THE UNIVERSITY OF UTAH

INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES

January 22, 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

None

Review of November 20, 2025 Minutes

Motion: **Approve**
Vote for Motion: 14 in favor of the motion
7 Abstain

Old Business

#79-25 Gianna Hammer. Antigen Presenting Cells and Inflammation.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 1/9/26.

Protocols for Review With 3 Year Approval

#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:

- **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 [redacted] 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 [redacted] 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 https://learninghub.utah.edu/
  - BSL2 & BBP training link: https://learninghub.utah.edu/#/online-courses/b65002cc-068f-44d4-a760-2308bc1dff06
  - Viral Vectors Link: https://learninghub.utah.edu/#/online-courses/2038d73c-4bd0-4d4d-8a42-5afb8d3b14d5

- Please clarify if viral vectors (AAV, VSV) are being used or stored in the laboratory?
- Please clarify the locations of animal procedure and housing locations. Specifically, [redacted] used with these experiments?

PI Cites NIH Guidelines: III-D-1, III-D-4-a, III-D-4-b
Agent: Vesicular Stomatitis 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 ☐
Deletions: G-deleted
Transgenes and Sources: Arch T-GFP, GtACR2-EYFP, GCamp6f, dTomato from jellyfish 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: GFP from jellyfish

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 ☐| Respirator ☒
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Table
Vote for Motion: 19 For Motion | 2 Abstain

#02-26 Baoyu Liu. Beta-cell self-antigen recognition by diabetogenic CD8 T cells.

The overall focus of their research is to investigate specific antigen recognition by the immune system. They use novel biophysical methods (e.g. micropipette adhesion frequency assay and biomembrane force probe) to characterize how adaptive lymphocytes recognize their antigens in the context of viral infection, autoimmunity, and tumor immunology.

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

PI Cites NIH Guidelines: III-D-3, III-D-4, III-D-4-a, III-D-4-b, III-D-4-c-(2), III-D-8, III-E, III-E-1
Agent: Influenza A (PR8)
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: LCMV (Armstrong 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 ☐
Agent: MSCV
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: T cell Receptor from mouse source

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 with contingencies at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 17 For Motion | 4 Abstain

#03-26 Bai Luo. Genome Wide Screens Using CRISPR/Cas9; AAV Packaging. AAV; Lentivirus. BSL-2+. Renewal.

The Drug Discovery Core at the University of Utah is an established Service/Recharge center that provides compound collections for screening by University of Utah Faculty. The core also offers CRISPR knockout/knockin cell line production. In collaboration with the Mutation Generation and Detection Core, they offer a full cell line generation service from sgRNA design/construction to final cell line generation/verification. The core also offers viral packaging service, including lentivirus and adeno-associated virus packaging, titrations, concentrations and transductions of cells of interest. This includes lentivirus delivery of Cas9 and sgRNA.

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-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 ☐
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 ☐

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: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 Enhanced (BSL-2+)
Vote for Motion: 20 For Motion | 1 Abstain

#04-26 Sungjin Park. Neuron-glia Interactions for the Development and Function of the Nervous System.

They are currently investigating the signaling mechanisms in the nervous system and the sensory system. In particular, they are focusing on neuron-astrocyte communications and ECM formation.

PI has not responded to pre-screen memo.

- **SciShield:** https://utah.scishield.com/node/604003/biologicals/bioSummary
  - Submit all the changes made to SciShield by "Certifying" the registration. There is a big blue oval button that says "Certify" on the bottom of the screen when you follow the link. An email has been sent to PI from SciShield with instructions on how to accomplish this.
    - Note: Only the PI is able to certify the registration.
- **Documentation:**
  - The recombinant expression of alpha toxin from Clostridium septicum in a non-K12 strain of E. coli (such as BL21), requires registration with the NIH Office of Science Policy (OSP) according to Appendix F-I of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Contact the Biosafety Office for next steps.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-D-4-c-(2), III-E, III-E-1, III-E-3
Agent: Tetrodotoxin and Alpha 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 ☐
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: luciferase from gaussian princeps

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: Arc promoter, PGK, luciferase, GDPD2, HAPLN1, GFP, TIMP-2, HRP from jellyfish and mouse sources.

