THE UNIVERSITY OF UTAH

INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES

July 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

Cecilia for protocol #52-26.

Review of June 18, 2026 Minutes

Motion: **Approve**
Vote for Motion: 15 in favor of the motion
2 Abstain

Old Business

#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. PI has not responded to post-review memo. Reminder email sent 5/14/26, 6/11/26.

#29-24.10 Allison Carey. Amendment to add Mycobacterium tuberculosis and Mycobacterium bovis.

Their lab is focused on the genetics and genomics of pathogenic mycobacteria, including the global health pathogen Mycobacterium tuberculosis and a group of environmental mycobacteria called 'non-tuberculous mycobacteria' (NTM). They seek to understand how bacterial genetic diversity impacts clinically relevant phenotypes including antibiotic resistance, pathogenesis, and vaccine escape. They use advanced bacterial genetic tools including transposon mutagenesis and barcoding combined with in vitro models as well as mouse and cell culture models of infection to address these questions.

Specific comments in the lab-specific BSL-3 manual have been provided. Establishment of BSL-3/ABSL-3 Facility Governance policy is still underway. The protocol is approved on the contingencies that: 1) comments are addressed in

the lab-specific BSL-3 manual to the satisfaction of the BSL-3 Operations Team, 2) BSL-3/ABSL-3 Facility governance is finalized and approved by the VPR, 3) the facility is commissioned and operational.

#48-26 Nitin Phadnis. Molecular basis of speciation in Drosophila; Molecular basis of segregation in Drosophila.

Understanding the genetic and molecular basis of speciation in Drosophila.

PI has not responded to post-review memo. Reminder email sent 06/11/26, 7/9/26.

#44-26 Darrel Davis. Antiviral Drug Discovery; SARS-CoV-2 Drug Discovery.

Antiviral and Anticancer Drug Discovery.

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

- **SciShield:**
  - Remove [redacted] as a delegate from the lab.
- **Documentation:**
  - To ensure effective lab leadership, the IBC requires the PI to complete all biosafety training relevant to the lab protocols. Provide documentation that Darrell Davis has completed:
    - BSL-2/BBP training,
    - Viral Vector Training
    - Biosafety Manual Review

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 7/9/26.

#50-26 Alessandra Angelucci. Anatomy, Physiology, and imaging of the visual cortex in the non-human primate.

Visual Neuroscience.

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

- In SciShield:
  - In the Animal Source Materials Survey, select “Obtain cell lines or tissues that carry human transmissible pathogens.”
- Documentation:
  - Provide training documents for laboratory personnel.

PI has not responded to Post-Review Memo

#53-26 Josh Bonkowsky. Development and Leukodystrophy Disease in the Zebrafish Nervous System; Gene Therapy and Microglial Transplant in a Rodent Model of Vanishing White Matter Disease; Investigating PEX 1 and ATAD1 gene therapy in vitro and in vivo for Peroxisomal Biogenesis Disorders (PBDs); Elucidating the Role of Microglia, Astrocytes, and the Integrated Stress Response (ISR) in Adrenoleukodystrophy (ALD).

Developmental neurobiology.

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

- Provide training documentation for all lab workers, including the PI.

PI responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 7/9/26.

#07-24.01 Saffeez Saffarian. Amendment to add H1N1 influenza A.

They are currently investigating the replication cycle of negative sense RNA viruses using VSV as a model system. Specifically they are interested in the mechanism by which RNA dependent RNA polymerases transcribe and replicate their genome. They are also investigating the budding of HIV virus, specifically focusing on the essential interactions that lead to production of infectious HIV particles from the host cell.

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

- **In Biosafety Manual:**
    - In appendix 4, H1N1 Reverse Genetics and Nanoluc Reporter Protocol, replace ALL references to glass beakers and glass labware with plastic.

PI responded to post-review memo. Approval pending training verification.

