Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, October 21, 2025

Present:	Henrique Borges da Silva, Richard Chichester, John Copland, Marion Curtis, John Jasker, Richard Kennedy, Daniel Montonye, Suzannah Schmidt-Malan, Russel Sinor, Melanie Swift, Elitza Theel
Absent:	Hind Fadel, Madiha Fida, Marina Hanson, Kathleen McNaughton
Mayo Guests:	
Guests:	
Duration:	11:30 AM - 1:30 PM

Minutes approved

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve September Meeting Minutes

  Meeting minutes approved.

- 3. DURC Publication

  Information regarding DURC publication.

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

Note Items

Approvals

- **Alexandre Maia Update of CRISPR-mediated genomic and epigenomic modulation of cancer cells**
  Review Type: Update Application
- **Lauren Dalvin Update of Mechanisms of Uveal Melanoma Pathogenesis**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **Pooja Advani Update of An Open-label, Phase 1, Multicenter Study to Evaluate the Safety and Preliminary Anti-tumor Activity of NT-175 in HLA-A*02:01-Positive Adults with Unresectable, Advanced/Metastatic Solid Tumors Positive for TP53 R175H Mutation**
  Review Type: Update Application
- **Nathaniel Traaseth Update of Growth inhibition assays in pathogenic bacteria**
  Review Type: Update Application
- **Anastasia Zekeridou Update of A Phase 2 Open-Label, Single-Arm, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, in Subjects with Treatment Refractory Stiff Person Syndrome (KYSA-8)**
  Review Type: Update Application
- **Megan Weivoda Update of Use of lentiviral particles to track mouse multiple myeloma cells**
  Review Type: Update Application
- **Michael Kattah Update of Genetic regulation of epithelial injury in ulcerative colitis**
  Review Type: Update Application
- **Debabrata Mukhopadhyay Update of The role and regulation of angiogenic growth factors in cancer**
  Review Type: Update Application
- **Alina Oancea Update of MC10029 BAFF-R CAR-T Manufacturing**
  Review Type: Update Application
- **Bogang Wu Mechanistic and Therapeutic Investigation of Immune Dysregulation in Cancer and Immune Disorders**
  Review Type: Update Application
- **Doo-Sup Choi Repetitive Transcranial Magnetic Stimulation (rTMS) in Alcohol Use Disorder (AUD) and depression**
  Review Type: Update Application
- **Nikolaos Skartsis Update of EZH2-FoxP3 Protein Interactions in Tregs**
  Review Type: Update Application
- **Osama Abulseoud Update of Studying the potential role of high serum ferritin in the development of post-COVID-19 neuropsychiatric manifestations**
  Review Type: Update Application
- **Doo-Sup Choi Alcoholism and Substance Dependence Study in Mice**
  Review Type: Update Application
- **Xin-Ming Shen Update of Congenital Myasthenic Syndromes**
  Review Type: Update Application
- **Ryan Demkowicz Permission to send microbiologic culture isolates of Mycobacterium species for antimicrobial susceptibility testing.**
  Review Type: New Application
- **Bogang Wu Mechanistic and Therapeutic Investigation of Immune Dysregulation in Cancer and Immune Disorders**
  Review Type: Update Application
- **Jann Sarkaria Update of Evaluating mechanisms of therapeutic resistance in glioblastoma multiforme**
  Review Type: Update Application
- **Chun-Wei Chen Update of Research lab operation - David Chen Lab**
  Review Type: Update Application

Protocols Reviewed

- **Terra Lasho** CRISPR Lentiviral ASXL1

Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing AmpR, BlastR, Cas9, KRAB, PuroR, and TagRFP to study key genomic loci (putative enhancer regions) that are specific to aberrant oncogenic gene expression in ASXL1-mutant chronic myelomonocytic leukemia (hematologic malignancy).

The 2+ designation infers the use of Biosafety Level 2 facilities and biocontainment equipment and Biosafety Level 3 practices.

This study aligns with sections III-D-3-a of the NIH Guidelines.

This application must be updated with any other genetic modifications made during the course of experimentation. This is required by the NIH Guideline and Mayo Clinic policy.

