June 19, 2025
Meeting was convened at 11:00 AM

Voting Members Present: Cecilia Gerstner (IBC Chair), Jeff Clifford (IBC Vice Chair)
Debbie Eckert (BSO), Chris Hunter (ABSO), Isaac Martineau (Biosafety Specialist), Ricky Bell (IBC Member), Jessica Brown (IBC Member), Allison Carey (IBC Member), Scott Cho (IBC Member), Dave Gillespie (IBC Member), Karla McHale (IBC Member), Alton Swennes (Animal Expert), Robert Sperling (IBC Member), David Thomas (IBC Member), Wendy Zhu (IBC Member)

Quorum was present; 7 are required to conduct business.

Conflict of Interest Declaration

Dave G has a conflict of interest with protocol #70-25

Review of May 15, 2025 Minutes

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

Old Business

#66-23.01 Jessica Brown. Amendment to add new project titled *Field Collection of Cryptococcus neoformans.* BSL-2+.

PI is still addressing the post-review.

#29-25 Jens Lohr (Cell Therapy/CellReGen). CAR-T Production.

PI responded to post-review. Responses were evaluated by BSO and ABSO. Approval granted 6/4/25.

#44-25 Shelley Lawrence. Biomimetic Macrophage Nanosponges as a Broad-Spectrum Therapeutic for Single Pathogen- and Peritonitis- Mediated Neonatal Sepsis; Optimation and Validation of a Rapid and Small Volume Pathogen Diagnostic Tool for HCMV.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **SciShield:**
  - On the Pathogen Form for E. coli O18
    - Step 3 Safety: Biocontainment Animal Housing is marked “No.” Since they are using these bacteria in mice, change to ‘yes.’
  - On the Pathogen Form for Streptococcus agalactiae
    - Step 3 Safety: Biocontainment Animal Housing says “N/A.” Since they are using these bacteria in mice, change to ‘yes.’
    - Step 3 Safety, it is stated that there are no health restrictions for handling the agent. Consult Dr. Andy Phillips [redacted] at Occupational Medicine to discuss health restrictions or warnings to immunocompromised workers regarding the risk factors of working with this agent.
  - Contact the biosafety office (biosafety@ehs.utah.edu) to add ABSL2 housing space in the registration.

- **Biosafety Manual:**

- In Section I. Experimental Procedures:
  - In the SOPs for E.coli and GBS administration to animals, indicate if injections are done in a biosafety cabinet.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 5/30/25.

#50-25 Sihem Boudina. Mechanisms of Fat Expansion and the Metabolic and Cardiovascular Alterations Associated. Lentivirus, Retrovirus, Adenovirus, AAV. BSL-2+/ABSL-1. Renewal.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- In SciShield:
  - In the Viral Vector Form-recombinant adeno-associated viruses
    - In this form 'adenovirus' is referred to in multiple locations. Clarify if adenovirus (AdV) or adeno-associated virus (AAV) is used in these experiments. If AAV is used:
      - In Step 1: Update the virus type to be Adeno-Associated Virus.
      - There are many mentions of adenovirus (AdV) instead of adeno-associated virus (AAV). PI needs to clarify which of these viral vectors will be used. If AAV, change all information on the form to be relevant for AAV. If adenovirus, PI needs to archive the current form and create a new form for the adenovirus.
    - If Adenovirus is used in this context, contact the Biosafety Office (biosafety@ehs.utah.edu) for next steps.
- Biosafety Manual:
  - On the 'Biological Agents Used in this Laboratory' (page 3), add "storage only" after both retrovirus and lentivirus. Replace "recombinant adeno-associated viruses" with "adenoviruses."
  - In the Signature and Acknowledgement of Risk (pg.4) the review date is indicated as September 05, 2025. PI needs to clarify and correct.
  - In the Table of Contents, correct the section header to match the associated section in the manual (e.g., the table of contents indicates section F. to be 'General BSL-2-Enhanced Laboratory Practices, Including Engineering and Work Practice Controls' However, this section is labeled as 'Laboratory-Specific Standard Operating Procedures' in the manual)
  - In Section D, "Agents Used in Lab," add information for adenovirus.
  - In section F. Laboratory-Specific Standard Operating Procedures.
    - Add a statement to the SOPs indicating the lentiviral and retroviral vectors are maintained as 'Archival storage only. Contact the IBC prior to use'
    - Provide an SOP for the use of adenovirus.
  - Provide, as an appendix, Viral Vector maps for viral constructs in the laboratory (i.e., Adenovirus, Adeno-associated virus).