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 with contingencies at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 19 For Motion | 2 Abstain

#09-26 Martin Golkowski. Hepatocellular Carcinoma PPG; Studying kinase functions in liver cancer therapy resistance and metastasis; U-PAG Proteomics Summer Workshop.

Outstanding issues to be resolved:

- **In SciShield:**
  - In the Recombinant or Synthetic Nucleic Acid Molecules Survey, change:
  - Q6-B) to “Yes” Due to use of helper plasmids during lentiviral vector production.
  - Answer Q11.
    - The most common reasons for this question to be answered ‘yes’ include protein expression in non-K12 E. coli (such as BL21) or transfection of expression plasmids into mammalian cells.
  - In the Project Form Studying kinase functions in liver cancer therapy resistance and metastasis
  - Remove ABSL-1 containment. Animal containment is not required on this project as work is done by the PRR Core Facility.
  - Verify that personnel listed on the projects are current.
- **In Biosafety Manual:**
  - In Section B.1., Risk Assessment, for lentivirus include the risk of inflammation and integration at an exposure site.
  - In Section B.3, Prophylaxis and treatment options, include the recommended post-exposure prophylaxis for a lentiviral vector exposure to be:
    - Dolutegravir 50 mg taken once a day for 7 days AND Tenofovir disoproxil fumarate 300 mg taken once a day for 7 days. Treatment should begin as soon as possible, and definitely within 72 hours.
  - In Section B.4., Methods of Disinfection and Inactivation, change "bleach" to "a freshly prepared 1:10 dilution of bleach"
  - Section C.3: Hepatitis B vaccination records are maintained in digital format by the Occupational Medicine Team. Remove the two paragraphs, starting with “However” and ending with “Student Health Clinic.”
    - Remove Appendix 4. Hepatitis B Vaccination Attestation forms are digitally managed by the Occupational Medicine Program.
- Section C.6 Incident Reporting:
  - The contact information for the University of Utah Benefits Department is incorrect.
  - PI needs to update with correct information or remove the statement '
    - *The Benefits Department is located:*
      250 East 200 South, Suite 125

      Salt Lake City, Utah 84111

      Phone: 801.581.2169
  - In Section D.2. PI needs to add the following information: safety goggles or safety glasses must be worn, including when using a faceshield.
  - 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.”
  - The 39-page Exposure Control Plan is superfluous, and it can be removed. Section B.3., Bloodborne Pathogen Regulations, serves as the Exposure Control Plan.
- **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 the biosafety office if their IBC registration contains proprietary information that cannot be included in the minutes.
  - Verify laboratory signage (BSL2/ABSL2 Warning sign) is up to date. Contact the Biosafety Team (biosafety@ehs.utah.edu) for updated signage as needed.
  - As shipping is indicated in the registration. PI needs to provide documentation that personnel have completed the Shipping Category B Infectious Substances and Dry Ice Training within the past two years.

- Consult with Dr. Andy Phillips [redacted] at Occupational Medicine Clinic regarding enrollment in the Immunocompetence and Hepatitis B Programs. Provide him with the lab name and all lab personnel uNIDs.
- Provide documentation that personnel have completed the Bloodborne Pathogens Exposure/BSL2 training within the past year, as determined by their job duties.
    - The IBC recognizes the BBP/Needlestick awareness training module offered by U Health, this training does not have a BSL2 training component. EHS offers a BSL2/BBP combination course.
    - While the BBP component is required annually, the BSL2 training is valid for 3 years.
    - PI needs to confirm the BSL2 training date listed in the training records in SAM are resulting from the EHS BSL2/BBP course.
    - Information on training can be found at: https://ibc.utah.edu/training.php .
    - Training courses can be registered on LearningHub https://learninghub.utah.edu/

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 ☐|

Transgenes and Sources: shRNA's from synthetic sources

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: Solid Front Rear Closing Gown, Double Gloves, Safety Glasses
Motion: Approve with contingencies at Biosafety Level 2 Enhanced (BSL-2+)
Vote for Motion: 20 For Motion | 1 Abstain

#17-25.01 Jun Yang. Amendment to add AAV vector.