#39-25.02 Hossein Montazerian. Amendment to add Staphylococcus aureus to animals.

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

SciShield

- Consult with the Office of Comparative Medicine for assistance with locating the proper housing and procedure spaces.

Documentation:

- Verify the list of workers included with the SciShield registration is accurate and congruent with the workers listed on the biosafety manual attestation roster and with workers listed in SAM.
    - The table below represents workers currently attached to a BSL2 project listed in SciShield.
- Verify all personnel have completed the following training modules
    - Bloodborne Pathogens/BSL2 training
    - Biosafety Manual Review and attestation
    - Animal Biosafety Level 2 Training
- Only personnel listed in the table and who have completed 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 responded to post-review memo. Responses were evaluated by BSO and ABSO. Approval granted 7/10/26.

Protocols for Review With 3 Year Approval

#49-26 Matthew VanBrocklin. CVA21; Human Rhinovirus.

Cancer research, immunotherapy, and virotherapy, utilizing in vitro and in vivo modeling studies.

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

- Spaces – I have added all the spaces to your protocol that you mentioned in the post-review response. Check the project forms and pathogen forms for accuracy.
- From the Animal Source Materials Survey and Rhinovirus pathogen form– I removed the selection of “introducing human pathogens into animals” and removed any descriptions of animal work that I have found.

PI Cites NIH Guidelines: III-D-3, III-E
Agent: Human Rhinovirus
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: Enterovirus picornovirus
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: 16 For Motion | 1 Abstain

#52-26 Nels Elde. Evolutionary potential of a model poxvirus; Investigating horizontal gene transfer in coronaviruses; Defining the antiviral effector repertoire of divergent species; Co-evolution of Guanylate Cyclase C and uroguanylin in mammals; Infection Biology in Zebrafish.

Host-pathogen interactions are battlefronts for influence over host functions. From an evolutionary perspective each interaction can bear heavily on the fitness of both hosts and pathogens. Therefore, these interactions drive some of the most rapid evolution found in nature and can provide basic insights into the evolutionary process.
They study the consequences of pathogen-driven evolution on cells and host immunity factors. Protein surfaces at these interfaces often evolve in a manner resembling molecular arms races. They are also interested in cases where pathogens use molecular mimicry to gain advantages against hosts. In addition, they use experimental evolution to determine the evolutionary potential of viruses and understand the rules by which they adapt.
While experiments based on phylogenetic reconstructions, provide a powerful means of retrospectively studying host-pathogen interactions, experimental evolution offers a prospective view of virus evolution where potential adaptations can be monitored in real-time. Recent advances in deep sequencing coupled with recombinant tools make it possible to quickly determine the genetic basis of a variety of adaptations. They are using experimental evolution to address open questions related to virus evolution, such as mechanisms of rapid evolution and the trade-offs between host range and virulence

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

- **SciShield:**
  - Verify the personnel listed on the Pathogen and Viral Vector Forms are current and reflect workers listed in the Project Forms.
    - References to legacy staff are included in the Pathogen/Viral Registration forms. Update Step 5 on all Pathogen/Viral registration forms as necessary to include current personnel.
  - The Microbial Agent Survey indicates planned work with Spring Virema of Carp Virus (SVCV) and that it is a select agent. Although SVCV is not a select agent, they must determine if they will need a USDA permit for their work.
    - Remove the reference, found in the Microbial Agents Survey, to SVCV being a select agent.
    - Verify if a USDA permit is required for this viral agent.
  - Edit an existing project description or create a new project to describe the work with Spring Virema of Carp Virus (SVCV)
  - Edit an existing project description or create a new project to describe the work with the human sperm samples.
    - Specify the source of the sperm as well as use of it in the lab.