As a reminder to the lab, eye protection must be worn whenever there is the possibility of a spill or splash. All samples considered biosafety level 2/2+ and those items that may be potentially contaminated must be disinfected before removal from a biosafety cabinet for final disposal in regulated medical waste (red bins). Proper waste disposal will be audited yearly. Any questions can be directed to the Biosafety Office and/or Waste Management.

Animal work with the approved biohazardous agents must be listed in an approved IACUC protocol prior to the onset of experimentation in the animal model. All biohazardous agents must be approved by the IBC prior to work in an animal model.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Yi Lin** A Phase 1b Multicenter, Open-Label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants With B-Cell Non-Hodgkin Lymphoma

  The Biological Hazard Application, Bios00002058, for "A Phase 1b Multicenter, Open-Label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants With B-Cell Non-Hodgkin Lymphoma" (IRB 25-009903) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of JNJ 90014496, a third-generation chimeric antigen receptor or CAR T cell therapy that uses a novel 3rd generation lentiviral vector 4-1BB Bi-specific approach to target CD20 and CD19 aiming to treat relapsed or refractory B cell non-Hodgkin lymphoma in a clinical trial.

  This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

  This trial is approved for administration at the Mayo Clinic Rochester, Mayo Clinic Jacksonville, and Mayo Clinic Scottsdale locations.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Kay Medina** Monoclonal Antibody Screening to detect mutant osteoprotegerin protein by flow cytometry

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the generation of a monoclonal antibody (mAB) against the mutant form of the protein osteoprotegerin (mOPG). The Antibody Hybridoma Core will use a lentiviral transduced cell line to identify a monoclonal antibody that specifically recognizes mOPG. The goal is to generate a mAB specific for mOPG for diagnostic purposes.

  The 2+ designation infers the use of Biosafety Level 2 facilities and biocontainment equipment and Biosafety Level 3 practices.

  This study aligns with sections III-D-3-a of the NIH Guidelines.

  This application must be updated with any other genetic modifications made during the course of experimentation. This is required by the NIH Guideline and Mayo Clinic policy.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Girish Mour** A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate Efficacy and Safety of ALXN2030 in Adult Patients with Antibody-Mediated Rejection after Kidney Transplantation

  The Biological Hazard Application, Bios00002097, for "A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate Efficacy and Safety of ALXN2030 in Adult Patients with Antibody-Mediated Rejection after Kidney Transplantation" (IRB 25-002858) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of ALXN2030, a novel, noncoding Ga1NAc-conjugated double-stranded C3-drected 36mer SiRNA that has been optimized for subcutaneous administration and is being developed for the treatment of disease states involving dysregulated complement activity in a clinical trial.

  This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

  This trial is approved for administration at the Mayo Clinic Phoenix location only. If the enrollment of patients at either Mayo Clinic Jacksonville or Mayo Clinic Rochester is desired, the laboratory is directed to inform the IBC of the expansion.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Elie Naddaf** A PHASE 1 STUDY OF ANITOCABTAGENE AUTOLEUCEL FOR THE TREATMENT OF SUBJECTS WITH NON-ONCOLOGY PLASMA CELL-RELATED DISEASES

  The Biological Hazard Application, Bios00002084, for "A PHASE 1 STUDY OF ANITOCABTAGENE AUTOLEUCEL FOR THE TREATMENT OF SUBJECTS WITH NON-ONCOLOGY PLASMA CELL-RELATED DISEASES" (IRB 25-010350) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of Anitocel, autologous (participant-derived) T cells engineered with a non-replicating lentiviral vector to add a chimeric antigen receptor that allows the T cells to recognize BCMA, in a clinical trial.

  This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

  This trial is approved for administration at the Mayo Clinic Rochester location only. If the enrollment of patients at either Mayo Clinic Phoenix or Mayo Clinic Jacksonville is desired, the laboratory is directed to inform the IBC of the expansion.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Matthew Starr** ACHIEVE-AbbVie M24-528

  The Biological Hazard Application, Bios00002092, for "ACHIEVE-AbbVie M24-528" (IRB 25-005487) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of surabgene lomparvovec (ABBV-RGX-314), a recombinant adeno-associated virus type 8 (AAV8) vector containing a

synthetic gene that encodes a soluble anti-VEGF antibody fragment (Fab) for people with wet age-related macular degeneration (nAMD) in a clinical trial.

This study aligns with section III-C Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation of the NIH Guidelines.