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 6/4/25.

#51-25 Amandine Chaix. Diet, lipids, metabolism, obesity, and cancer. Lentivirus. BSL-2/ABSL-1. New Registration

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **SciShield:**
  - In the table of Bacteria Used in Lab: Add E. coli strains used for plasmid expression.
  - In the Recombinant or Synthetic Nucleic Acid Molecules Survey:
    - If they are using non-K-12 strains of E. coli, under the 'Form Questions' tab, change the answer of Question 11 to 'yes' and indicate the use of plasmids in non-K12 E. coli in the text box.
    - If they are using K-12 strains of E. coli, under the 'Exempt Experiments' tab, change the answer of Question 8 to 'yes' and cite Appendix C-II of the NIH Guidelines in the text box.
  - Archive the Viral Vector Registration Form for AAV.

        - This work does not include laboratory specific information relating to AAV usage, and the IBC is not willing to review or approve it in this generic form. When ready to have this work reviewed, PI needs to submit an amendment for AAV approval when details can be provided.
        - Remove references to AAV from the SciShield registration and biosafety manual.
    - In the Project Form 'Diet, lipids, metabolism, obesity and cancer'
        - Clarify the source of the human breast cancer cell line.
    - In the Microbial Agents Survey, remove reference to adenovirus.
- **Biosafety Manual:**
    - Remove references to adenovirus usage as adenovirus is not contained in this registration.
    - Clarify if unfixed cells will be used outside of the biosafety cabinet (i.e., during step 7 of the 'Transduction of cells' SOP).
        - If unfixed cells are used out of containment, incorporate the attached 'Human cell use at BSL-1 SOP'
    - Remove SOPs relating to animal injections as this registration does not currently contain procedures which require injections to animals.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 5/21/25

#54-25 Wes Sundquist. HIV1 assembly, budding, maturation, and restriction; RetroCHMP3 blocks budding of ESCRT-dependent viruses; Host pathogen interactions and innate immune responses to HIV; ESCRT-III Cofactors in Cell Division; Characterization of non-lytic release of adeno-associated virus. HIV, Murine Leukemia Virus, Vesicular Stomatitis, AAV. BSL-3. Renewal.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **In SciShield:**
    - PI needs to add the strain of E. coli used in the lab to the table titled "Bacteria Used in Lab."
    - The use of replication-competent vesicular stomatitis virus is indicated in the 'Viruses Used in Lab' table, the 'RetroCHMP3 blocks budding of ESCRT-dependent viruses' project form, and a viral form. However, the biosafety manual does not include its use. If it is no longer used or stored in the lab, PI needs to remove it from the virus table and project form and archive the viral form.
    - There is a viral vector form indicating the use of LentiCRISPR.v2 for targeting host genes involved in viral latency. However, that does not agree with the Gene Editing Questionnaire in Appendix 6 of the biosafety manual. PI needs to archive the viral form it if is no longer used or stored in the lab.
- **In the Biosafety Manual:**
    - PI needs to remove Black Box Warnings from Section B that do not apply to ytheir lab.
    - PI needs to remove Animal Biosafety Level 2 trainings from Section C.
    - If replication competent VSV is used in the lab, PI needs to replace the risk assessment for VSV "as a helper vector" in Section D for that of replication-competent VSV.
    - If lentiCRISPR v.2 is used in the lab, PI needs to update Appendix 6, Gene Editing Questionnaire.. If it is not used in the lab, PI needs to remove references to it from the biosafety manual.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 6/9/25.

