update the description to indicate the mouse work has been completed and bioinformatics analyses are now ongoing. There is no active IACUC protocol at this time; however, a new IACUC protocol will be submitted prior to resuming the rodent studies described."
  - In the Project Form *'Characterizing ATF4 pseudogenes'*.
    - Verify the listed personnel is complete and includes all personnel who conduct work with Lentiviral viral vectors.
  - In the Viral Vector Registration Form (Lentivirus)
    - Step 1 "Have any changes been made to the natural host range or tropism?" Update this question to 'Yes' to reflect VSV use.
- **Biosafety Manual:**
  - In Section B. Background.
    - Expand 'Step 2' to include 'The major risks associated with lentiviral vectors are insertional mutagenesis and local inflammation.'
  - In Section C.1. Training:
    - The link provided to the institutional biosafety manual is not valid.
    - For updated training information, PI needs to see the IBC training website, here: https://ibc.utah.edu/training.php
  - 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."
  - In Section G, Experimental Procedures:
    - In the Lentivirus Infection Protocol it states, "Lentiviruses are safe reagents because they are replication deficient." This is not an adequate Biosafety risk statement and underestimates the risk of working with these viral particles. Change to, "The lentiviruses used in this lab are designed to be low risk, as there is a very high barrier to the formation of replication competent viruses. However, they are capable of one round of entry and integration into a human cell. An exposure event can lead to insertional mutagenesis at the target site."
    - At the end of Section G, identify any downstream procedures, if any, that will be conducted on the live cells. Note that for any downstream assays that require removal of the cells from the BSC, describe how the cells will remain under containment, or indicate that the cells are lentivirus-free (have been passaged for 72 hours or longer and have undergone 5 or more media changes and/or washes) and pathogen-free as indicated in the SOP for work with 'Human cell use at BSL1'
  - Appendix 2 Post-exposure Standard Operating Procedure
    - In Signs and Symptoms of Exposure/Infection with this agent: Include 'The major risks associated with lentiviral vectors are insertional mutagenesis and local inflammation.'
      - Incorporate the following information for lentivirus post-exposure prophylaxis:
        - Visit the Occupational Medicine Clinic. Managing occupational exposure to HIV-based viral vectors relies on the use of antivirals targeting the pre-integration steps, in order to prevent

insertional mutagenesis. Post-exposure prophylaxis (PEP) should be administered as soon as possible. The following post-exposure prophylaxis are available:
    - 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.
- Appendix 5 'Model Lentivirus Protocol':
    - This SOP appears to be template stock. Remove this SOP to avoid confusion with the laboratory SOP as supplied in Section G.
- Appendix 6 Testing Lentiviral Vector Stocks for Replication Competent Virus:
    - This SOP appears to be template stock. Confirm testing for replication competent viral vector stocks is carried out within the laboratory. If this testing is completed, provide a laboratory specific SOP describing the method. However, as the Lentiviral Vector is 3rd generation RCV testing is not required and this section their be archived.
- Remove Appendices 8, 9, 10 as these sections are not applicable to this manual.
- Due to the use of human source material (e.g. human cell lines), an Exposure Control Plan (ECP) must be included into the biosafety manual. Incorporate Section D and Appendix 10 of the template biosafety manual https://ibc.utah.edu/_resources/documents/templates/biosafety_level_2__manual_template2024.docx into their current biosafety manual. This can be included as an appendix or by creating section C.8.

- **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 program 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 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 individuals listed below are listed as active personnel on the Project Form(s) in SciShield.
    - Only personnel listed in the table and who have provided complete all required training requirements will be approved for work under this registration.
    - To update active personnel, PI needs to log in to SciShield and revise the personnel listed on the Project Form(s).
    - Information on training can be found at: https://ibc.utah.edu/training.php

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4-a, III-E
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: ATF4, ATF4P1, ATF4P2, ATF4P3, ATF4P4 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 with contingencies at Biosafety Level 2 (BSL-2)
Vote for Motion: 19 For Motion | 1 Abstain

#127-22.03 Yue Lu. A digital microfluidic approach to rapidly determine the sterility of biopharmaceutic delivery vesicles; digital microfluidic methods to monitor the human gut microbiota. Amendment to add new projects with many bacterial agents. BSL-2.