- Add OC43 and monkeypox to the viruses used in lab table.
- Add Cryptococcus neoformans to the fungus/yeast used in lab table.
- On the Pathogen Registration Form - Cryptococcus neoformans:
    - Step III: Safety, update the “Describe the use of PPE” section. Lab coats, gloves, and safety glasses are a minimum requirement for this work. Those using a respirator will enroll in the Occupational Medicine Respiratory Protection Program. (Remove reference to [redacted] and OEHS).
    - Step IV: Risk Assessment, in the “Provide a risk assessment for working with this agent” section, apply similar updates regarding respiratory protection.
- On the Pathogen Registration Form - OC43:
    - Step III: Safety, update the explain section of the “Are there any health restrictions for handling these agents?” to remove the reference to [redacted]
- On the Pathogen Registration Form - Monkeypox form:
    - Step IV: Risk Assessment, review this section and provide relevant updates to vaccination and/or antiviral recommendations.
- On the Viral Vector Registration Form - Third generation lentiviral packaging system (Trono Lab) form,
    - Step 1 update the question. *Have any changes been made to the natural host range or tropism*? to be 'Yes' due to changes in tropism (VSV pseudotype)
    - Step 5: Safety: Include nitrile gloves in the "General Personal Protective Equipment" list.
- On the Viral Vector Registration Form - lentiCRISPR v2 form,
    - Step 1 update the question. *Have any changes been made to the natural host range or tropism*? to be 'Yes' due to changes in tropism (VSV pseudotype)
- On the Viral Vector Registration Form-pSCRPSY
    - Step 1 update the question. *Have any changes been made to the natural host range or tropism*? to be 'Yes' to changes in tropism (due to VSV pseudotype)
- Create a Pathogen Registration Form for the use of Spring Virema of Carp Virus:

- **Biosafety Manual:**
    - Section B. Background
        - Add to the risk assessment of Coxsackievirus B3 (CVB3) to include the risks to immunocompromised individuals.
        - Add a risk assessment for Monkeypox.
        - Provide information supporting Spring Virema of Carp Virus (SVCV)
    - Section C.6. Hepatitis B Vaccination
        - Hepatitis B vaccination records are maintained in digital format by the Occupational Medicine Team. Delete the paragraph beginning 'However, if an employee chooses to decline vaccination, the employee must sign a declination form.'
        - Update the statement 'Vaccination will be coordinated and paid for through OEHS, as provided by the Student Health Clinic.' to indicate replace 'Student Health Clinic' with 'RedMed'
    - Section C.8 Incident Reporting:
        - The contact information for the University of Utah Benefits Department is incorrect.
        - PI needs to update with correct information.

            The Benefits Department is located:

            250 East 200 South, Suite 125

            Salt Lake City, Utah 84111

            Phone: 801.581.2169

    - Clarify the process for laundering reusable lab coats(as indicated in SciShield)
        - If reusable laboratory coats are utilized, provide a description of the laundering process.
        - Section L of the BSL2 Biosafety Manual Template https://ibc.utah.edu/_resources/documents/templates/biosafety_level_2__manual_template2024.docx contains a reference for this information.
        - Create ‘Section I: Laundry: in the current biosafety manual to describe this process.
    - Appendix 2 Post-exposure Standard Operating Procedure