#55-25 Judson Torres. Analysis of melanocyte and melanoma RNA, protein and DNA; Analsysis of melanocyte and melanoma cell behavior; Manipulation of primary human melanocytes and melanoma cells. Lentivirus. BSL-2+/ABSL-2. Renewal.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **In SciShield:**
    - Add a brief description for lentiviral injections into mice to the project form titled "Manipulation of primary human melanocytes and melanoma cells"
        - They can use the description found in Viral Vector Form for pLVX which reads "Established genetically engineered mouse models of melanoma will be used. Tumors will be induced to grow on the skin of the animals. Once tumors are established, they will be topically transduced with lentiviral particles expressing cDNAs that are hypothesized to either inhibit or promote

tumorigenesis. The rate of tumor growth will be monitored until the end point of the experiment or mouse shows signs of distress"
        - Change the containment in this project from ABSL-2+ to ABSL-2. The University of Utah does not have a definition or designation for ABSL-2+ currently.
- **In the Biosafety Manual:**
    - In section B.2 Black Box Warnings, PI needs to remove the ones not applicable to ytheir lab.
    - In Section B.5:
        - Add Viral Vector Training upon initial assignment and every 3 years
        - Add Animal Biosafety Level 2 Training upon initial assignment and every 3 years
    - 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 ytheir 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."

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 5/23/25.

#58-25 Jared Rutter. MIDAS: Mass-spectrometry-based analysis of metabolism; Pyruvate Metabolism in Health and Disease; ADVANCING NOVEL CYANIDE COUNTERMEASURES; Mitochondrial Biochemistry: From Mechanisms to Disease; Substrate and functional characterization of orphan solute carriers. AAV, Lentivirus, Murine Leukemia Virus. BSL-2+/ABSL-1+. Renewal.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **In SciShield:**
    - Verify that personnel listed are up to date. They see some training records for laboratory staff who are not associated with any projects in SciShield. Only those listed on the projects will be approved to work in BSL-2 conditions on the Approval Letter.
    - Are they using Lemur tissue in ytheir lab? If not, PI needs to remove the Non-Human Primate Source Materials Survey.
        - If they are using them, PI needs to provide the source of the tissue.
    - Are they using AAV in animals only or are they using it in cell culture as well? PI needs to add a statement to the Viral Vector Form pAAV regarding its use.
    - The biosafety manual references alpha-hemolysin toxin. If they are still using this agent, PI needs to fill out the Biological Toxins Survey, and add it to the table titled "Biological Toxins Used in Lab"
    - Remove references to handling transduced cells at BSL-1 after 5 media changes over a 72-htheir period. These references are found in:
        - Viral Vector Registration Form pQXCIP, Step 4
        - Viral Vector Registration Form pLenti-Puro, Step 4
        - Viral Vector Registration Form LentiCRISPRv2-GFP, Step 4
        - Viral Vector Registration Form pLenti-BLAST, Step 4
        - Viral Vector Registration Form pQXCIZ, Step 4
        - Viral Vector Registration Form pLKO.1-Puro, Step 4
        - Viral Vector Registration Form pLVX-TetONe-Puro, Step 4
        - Viral Vector Registration Form pLenti-sgRNA-Puro, Step 4
        - Viral Vector Registration Form pMCSV, Step 4
        - Viral Vector Registration Form LentiCRISPRv2-BlastR, Step 4
        - Viral Vector Registration Form pCW57.1, Step 4
    - Alternatively, if they wish to work with these cells at BSL-1, they will need to incorporate the attached SOP into their biosafety manual and into their laboratory practices.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 5/23/25.

#78-23.01 Carol Lim. Novel Re-engineered p53 Hybrid for Gene Therapy of Hepatocellular Carcinoma. Adding Ad5/F35 and AAV8. Amendment.