The Digital Pharmaceutics Laboratory aims to develop and apply state-of-the-art technologies to understand disease pathologies and treatment response as well as develop treatment strategies for cancer, infectious disease, and beyond.

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

- **In SciShield:**
    - In the Pathogen Forms under Step III Safety, change references of "10% bleach" with "a freshly prepared 1:10 dilution of bleach"
- **SOPs**
    - Change all references of "10% bleach" to "a freshly prepared 1:10 dilution of bleach"
    - SOP 5: Stool Sample Digital Microfluidic Processing, add a note in the beginning to indicate "all stool sample microfluidic processing will take place in a BSC" as done for other SOPs.

- **Biosafety Manual:**
    - Provide a separate BSL-2 Biosafety Manual for work with this secondary work location.
    - A current Biosafety Manual Template can be located at https://ibc.utah.edu/_resources/documents/templates/biosafety_level_2__manual_template2024.docx
    - In the manual include the Risk Assessment (in Section C) and SOPs (in Section F) that were provided for IBC review, after applying the above corrections to the SOPs.
    - The biosafety manual can be uploaded into SAM.

PI Cites NIH Guidelines: Exempt
Agent: Staphylococcus aureus (MSSA), Pseudomonas aeruginosa, Clostridium sporogenes, Candida albicans
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: 19 For Motion | 1 Abstain

Protocols for Review With 5 Year Approval

#27-26 Franz Vinberg. Mechanisms of dark adaptation in human and non-human primate donor eyes; Synaptic plasticity in retinal degeneration.

They work to understand mechanisms in the retina that enable vision over a wide range of light intensities and colors, and how these mechanisms are affected in major blinding diseases including age-related macular degeneration (AMD) and diabetic retinopathy.

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

PI Cites NIH Guidelines: III-D-4, III-D-4-a, III-E-3
Agent: Work with transgenic animals
Tissue Culture ☐ | Animal Work ☒ | Patient Samples ☐ | Human Gene Transfer ☐ | Environment Samples ☐
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 1 (ABSL-1)
Vote for Motion: 19 For Motion | 1 Abstain

#33-26 Marina Venero Galanternik. Mechanism of meningeal development and function.

Research in the Venero Galanternik lab focuses on the meninges, an extremely important but poorly understood set of membranous tissues that envelop and protect the vertebrate central nervous system (CNS). The meninges are essential for waste removal from the brain and brain homeostasis, and they protect the CNS from mechanical insults and infection. Meningeal dysfunction due to disease is both highly prevalent and associated with high levels of morbidity and mortality. It is estimated that nearly 3 million cases of meningitis occur globally each year, causing the death of approximately 30% of these patients, and survivors are frequently left with permanent neurological damage. Similarly, pathological meningeal waste accumulation associated with a variety of chronic diseases and with aging is highly associated with neurodegeneration and neurocognitive decline. Despite their critical roles, little is known about resident meningeal cell populations and how they work together to accomplish their important protective functions.

Outstanding issue to be resolved, which were communicated to PI through email.

- Rooms and spaces for where fish are kept need to be updated in SciShield.

PI Cites NIH Guidelines: III-D-4-a
Agent: Transgenic zebrafish
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 1 (BSL-1) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 19 For Motion | 1 Abstain

#37-26 Thomas Luo. Neural circuits underlying cognition in rodents. AAV. BSL-1/ABSL-1. New Registration.

Brains make decisions, shift attention, and learn through the coordinated activity of thousands to millions of neurons. Although individual neurons may appear noisy or disorganized, together their activity forms structured patterns that reveal how the brain computes.

The Luo Lab studies these collective dynamics using large-scale neural recordings in rats performing complex tasks, combined with machine learning models. They aim to understand how neural circuits filter incoming signals, store information, and guide actions, as well as how these computations vary across brain regions, adapt with learning, and

depend on specific cell types. Ultimately, their goal is to uncover the emergent functions of biological neural networks that give rise to intelligent behavior.