        - Incorporate the following information for Recombinant Lentivirus and Recombinant HIV Particles SOP post-exposure prophylaxis:
            - Visit the Occupational Medicine Clinic. Post-exposure prophylaxis (PEP) should be administered as soon as possible, within 72 hours following any exposure. The following post-exposure prophylaxis regimens are available:
                - Preferred single-tablet regimen:
                    - Bictegravir (50 mg)/tenofovir alafenamide (25 mg)/emtricitabine (200 mg) (Brand name: Biktarvy) once daily
                - Preferred multi-tablet regimen:
                    - Dolutegravir (Brand name: Tivicay) 50 mg taken once a day for 7 days
                    - Tenofovir disoproxil fumarate/emtricitabine (Brand name: Truvada) 300 mg taken once a day for 7 days
    - Remove Appendix 5. Hepatitis B Vaccination Attestation forms are digitally managed by the Occupational Medicine Program.
    - The IBC requires laboratory-specific SOPs to be included in the biosafety manual.
        - Include a section with SOPs for all viral vectors, pathogens, and human source materials.
        - Be sure to include SVCV and human sperm, since they were added to their registration and no details of their use have been provided.
- **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 associated with the agents used in their laboratory, enrollment in the Occupational Medicine Hepatitis B program and the Immunocompetence program is required, regardless of vaccination status.
        - Contact Dr. Andy Phillips (xxxxxxxx@xxx.utah.edu) with Occupational Medicine for access to the health screening questionnaire in Open Range.
        - In the email, provide the lab name and all lab personnel [redacted] to Dr. Phillips.
        - Once contact with Dr. Phillips has been obtained this item is considered complete by the IBC.
    - The individuals [redacted] 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-2, III-D-3, III-D-4, III-D-4-a, III-D-4-b, III-E-1
Agent: Vaccinia virus (Western Reserve, IHD-J, Copenhagen)
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: Cryptococcus neoformans
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: Coronavirus OC43
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: Equine Coronavirus
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: Mouse Hepatitis 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 ☐
Agent: Yellow Fever Virus (17-D)
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: Dengue 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 ☐
Agent: Zika 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 ☐
Agent: Coxsackievirus B3
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: Venezuelan Equine Encephalitis Virus TC-83
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 ☐
Insertions: GFP reporter
Agent: West Nile 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 ☐
Agent: Rhabdovirus Indiana Vesiculovirus
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: 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: C15ORF48 from human sources

Agent: Retroviral 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: Glutamate Cyclase-C (GC-C) from primates

Agent: Adeno-Associate Viral 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: harbiTRIM from iguana 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: 16 For Motion | 1 Abstain

#55-26 Katsuhiko Funai. Cellular Handling of Lipids in Metabolic Stress.

The main areas of interest of the laboratory are cellular processes by which skeletal muscle handles substrate overload during metabolic stress. As skeletal muscle is an organ with the highest metabolic demand, metabolic changes that occur in skeletal muscle have tremendous consequences on whole-body metabolism. Specifically, they are interested in the cellular fate of lipid molecules in skeletal muscle. They utilize cell lines, genetically-modified mice and primary muscle cells from human subjects to examine mechanisms whereby skeletal muscles develop and/or evade toxic effects of lipid influx.

Outstanding issues to be addressed which were detailed to PI in an email

- **Biosafety Manual:**
  - Remove Appendix 4 from the Table of Contents as this appendix was removed with a prior amendment.

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4-a, III-D-4-c-(2), III-E-3
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: LPCAT3, ALDH7A1, PISD, TAZ, TSP1, GPx4, MCAT, TTC19, NNT, CLS from mouse and human sources

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: EGFP from Aequorea source; iCre from bacteriophage 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) and Animal Biosafety Level 1 (ABSL-1)
Vote for Motion: 17 For Motion | Abstain

#56-26 Tingting Hong. Cardiomyocyte membrane organization in normal and failing hearts.

They focus on cardiac membrane organization and function, with particular interests on T-tubule microdomain function and regulation.

Outstanding issues to be addressed which were detailed to PI in a post-review memo.

- **Biosafety Manual:**
  - Appendix 2: Post-Exposure Standard Operating Procedure
    - In the Modes of transmission section of the table, the description provided relates to Adenovirus. Update to provide information relative to AAV. You can use the following text:
      - AAV may be transmitted by aerosol, droplet exposure to the mucous membrane, ingestion and injection (i.e., needle stick).

PI Cites NIH Guidelines: III-D-1, III-D-3, III-D-4-a, III-D-4-c-(2), 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: Bin1 from mouse source

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: GFP, Bin1 from mouse 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: 17 For Motion | Abstain

#57-26 Minna Roh-Johnson. Cell Biological Mechanisms of Cancer Cell Behavior; CAR-Macrophage inhibition of melanoma brain metastasis; Regulation of Cell Migration.