Outstanding issues that were to be resolved and were communicated to PI in post-review memo:

- **In the Biosafety Manual:**
  - Section C.4
    - Step 6, remove 70% ethanol wipe after spraying bleach since these are incompatible reagents that will produce a small amount of chlorine gas. Follow up with a water wipe after bleach instead.
    - Step 16 PI needs to add that they will decontaminate the outside surface of the beaker when it is removed from the biosafety cabinet.
    - Step 18, vacuum traps must be changed twice a week.
    - Step 20, PI needs to specify the disinfectant used.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 5/20/25.

#86-23.02 Zak Davis. Amendment to add CAV and G-Deleted Rabies Viral Vector.

Instead of sending a post-review memo, the BSO met with PI to discuss safety concerns and the safety record of the use of G-deleted rabies virus vectors.

Protocols for Review, Requiring IBC Approval Before Initiation

#49-25 Hamid Ghandehari. Water soluble polymers to target tumor-associated extracellular matrix for delivery of MMP inhibitors, Biological Fate and biocompatibility of dendritic and silica-based nanoconstructs; Localized delivery of glycosaminoclycan ethers for the treatment of radiation- induced proctitis; Bioinks for 3D-bioprinting of Vascular grafts; Targeted Delivery of Anti-inflammatory Agents for Treatment of Chronic Rhinosinusitis; Development and preclinical assessment of local transdermal delivery systems for chemoprevention of nevus formation and melanoma; Optimizing Drug Exposure in Patients Supported with Extracorporeal Membrane Oxygenation; Liposomal Delivery of MS4A3 mRNA For Treatment of Chronic Myeloid Leukemia.

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

PI Cites NIH Guidelines: III-D-1, III-D-2, III-D-3, III-E
Agents: Pseudomonas aeruginosa, Staphylococcus aureus, Adenovirus
Transgenes and Sources: ADeasy GFP – From Jellyfish
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☐ | Vortexing ☒ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization☐ | Safer Sharps☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 14 For Motion
1 Abstain

#61-25 Michael Pulsipher. Developing CAR-T immunotherapy for pediatric tumors.

They are proposing to investigate strategies to improve CAR-T function beyond ALL.They aim to study:
1) Tumor microenvironment: They have generated a murine version of Disialoganglioside (GD2) CAR-T cells and established an immunocompetent murine model of neuroblastoma. In contrast to the immunocompromised mouse model, transgenic and syngeneic models of neuroblastoma develop tumors that contain immune compartment. They propose to study the alteration in the immune compartment of TME in mice treated with murine CAR-T cells. To this goal, they have developed a cutting-edge tool based on CyTOF immunophenotyping that will assist in detecting critical changed in the tumor microenvironment. They also propose to investigate the efficacy of murine CARs in these models and determine the optimal signaling system that produces the most efficacy in the immune-competent environment.

2) Lack of ideal tumor-associated antigens and risk of CAR-T cells toxicity against nonexclusive antigens: They have generated gated CAR-T cells based on the combinatorial strategy that targets two antigens in a sequential and logical manner. These CAR-T cells don't harm cells that express one of two target antigens and only show killing if both antigens on the cell membrane are presented. Gate CAR-T cells can target tumors that lack exclusive antigens by targeting a unique combination of two antigens that identify that tumor. Gated CAR-T cells have significantly higher specificity and precision in targeting tumor cells. They are proposing to investigate the gated strategy for pediatric solid tumors and leukemia, including neuroblastoma and acute myeloid leukemia.
3) Short live CAR-T cells and lack of CAR-T cell persistence. Lack of persistence is multifactorial and varies for each tumor model. Lack of adequate stimulation, low target density on tumor cells, an intrinsic characteristic of each particular T cell signaling responsible for T cell exhaustion and impact of tumor microenvironment on T cell are some of the factors that impact T cell persistence. They are proposing to investigate the intrinsic extrinsic factors that impact CAR-T persistence. They aim to identify the intervention that could tip the balance in favor of T cell longevity and improve overall CAR-T function.