They are investigating the function of several genes in photoreceptors and hair cells in vitro and in vivo. For the in vivo studies, they utilize various mouse mutant models. For the in vitro studies, they will use a combination of molecular, cellular and biochemical approaches. The genes They are interested in are directly associated with human inherited retinal degeneration and hearing loss.

Outstanding issues to be resolved:

- **In SciShield:**
    - In the Project form, *Mechanistic and therapeutic studies on retinal degeneration and hearing loss using mouse,* remove all references to lentivirus, lentiviral vectors, and CRISPR/Cas9.
    - In the Human Source Materials Survey, remove references to iPSCs.

PI Cites NIH Guidelines: III-D-1, 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: CFAP418, CFAP418 point mutations, RAB28, RAB28 mutants

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 with contingencies at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 21 For Motion

#35-23.02 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.

Concerns were raised during the meeting about potentially growing up many pathogens and flushing them down the sewer. Aerosolization during the flush is a significant concern, as well as disinfecting the bathroom after the culture has been flushed.

Agent: Sewer Sample Culture
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☒ | 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: Denied
Vote for Motion: 18 For Motion | 3 Abstain

Protocols for Review With 5 Year Approval

#05-26 Martin Horvath. MutY Structure and Mechanism; Carotenoid Binding Proteins; Tail fiber proteins from tailocins.

The Horvath Lab (HL) is studying the structure and mechanism of proteins. There are three systems: (1) DNA base excision repair enzymes MutY, OGG1 and EndoIII; (2) tail fiber proteins called tailocins; and (3) carotenoid interacting proteins of the primate eye. They purify proteins expressed from recombinant bacteria, test enzyme activity with synthetic double stranded DNA (12 base pairs) and DNA:RNA hybrids, and measure the mutation rate of MutY in laboratory strain *E. coli.*

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

PI Cites NIH Guidelines: III-E
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 1 (BSL-1)
Vote for Motion: 19 For Motion | 2 Abstain

#06-26 Nichole Link. Genetics of microcephaly; RNA binding proteins regulate brain formation and function.

Their goal is to transform the diagnosis and study of neurological diseases by developing a pipeline to identify causative mutations associated with disease, decipher mechanisms of disease pathogenesis, and characterize the

function of these genes during development. Next generation sequencing has greatly accelerated the discovery of human genetic diseases, but causative mutations are often difficult to pinpoint. Model organisms can facilitate disease identification and characterization, and the fruit fly is particularly suited for this role. They established a discovery platform to investigate novel causes of microcephaly using a human centric approach. Using Drosophila, They assess the function of human variants associated with microcephaly to: 1) promote diagnoses for patients and identify novel genes associated with the disease, 2) illuminate essential pathways for normal brain development, 3) provide a model to elucidate mechanisms of development and disease, and 4) in some instances, enable development of therapeutics.

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

PI Cites NIH Guidelines: III-D-1, III-D-3, III-E, III-E-1
Agent: Transgenic drosophila
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 1 (BSL-1) and Arthropod Biosafety Level 1 (ABSL-1)
Vote for Motion: 18 For Motion | 3 Abstain

#08-26 Crystal Hicks. Production of Genetically Modified Cell Lines.

The Mutation Generation and Detection Core (MGD) Facility specializes in providing Crispr-Cas9 DNA nucleases to induce targeted mutations in a genomic region of interest. Crispr-Cas9 DNA nucleases are a cutting edge technology for performing reverse genetic studies in multiple model systems, including, but not limited to Zebrafish, Drosophila, C. elegans, Mouse, and mammalian tissue culture. The MGD Core also offers services for performing custom analyses for mutation detection and genotyping.