PI responded to pre-screen memo.

- **SciShield:**
- In the '*Viral Vector Registration Form-pAAV-hSyn-ACh4.3, pAAV-CB7-CI-mCherry-WPRE-RBG*'
    - Step 1. '*Does their vector system include a helper virus?*' is marked 'Yes'. Verify if a helper virus, such as adenovirus, is used. Typically, helper genes are provided via plasmid, rather than a full helper virus.
- In the Viral Vector Registration Form'-*pAAV-hsyn-NE2m(NE3.1), pAAV-CB7-CI-mCherry-WPRE-RBG*'
    - Step 1. '*Does their vector system include a helper virus?*' is marked 'Yes'. PI needs to verify if a helper virus is used.
    - Step 4. *'Will this virus (or cells transduced by this virus) be used in laboratory animals?*' Is answered 'No'. However, the description indicates animal model use. PI needs to clarify.
- In the Viral Vector Registration Forms-*'pAAV-Ef1a-DIO hChR2(E123T/T159C)-EYFP' and 'pAAV-hSyn1-SIO-eOPN3-mScarlet-WPRE'*
    - Step 4. *'Will this virus (or cells transduced by this virus) be used in laboratory animals?*' Is answered 'No'. However, the description indicates animal model use. PI needs to clarify.

PI Cites NIH Guidelines: III-D-1, III-D-4-a, III-D-4-c-(2), 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: FusionRed, mcherry, hSyn-Ach4.3, Ef1a-DIO hChR2(E123T/T159C)-EYFP, hSyn1-SIO-eOPN3-mScarlet-WPRE from synthetic 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 1 (BSL-1) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 19 For Motion | 1 Abstain

#38-26 Samuel Hobbs. Structural determination of bacterial immune proteins.

Their lab is focused on studying the biochemical details of how bacteria and their viruses (phages) interact. They are specifically interested in the mechanisms that bacteria use to sense phage infection has occurred and the mechanisms that phages use to overcome bacterial defense systems. Their primary approach involves purifying bacterial or phage proteins and using a combination of biochemical assays and structural biology (including X-ray crystallography and cryogenic electron microscopy) to determine the function of those proteins. The long-term goal of this research is to apply what they learn to human health through the development of phage therapy (using phages to fight bacterial infections in humans) and to identify mechanisms of antiviral immunity that are conserved from bacteria to humans.

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

PI Cites NIH Guidelines: III-D-2
Agent: Plasmid manipulations
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 Biosafety Level 1 (BSL-1)
Vote for Motion: 19 For Motion | 1 Abstain

Protocols for Review, Requiring IBC Approval Before Initiation, Transfer of rsNA into Humans

#43-26 Russell Butterfield. RGX-202-1101: A Phase 1/2/3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD).

PI Cites NIH Guidelines: III-C
Agent: RGX-202
Tissue Culture ☐ Animal Work ☐ Human Gene Transfer ☒
Agent Characteristics: Attenuated/Vaccine Strain ☐ | Replication Incompetent ☒ | Replication Competent ☐ | Second Generation ☐ | Third Generation ☒ | Expanded Tropism ☐ | Narrowed Tropism ☐ | Wild Type Tropism ☒| Antibiotic Resistance ☐ | AAV Based ☒ | Adenovirus Based ☐ | Lentivirus Based ☐
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐ | Oncogene ☐
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization☐ | 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: 19 For Motion | 1 Abstain

Lab/Protocol Closures

None

Spills and Incidents

Incubator spill in Saffarian Lab.

Other Business

Celebration for 15+ years of service, recognizing: Bob Sperling (32 years), John Kriesel (22 years), Neil Bowles (18 years), and Dave Gillespie (15 years)

The IBC meetings for May – Aug will be held in HSEB 3420

- May 21, 2026 11AM
- June 18, 2026 11AM
- July 16, 2026 11AM

- August 20, 2026 11AM