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

PI Cites NIH Guidelines: III-D-1, III-D-4-a, III-D-4-(c), III-E-1, III-E-3
Agents: Lentivirus
Transgenes and Sources: CAR from human and mouse. Fluorescent marker from jellyfish.
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☒ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization☐ | Safer Sharps☐
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: 15 For Motion

#62-25 John Kriesel. Investigating Intrathecal Antibodies Against Twenty Bacteria in the Spinal Fluid From Patients With Demyelinating Diseases.

Clinical Virology, DNA/RNA Sequencing, Serology

Outstanding issues to be addressed:

- **Biosafety Manual:**
  - Multiple agents are found in SciShield, which are not described in the biosafety manual, Section C.
    - Bacteria:
      - Aerococcus spp.
      - Peptostreptococcus spp.
      - Prevotella spp.
      - Parabacteroides spp.
    - Fungi:
      - Nakaseomyces
      - Debromyces
    - Viruses:
      - CMV
      - EBV
      - Herpes Simplex Types 1 and 2
      - Human herpesvirus Type 6 and 7
      - Tobamovirus
  - If they are using these agents, PI needs to update ytheir biosafety manual to include them.
    - Include these agents in the table of Biological Agents Used in this Laboratory(pg3)
    - Provide information in Section C for these agents.

- Provide an SOP for the use of the fungi and viral agents in Section F of the manual.

PI Cites NIH Guidelines: N/A
Agents: Haemophiles parainfluenzae, Streptococcus spp., Bacteriodes spp., Alistipes finegoldii, Capnocytophaga ochracea, Erysipelothrix rhusiopathiae, Fusbacterium nucleatum, Parabacteroides distasonis, Pseudomonas aeruginosa, Odoribacter, Wolbachia, Stigmatella, Herpes Simplex 1 & 2, Emmonsia ustilago
Transgenes and Sources: N/A
Tissue Culture ☒ Animal Work ☐
Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐ | Storage of Agents ☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization☐ | Safer Sharps☐
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: 15 For Motion

#63-25 Matthew Wachowiak. Dynamics and Modulation of Glomerular Coding in the Olfactory Bulb.

The goal of their research is to understand sensory encoding and brain processing of olfactory information.

Outstanding issues to be addressed:
- **SciShield:**
  - Verify the list of personnel attached to the Project Form is complete.
    - The '*Viral Vector Form – AAV2'* contains personnel not listed in the Project Form.
- **Biosafety Manual:**
  - In Appendix 1 (pg18) [redacted] is listed as an emergency contact. However, [redacted] is not listed as personnel. PI needs to clarify and/or update as necessary.
  - In section I (pg14) Update the text 'Biosafety Officer (EHS): Neil Bowles'
    - Remove the name 'Neil Bowles' from the template as Dr. Bowles is no longer affiliated with the University.

PI Cites NIH Guidelines: III-D-4, III-D-4-a, III-D-4-c-(2), III-D-8
Agents: AAV, CAV2
Transgenes and Sources: ChR2 from green algae; GCaMP from synthetic source; GFP from jellyfish
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization☐ | Safer Sharps☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve at Biosafety Level 1 (BSL-1) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 14 For Motion
1 Abstain

#67-25 Alli Weis. Bacterial modulation of intestinal diseases centered on mucosal and tumor immunology.

Microbiology, immunology, tumor immunology.

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-D-4-c-(2), III-E-3
Agents: Fusobacterium nucleatum, Citrobacter rodentium, Clostridium, Salmonella typhimurium, Bacteroides uniformis, Bacteroides fragilis, Akkermansia muciniphila, Candida albicans

Tissue Culture ☐ Animal Work ☒
Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☐ | Safer Sharps☒
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: 15 For Motion

#68-25 Albert Park. Cytomegalovirus Induced Hearing Loss Pathogenesis; Does HCMV Generate Neutrophil Extracellular Traps; Cochlear implant modeling in the murine inner ear; Understanding childhood cholesteatoma.