Cancer cells hijack mechanisms of normal development. In a complex milieu of an animal, in which there are many different signals from many different cells, how does a cell parse through this information to know when and where to migrate? Their long-term research goal is to identify these signals, how they are communicated, and how they are

interpreted into a downstream response to regulate cell motility during development and cancer. They use a combination of animal models (zebrafish and mouse) and cell culture-based models, taking advantage of the strengths of each system to answer outstanding questions in cancer cell biology.

Outstanding issues to be addressed which were detailed to PI in an email.

- SciShield:
  - The locations where research is conducted must be included with your registration. PI needs to send a list of Rooms and/or Spaces used along with a brief descriptor of how the space is used (i.e., lab, surgical, cell culture, etc.) to the Biosafety Office at biosafety@ehs.utah.edu
    - Include all locations where research is conducted, [redacted]
    - After the spaces have been created, you will be notified and may return to the Project Form(s) to link the space with appropriate project(s).
- **Documentation:**
  - All personnel listed on this registration, including the Principal Investigator, are required to complete the applicable training modules identified in the Training Profile table (below). IBC approval will be withheld until personnel records are accurate and all required training requirements have been satisfied.
    - Personnel who are no longer participating in the project must be removed from the registration in SciShield.
    - 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-D-4-c-(2), iii-E, III-E-3
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: psPax-2, Cre, mit-mEmerald, loxp-dsRed-loxp-GFP, CSPG4-scFv, TMEM-eGFP, Paxillin
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: 17 For Motion | Abstain

#58-26 Alissa Trzeciak. Hematopoiesis in steady state and disease.

The central focus of their research program is to understand the molecular mechanisms underlying myeloid cell development at steady-state and how myelopoiesis quickly adapts during systemic inflammation and sepsis.

Outstanding issues to be addressed which were detailed to PI in a post-review memo.

- **SciShield:**
  - Update references of “10% bleach” and “Clorox” to be “a freshly prepared 1:10 dilution of bleach”.
  - Create a Project Form to describe:
    - The use of Lentiviral Viral Vectors.
    - The use of Adeno-Associated Viral Vectors.
  - In the Microbial Agents Survey:

        - Update the description found in the ‘Bloodborne Pathogens tab to indicate human cell lines are classified as bloodborne pathogens. The bacterial and viral agents listed in the description are not classified as bloodborne pathogens.
- Remove references to 'UV Inactivation' as UV disinfection is not a validated method. A fact sheet with additional information relating to UV use within a biosafety cabinet can be found at https://ibc.utah.edu/library/ultraviolet-lamps-in-biological-safety.php
- In the Recombinant or Synthetic Nucleic Acid Molecules Survey:
    - Update Q7-E to 'Yes'.
- In the table of Viruses Used in Lab:
    - Replace ' Adenoviruses, human (all types)' with Adeno-Associated Virus.
- In the table of Plasmids Used in Lab:
    - Include all plasmids used for the assembly of viral vectors (e.g. psPAX, pVSV-g, pMDLg, PcL-Eco, etc.)
- In the Pathogen Registration Form Bacteria - Staphylococcus aureus
    - In Step III: Safety:
        - Provide information on health restrictions to immunocompromised individuals. Consult with Occupational Medicine for assistance as needed.
        - Indicate the availability of antibiotic therapy as a post-exposure treatment option.
        - Update references to 'Clorox' to be a freshly prepared 1:10 dilution of bleach for disinfection of laboratory spaces. Indicate ‘Virkon’ (provided by OCM) will be used as a disinfection agent within the vivarium spaces.
- In the Pathogen Registration Form Bacteria - Escherichia coli O111
    - In Step II: Project Information:
        - Clarify the use of E. coli. This form indicates in-vitro and in-vivo usage, however, the SOP provided in the biosafety manual does not describe in-vitro use.
    - In Step III: Safety:
        - Provide information on health restrictions to immunocompromised individuals. Consult with Occupational Medicine for assistance as needed.
        - Indicate the availability of antibiotic therapy as a post-exposure treatment option.
        - Remove the reference to using 70% ethanol and UV light as the primary disinfection method. Update references to indicate a freshly prepared 1:10 dilution of bleach for disinfection of laboratory spaces. Indicate ‘Virkon’ (provided by OCM) will be used as a disinfection agent within the vivarium spaces.
- In the Pathogen Registration Form - Streptococcus pneumoniae:
    - In Step III: Safety:
        - Provide information on health restrictions to immunocompromised individuals. Consult with Occupational Medicine for assistance as needed
        - Inquire with Occupational Medicine to discuss the availability of a pre-exposure prophylaxis vaccination. Dr. Andy Phillips xxxxxxxxx@xxxxxxxx is the point of contact for the Occupational Medicine team.
        - Indicate the availability of antibiotic therapy as a post-exposure treatment option.
        - Remove the reference to using ‘70% ethanol and cavicide bleach’ as the primary disinfection method. Update references to indicate a freshly prepared 1:10 dilution of bleach for disinfection of laboratory spaces. Indicate ‘Virkon’ (provided by OCM) will be used as a disinfection agent within the vivarium spaces.
- Pathogen Registration Form - Lymphocytic Choriomeningitis Virus (LCMV)
    - Step II: Project Information:
        - The biosafety manual indicates LCMV is used in an animal model, however, this form indicates in-vitro use only. PI needs to align the use of LCMV.
    - In Step III: Safety:
        - Provide information on health restrictions to immunocompromised individuals. Consult with Occupational Medicine for assistance as needed
        - Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach
- In the Pathogen Registration Form Mouse Hepatitis Virus
    - Step I: Pathogen Information:

- Provide the MHV strain information.
- Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach
- Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach will be used in any laboratory spaces and 'Virkon' (provided by OCM) will be used as a disinfection agent within the vivarium spaces.

- In the Pathogen Registration Form - Mouse-adapted influenza virus
  - In Step III: Safety:
    - Provide information on health restrictions to immunocompromised individuals. Consult with Occupational Medicine for assistance as needed
    - Indicate the availability of the seasonal annual influenza vaccine and antivirals as pre- and post-exposure prophylaxis, respectively.
    - Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach will be used in any laboratory spaces and 'Virkon' (provided by OCM) will be used as a disinfection agent within the vivarium spaces.
    - Indicate an N-95 respirator mask will be used for any manipulations done outside of a biosafety cabinet (e.g spill response), as described in the biosafety manual SOP.
      - Schedule respirator fit testing with Occupational Medicine via the RedMed Clinic.
- In the Viral Vector Registration Form-pLentiGuide-puro
  - Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach.
- In the Viral Vector Registration Form-pMSCVneo-HA-ER-Hoxb8
  - In Step III: Safety:
    - Update the disinfection method to indicate a freshly prepared 1:10 dilution of bleach
- In the Viral Vector Registration Form-pAAV-CAG-tdTomato:
  - Step 5 Safety:
    - Respiratory protection with AAV is not required, however, if users elect to use a respirator, contact the RedMed clinic for fit test clearance.
- A reference to murine cytomegalovirus (mCMV) was found within the table of Viruses Used in Lab. This reference has been administratively removed by the biosafety office.
- In the Project Form *'WNK1 Signaling in Acute Myeloid Leukemia'*
  - Update the 'Description of Experimental and Procedural Details' to indicate
    - Transduced cells should be considered potentially infectious and handled at BSL-2 until they have undergone at least 5 washes (minimum 50-fold dilution with each wash), and 72 hours has passed since viral transduction.
- In the Pathogen Registration Form - Mouse Hepatitis Virus
  - Step III: Safety:
    - As MHV is indicated for in-vitro usage only, update the following responses:
      - 'Are needles, glass or other sharps used with this agent?' to be 'No'
      - 'Biocontainment Housing to be 'No'