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

PI Cites NIH Guidelines: III-E
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 1 (BSL-1)
Vote for Motion: 18 For Motion | 3 Abstain

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

10-26 Douglas Sborov (IBC_00000397). AstraZeneca D8310C00001 (SIRB) >> A Phase Ib/II Study of AZD0120, Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR T) Therapy Directed Against CD19 and B-cell Maturation Antigen (BCMA) in Participants With Relapsed/Refractory Multiple Myeloma (DURGA-1). BSL-2

- **Notes:**
  - To evaluate the safety and tolerability of AZD0120 in participants with relapsed/refractory MM
  - To determine the recommended Phase II dose (RP2D) of AZD0120
  - CAR-T transduced by 3rd gen lenti

PI Cites NIH Guidelines: III-C
Agent: AZD0120
Tissue Culture ☐ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☒ | Environment Samples ☐

Agent Characteristics: AAV Based ☐ | Adenovirus Based ☐ | Lentivirus Based ☒ | 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☐ | 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: 10 For Motion

11-26 Brian Shayota (IBC_00000395). mRNA-3705-P101-EXT: A Phase 1/2, Global, Open-Label, Extension Study to Evaluate the Long-Term Safety and Clinical Activity of mRNA-3705 in Participants Previously Enrolled in Other Clinical Studies of mRNA-3705

- **Notes:**
  - This study is designed to assess the long-term safety and clinical activity of mRNA-3705 treatment in participants with isolated MMA due to MUT deficiency.

- **Risk Assessment:**
  - Q2. Describe the risks to Caregivers/Family Members that are being mitigated by the use of engineering controls.

PI Cites NIH Guidelines: III-C
Agent: mRNA-3705
Tissue Culture ☐ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☒ | Environment Samples ☐
Agent Characteristics: mRNA Based ☒ | AAV Based ☐ | Adenovirus Based ☐ | Lentivirus Based ☐ | 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☐ | 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 with contingencies at Biosafety Level 1 (BSL-1)
Vote for Motion: 10 For Motion

13-26 Paul Bernstein (IBC_00000396) CELESTE -- An Open-label, Multicenter, Two Part, Ascending Dose Followed by a Controlled Trial to Assess the Safety and Efficacy of a Subretinal Administration of AAVB-039 in Participants with Stargardt Disease (STGD1)

- **Notes:**
  - AAVB-039 is a recombinant adeno-associated viral (AAV8) vector
  - AAVB-039 (Dual AAV8.ABCA4)

- **Agent Information:**
  - Q2b. The registration describes the delivery of AAV via subretinal injection. Update this answer to 'Yes'
- **Documentation:**
  - You have indicated that the AAV can be shed in tears, nasal secretions, and blood. PI needs to provide a caregiver document that indicates procedures for family members/caregivers to follow to avoid exposure to these bodily fluids.

PI Cites NIH Guidelines: III-C
Agent: AAVB-039
Tissue Culture ☐ | Animal Work ☐ | Patient Samples ☐ | Human Gene Transfer ☒ | Environment Samples ☐
Agent Characteristics: AAV Based ☒ | Adenovirus Based ☐ | Lentivirus Based ☐ | 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☐ | 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 with contingencies at Biosafety Level 1 (BSL-1)
Vote for Motion: 10 For Motion

Pending Protocols

#98-25 Xinbo Yang. Electronics Scrap Recycling Advancement Prize (E-SCRAP). Cellulosimicrobium funkei. BSL-2. New Registration.

PI responded the Biosafety Office that they no longer wanted to pursue the approval and withdrew their proposal on 1/12/26.

Lab/Protocol Closures

None

Spills and Incidents

None

Other Business

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

Update on NIH Biosafety Modernization Listening Sessions

Next IBC meeting will be held on February 19, 2026.