Understand the pathogenesis underlying viral causes of hearing loss and model cochlear implants in mice in order to understand collateral damage associated with physical implantation and how this relates to human CI outcomes.

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

PI Cites NIH Guidelines: III-D-4-a, III-D-4-b
Agents: Cytomegalovirus, Murine Cytomegalovirus
Transgenes and Sources: GFP from jellyfish
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☒ | Sonicating☐ | Cell Sorting☒ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☐ | Safer Sharps☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Motion: Approve at Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 14 For Motion
1 Abstain

#69-25 Martin Distel. Modeling Pediatric Cancer in Zebrafish; Generation of transgenic zebrafish through single cell injections. Injecting transduced cancer cells into fish embryos.

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

Outstanding issues to be addressed:

- **SciShield:**
  - In the Project Form 'Modeling Pediatric Cancer in Zebrafish':
    - Change the containment to BSL-2.
- **In the Biosafety Manual:**
  - For the plasmids being injected into zebrafish, provide plasmid maps as an appendix, and update the Table of Contents to include these maps.
  - Delete the sections which are not pertinent to ytheir research, specifically the protocols detailing determining the infectious units and transduction of cells since the Pulsipher lab should be doing this (p. 42-44).
  - Provide ytheir SOP for injecting cells into zebrafish in the lab specific SOP section.

PI Cites NIH Guidelines: III-D-4, III-D-4-a
Agents: Transduced cells into zebrafish embryos
Tissue Culture ☒ Animal Work ☐
Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☐ | Safer Sharps☐
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: 15 For Motion

#70-25 Randy Jensen. A Rat model of pseudoprogression; Knocking down HIF-1a orthotopically via adenovirus and SELP; The role of Hif-1a in meningioma growth in vitro and in vivo; HIF-1a knockout with CRISPR/Cas9.

The Jensen lab investigates hypoxia in the context of glycolysis in gliomas and meningiomas, as well as developing animal models of pseudoprogression

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-E, III-E-1, III-E-3
Agents: Adenovirus, Lentivirus
Transgenes and Sources: Lenti – CAS9 from human; GFP from jellyfish; Hif-1a gRNA from human. Adeno – shRNA from human.
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☒ | Sonicating☐ | Cell Sorting☒ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☒ | Safer Sharps☒
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+) and Animal Biosafety Level 2 (ABSL-2)
Vote for Motion: 14 For Motion
1 Abstain

#71-25 Ademuyiwa Aromolaran. Unraveling Molecular Mechanisms of Cardiac Metabolic Disorders and Arrhythmias; Role for Leukotrienes in Type-2 Diabetes Related Ventricular Arrhythmias.

Metabolic disorders (including obesity, diabetes, lipotoxicity and inflammation) predispose to adverse electrical and structural remodeling leading to vulnerability to arrhythmias (atrial fibrillation, long QT syndrome), and ultimately the transition to heart failure and sudden cardiac death. This suggests that the obesity epidemic and related pathologies pose a significant public health problem, with over one-third of the world population being either overweight or obese. The underlying molecular mechanisms involved in this physiological link are poorly understood. However, if They have a good understanding of the cellular signaling pathways that are adversely remodeled in metabolic disorders, They may be able to develop more effective therapeutic and dietary interventions that may help to improve the longevity and quality of life of patients.

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

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4, III-D-4-a, III-E-1
Agents: Adenovirus
Transgenes and Sources: Herg1A, Herg1B, KCNQ1, KCNE1, Kv1.5KvBeta2, AMPK, PI3K, PP2A, Rab 4/11 from human
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒

Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☒ | Safer Sharps☒
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: 15 For Motion

#03-23.01 Baoyu Liu. Amendment to add MSCV.