- **Biosafety Manual:**
  - Section B. Training and Hepatitis B Vaccination Program
    - Include "Initial Viral Vector Training: Repeated every 3 years"
  - Section C. Agents Used in the Lab:
    - Step 7 pLentiGuide-puro, VSV-G Pseudotyped:
      - Update the Prophylaxis and Treatment Options to reflect the IBC preferred description:
      - Visit the Occupational Medicine Clinic. Post-exposure prophylaxis (PEP) should be administered as soon as possible, within 72 hours following any exposure to prevent integration. The following post-exposure prophylaxis regimens are available:
        - Preferred single-tablet regimen:
          - Bictegravir (50 mg)/tenofovir alafenamide (25 mg)/emtricitabine (200 mg) (Brand name: Biktarvy) once daily
        - Preferred multi-tablet regimen:
          - Dolutegravir (Brand name: Tivicay) 50 mg taken once a day for 7 days
          - Tenofovir disoproxil fumarate/emtricitabine (Brand name: Truvada) 300 mg taken once a day for 7 days
  - Appendix 7: Complete the Gene Editing Questionnaire

- Section E. Laboratory-Specific Standard Operating Procedures.
    - Provide an SOP describing the lentiviral vector production method.
    - Provide an SOP describing the MSCV viral vector production method.
    - Provide an SOP describing the AAV delivery procedure to animal models
    - The SOPs should include the step-by-step process a researcher would follow to conduct an experiment.
- In the SOP 'Recombinant Viral Vectors', Section D *'Step-by-Step Experimental Operational Procedure'*
    - Step 3 '*Washing Transduced Cells Prior to In Vivo Injection':*
        - Transduced cells should be considered potentially infectious and handled at BSL-2 until they have undergone at least 5 washes (minimum 50-fold dilution with each wash), and 72 hours have passed since viral transduction.
- In the SOP *'Murine Stem Cell Virus (MSCV) Retroviral Vector Systems'*, Section D *'Step-by-Step Experimental Operational Procedure'*
    - Step 3 '*Washing Transduced Cells Prior to In Vivo Injection':*
        - Transduced cells should be considered potentially infectious and handled at BSL-2 until they have undergone at least 5 washes (minimum 50-fold dilution with each wash), and 72 hours have passed since viral transduction.
    -
- **Documentation:**
    - Contact Dr. [redacted] xxxxxxxxx@xxxxxxxxx , Executive Director, Office of Comparative Medicine, to discuss the use of MHV.
    - To comply with NIH regulations, the IBC is required to publish minutes from convened meetings, which we provide on the IBC website https://ibc.utah.edu/meeting-minutes.php . PI needs to inform us if your IBC registration contains proprietary information that cannot be included in the minutes.
    - Due to the risks associated with the agents used in your laboratory, enrollment in the Occupational Medicine Hepatitis B program and the Immunocompetence program is required, regardless of vaccination status.
        - Contact Dr. Andy Phillips (xxxxxxxxx@xxxxxxxx) with Occupational Medicine for access to the health screening questionnaire in Open Range.
        - In the email, provide the lab name and all lab personnel [redacted] to Dr. Phillips.
        - Once contact with Dr. Phillips has been obtained this item is considered complete by the IBC.
    - All personnel listed on this registration, including the Principal Investigator, are required to complete the applicable training modules identified in the Training Profile table.
        - Personnel who are no longer participating in the project must be removed from the registration in SciShield.
        - 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
        - If you are unable to access the training materials, contact the biosafety office for assistance.