This trial is approved for administration at the Mayo Clinic Rochester location only. If the enrollment of patients at either Mayo Clinic Jacksonville or Mayo Clinic Scottsdale is desired, the laboratory is directed to inform the IBC of the expansion.

Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

Informed Consent documentation is adequate.

- **Michael Barry** Update of Vector Hybrids

  The committee has requested a risk mitigation plan to be added to the application for the concerns raised in section 3.01. Please reach out to biosafety@mayo.edu for assistance with this request.

- **Stijn De Langhe** Update of Lung stem cells

  Modification submitted to include the use of cultured basal cells that will be transduced with lentivirus containing EGFP in an animal model.

  Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing EGFP in an animal model.

  The 2+ designation infers the use of Biosafety Level 2 facilities and biocontainment equipment and Biosafety Level 3 practices.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of Influenza Virus (PR8 Strain) and SARS-Cov-2 in an animal model.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of Lab Adapted E. coli and plasmid constructed recombinant adeno-associated virus expressing EGFP in an animal model.

  This study aligns with section III-D-4 of the NIH guidelines.

  Due to the note of injection as the route of delivery, it is recommended that the laboratory take extra precautions during sharps (needle) usage when handling the animals. No recapping, sheering, bending, or breaking or removing the needle from the syringe is allowable. All sharps waste is to be placed in appropriate hard walled waste containers. If these actions must occur or are ongoing at this time, you must contact the Biosafety Office, IMMEDIATELY to discuss the proper handling of sharps. Your laboratory will be audited for the handling of sharps in the manner described above unless an exemption is on record with the IBC.

  As a reminder to the lab, eye protection must be worn whenever there is the possibility of a spill or splash. All samples considered biosafety level 2/2+ and those items that may be potentially contaminated must be disinfected before removal from a biosafety cabinet for final disposal in regulated medical waste (red bins). Proper waste disposal will be audited yearly. Any questions can be directed to the Biosafety Office and/or Waste Management.

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  Lentivirus and Lentiviral Vector Systems Guidance

- **Aaron Mansfield** Update of Preclinical drug testing and assay development for patient-derived tumors in a xenograft model

  Requested changes:

  1. Please add the BSL2 animal housing suite, Guggenheim 20-08, in section 1.02

2. Please add additional details on what will be done with the tumors after removal in section 2.02 question 3.

3. In section 4 question 6 should be checked no since the resistance is used for selection.

These changes will need to be addressed and returned to the IBC prior to final approval of the application.

Modification submitted to include the use of replication deficient, HIV-1 based lentiviral vector.

Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing ASCL1, GFP, immunoglobulin, luciferase, mCherry, MET, RET, or scFv-Fc in an animal model.

The 2+ designation infers the use of Biosafety Level 2 facilities and biocontainment equipment and Biosafety Level 3 practices.

This application must be updated with any other genetic modifications made during the course of experimentation. This is required by the NIH Guideline and Mayo Clinic policy.

This study aligns with section III-D-4 of the NIH guidelines.

The laboratory is reminded to use the appropriate animal cage labels (BSL2+) in the animal biosafety suite for all housed animals associated with this project. Housing at this level is required for the duration of the animal subject's life span post exposure to the biohazardous agent.

Due to the note of injection as the route of delivery, it is recommended that the laboratory take extra precautions during sharps (needle) usage when handling the animals. No recapping, sheering, bending, or breaking or removing the needle from the syringe is allowable. All sharps waste is to be placed in appropriate hard walled waste containers. If these actions must occur or are ongoing at this time, you must contact the Biosafety Office, IMMEDIATELY to discuss the proper handling of sharps. Your laboratory will be audited for the handling of sharps in the manner described above unless an exemption is on record with the IBC.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Rahmi Oklu** Update of Cell-Loaded Porous Microbeads for Biomedical Applications

Modification submitted to downgrade cell lines that have been transfected with lentiviral vectors.

Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing CEACAM5, GFP, and luciferase in an animal model.

The following lentiviral stock has been found negative for recombinant virus in a testing methodology approved by the IBC and therefore approval at BSL1/ABSL1 is approved. **Please note that any new batch of lentiviral stock must be tested before the IBC can downgrade the biosafety level from BSL2+ to BSL1.**

CEACAM5 pig fibroblast P5 and P9

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