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-8
Agents: MSCV
Transgenes and Sources: T-cell receptor from mouse
Tissue Culture ☒ Animal Work ☒
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☒
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☒ | Anaesthetization ☐ | Safer Sharps☒
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: 15 For Motion

#22-24.01 Lisa Lesniewski. Amendment to add diphtheria toxin. BSL2/ABSL1+.

Dr. Lesniewski's general laboratory interests include trying to understand how aging modulates the susceptibility of the vascular and metabolic systems to high fat feeding/obesity and to understand how aging modifies atherosclerotic burden and severity. Within these general research areas, Dr. Lesniewski examines the role that adipose inflammation plays in inducing systemic metabolic and vascular dysfunction with aging and high fat feeding, as well as the role of adipose tissue a in this systemic dysfunction. To examine these interests, Dr. Lesniewski utilizes dietary and genetic manipulation of rodent models to examine whole body and in vitro metabolic and vascular function. In addition, Dr. Lesniewski utilizes genetic and surgical models of atherosclerosis to elucidate novel pathways that modulate atherosIcerotic burden and severity across the lifespan.

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

PI Cites NIH Guidelines: III-D-4-b
Agents: Diphtheria Toxin
Tissue Culture ☐ Animal Work ☒
Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☒ | Sealed Rotor or Safety Buckets☐ | Anaesthetization ☐ | Safer Sharps☐
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+, 72 hours)
Vote for Motion: 15 For Motion

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

#65-25 Paul Bernstein (IBC_00000388). PBI-AMD-002 - STUDY OF VOY-101 IN SUBJECTS WITH ADVANCED NON-NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (JOURNEY).

VOY-101 is intended for the treatment of non-neovascular AMD in individuals with at least one complement factor H (CFH) risk allele.
By delivering protective CFHT protein to augment and restore tight complement regulation, VOY-101 is a novel, gene therapy approach to modulate CAP activation at the RPE/Bruch's membrane/choriocapillaris interface with the goal of halting or delaying AMD progression in
Chr1-risk AMD patients.

Outstanding issues to be addressed:
Agent Administration:

- In Section A.5., the IBC only allows recapping of needles when absolutely necessary. Needles (with attached syringes) should be disposed of in biohazard sharps waste containers immediately after use. The committee feels this protocol can be performed without needle recapping. PI needs to adjust the protocol to avoid the risk of recapping.

Training and Documentation:

- PI needs to have Pharmacy staff and other personnel involved with the preparation and administration of the agent consult with Dr. Andy Phillips [redacted] at Occupational Medicine Clinic regarding enrollment in the Immunocompetence Program. Include a statement or copy of correspondence into the documents section of ERICA.
- Provide training documentation for [redacted] to indicate they have received BBP training within the past year. The provided records are too old.

PI Cites NIH Guidelines: III-C
Agents: VOY-101
Tissue Culture ☐ Animal Work ☐
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization ☐ | Safer Sharps☒
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: 11 For Motion
12 Abstain

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 6/2/25.

#66-25 Ahmed Rayes. EN-374-101 A Phase 1/2 Open-Label, Single-Ascending-Dose Study of EN-374, a Helper-Dependent Adenoviral-Based Gene Therapy, in Participants with X-Linked Chronic Granulomatous Disease.

Primary Objective: To evaluate the safety of the EN-374 treatment regimen (HSC mobilization, immune prophylaxis, EN-374 dose and administration, and enrichment of HSCs with O6BG/TMZ)

Outstanding issues to be addressed:
Agent Information:

- Q6. Update the containment to be BSL2

Agent Administration:

- Q1 indicates agent will be prepared at Primary Children's Hospital. Q12 indicates there is a Part 1 (in adults) and Part 2 (in pediatric patients). Does this application include Part 1, administration in adults? And, if so, will the agent still be prepared at Primary Children's Hospital?
- Q10 indicates sharps will be used and techniques for safe use. PI needs to add the type of sharps that are used.