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)
Agent: Mouse Hepatitis 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 ☐
Agent: Lymphocytic Choriomeningitis 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 ☐
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: Cas9, Cre Recombinase, GFP, mCherry from synthetic sources

Agent: Retroviral 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: Hoxb8 from synthetic source

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: td Tomato from synthetic source

Agent: Murine CMV
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: MR Staphylococcus aureus
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: Streptococcus pneumoniae
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: Mouse Adapted Influenza A
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: E. coli O111
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: 17 For Motion | Abstain

Protocols for Review With 5 Year Approval

None

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

#63-26 Paul Bernstein. 2020-CL-0101 A Phase 1b, Open-label, Multicenter Dose-escalation Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of a Single Subretinal Dose of ASP2020 in Participants with Macular Dystrophies with a Stargardt-type Clinical Presentation.

Outstanding issues to be addressed which were detailed to PI in a post-review memo.

- Agent Information:
    - Question 5, given that bloodborne pathogen exposure is a risk associated with this agent, PI needs to add that a Hepatitis B vaccine is recommended prophylaxis.

PI Cites NIH Guidelines: III-C
Agent: ASP2020 (AAV based)
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)
Vote for Motion: 16 For Motion | 1 Abstain

#64-26 Bogdana Schmidt. CG Oncology CORE-008 >> A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC).

No concerns were raised during the meeting.

PI Cites NIH Guidelines: III-C
Agent: Cretostimogene Grenadenorepvec (Adenoviral based)
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 at Biosafety Level 2 (BSL-2)
Vote for Motion: 16 For Motion | 1 Abstain

Tabled/Pending Protocols

#19-25.03 JB. Lubin. Amendment to add Akkermansia ssp. Desulfovibrio piger, Citrobacter rodentium, and Candida ssp.

Their lab is dedicated to understanding of how the intersection of diet and microbial metabolism in the infant microbiome impacts neonatal infection and immunity. Their research is focus on mouse models of infant microbial communities and incorporates microbiology, genetics, biochemistry, bioinformatics and immunology.

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

- **SciShield:**
    - Describe the use of Candida in a relevant project form. In the description, include a brief description and rationale for the use of Candida in the gut. The IBC is concerned about the use of Candida auris due to its significant morbidity and mortality in hospital-acquired infections and its antifungal resistance.
    - In all of the Pathogen Registration Forms:
        - Step 3 Safety:
            - Remove reference to 'skirt' being worn as proper laboratory attire.
            - Update required PPE to include Lab coat, nitrile gloves, safety glasses.
            - Update to indicate centrifuge safety cups are used with all Risk Group 2 materials.
    - Provide individual Pathogen Registration Forms for each Candida species as the Risk Assessment is different for each of the listed strains.
        - Include the 'Institutional Collaborator' supplying the material in response to the question '*Where will they obtain the infectious agent?'*
        - Due to an elevated risk of work with Candida auris, include BSL2 Enhanced PPE of Solid Front/Rear Closing Lab coat, Double Nitrile Gloves, Safety Glasses.

- **Biosafety Manual:**
    - Provide an SOP for the use of Candida spp. The SOP should include the species of any animal model used, a description of the experimental procedure(s), a description of the laboratory biological safety containment used for the injection (e.g., indicate if a biosafety cabinet will be used during the injection), precautions for needle safety, and a brief overview of the injection process, including the route of administration and safety devices used during injection.
    - In the Handling and Administration of Pertussis Toxin (PTX) SOP
        - Step 3 states *'Load syringes inside the BSC immediately before injection; keep capped until animals are restrained.'*
            - It appears the syringe is loaded with Pertussis Toxin, then the needle is re-capped until the animal is restrained. Provide clarification of needle safety to indicate the needle is not recapped and does not pose a threat to worker safety.

Alternatively, the needle could be removed via the tool on the sharps container lid, and replaced with a new needle to avoid a recapping procedure.

Lab/Protocol Closures

None

Spills and Incidents

None

Other Business

None