Risk Assessment:

- Q2 indicates a risk of exposure to caregivers. Given that the vector may shed from patients, and that the recombinant genes are capable of integrating into host cells, it seems appropriate for caregivers to take precautions to avoid exposure to the patient's bodily fluids. PI needs to provide a Caregivers document.

Training and Documentation:

- PI needs to have Pharmacy staff and other personnel involved with the preparation and administration of the agent consult with Dr. Andy Phillips [redacted] at Occupational Medicine Clinic regarding enrollment in the Immunocompetence Program. Include a statement or copy of correspondence into the documents section of ERICA.

PI Cites NIH Guidelines: III-C
Agents: EN-374
Tissue Culture ☐ Animal Work ☐
Risk Assessment: Sharps☒ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization ☐ | Safer Sharps☒
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: 11 For Motion
12 Abstain

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted on 6/17/25.

Protocols for Review, Requiring IBC Notice Simultaneous with Initiation

#60-25 Markus Babst. ER-PM contact sites and maintenance of PM tension; Small molecule inhibitors of LAT1. Human cell lines. BSL-2. Renewal.

PI Cites NIH Guidelines: III-E
Agents: Plasmids into human cell lines.
Tissue Culture ☒ Animal Work ☐
Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☒ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization ☐ | Safer Sharps☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Approved at Biosafety Level 2 (BSL-2)

#73-25 Ofer Rog. Structure and dynamics of meiotic chromosomes. Plasmids with C. elegans. BSL-1. Renewal.

PI Cites NIH Guidelines: III-E.
Agents: Plasmids in C. elegans
Tissue Culture ☒ Animal Work ☐

Risk Assessment: Sharps☐ | Vortexing ☐ | Sonicating☐ | Cell Sorting☐ | Centrifuging☐
Risk Mitigation: Biosafety Cabinet☐ | Fume Hood☐ | Sealed Rotor or Safety Buckets☐ | Anaesthetization ☐ | Safer Sharps☐
Disinfectant: Freshly Prepared 1:10 Dilution of Bleach
PPE: Laboratory Coat, Gloves, Safety Glasses
Approved at Biosafety Level 1 (BSL-1)

Pending Protocols

#64-25 Jessica Sewell. The neural basis of sickness behavior. AAV into animals. BSL-1/ABSL-1. Renewal

They study the neurons that control sickness behaviors in mice.

PI requested more time to respond to pre-screen memo and to be reviewed in July.

- **SciShield:**
  - In the Recombinant or Synthetic Nucleic Acid Molecules Survey:
    - Change Q2) to Yes since they are working with recombinant diphtheria toxin subject to Section III-B-1 of the NIH Guidelines. Continue coordinating with the Biosafety Office to submit an approval request to NIH OSP. Ultimate IBC approval will be contingent on NIH OSP approval.
- **In the Biosafety Manual:**
  - Provide viral vector maps as Appendix 7
- **Documentation:**
  - 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.
    - Information on training can be found at: https://ibc.utah.edu/training.php
    - Training courses can be registered on Bridge https://utah.bridgeapp.com/learner/category/100

Lab/Protocol Closures

None

Spills and Incidents

[redacted] lab needlestick – determined to be non-significant as it was from a blunt Hamilton syringe that had been washed with disinfectant after use for mouse delivery of an ecotropic viral vector. No visible injury or bleeding. Researcher followed up with Occupational Medicine. A change in SOP to place needle in a conical tube following washing will be enacted.

Other Business

IBC Minutes Publication – BSO informed committee of the upcoming NIH requirement.

#36-25 Siwen Hu-Lieskovan. PI has not responded to renewal correspondence. IBC Chair messaged lab on 5/23/25.

NIH Guidance on Dangerous Gain-of-Function Research – BSO informed committee of the NIH's Implementation Announcement regarding Executive Order 14099.

Meeting concluded at 12:29 PM.

Next IBC Meeting will be held Thursday, July 17, 2025.