Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, September 15, 2026

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

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve August Meeting Minutes

  Meeting minutes approved.

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

Note Items

Approvals

- **Jessica Lancaster Update of Retroviral transduction of murine CD8+ T cells**
  Review Type: Update Application
- **Michael Barry Update of Gene Therapy**
  Review Type: Update Application
- **Nikolaos Skartsis Treg homeostasis during Inflammation**
  Review Type: Update Application
- **Victoria Clark Update of The exploration of meningioma and schwannoma driver mutations in vitro and in vivo**
  Review Type: Update Application
- **Jessica Lancaster Update of Tracking the expression of the extracellular ATP sensor P2RX7 by human lung tissue-resident memory CD4+ T cells in response to respiratory infections**
  Review Type: Update Application
- **Gavin Roddy Update of Stanniocalcin-1 for intraocular pressure reduction**
  Review Type: Update Application
- **Kirk Wangensteen Update of Mechanisms of tumorigenesis in liver**
  Review Type: Update Application
- **Arun Kanakkanthara Update of Effect of various gene loss or overexpression in ovarian cancer**
  Review Type: Update Application
- **Jessica Lancaster Role of extracellular nucleotides in CD8+ T cell immune responses to infection and cancer**
  Review Type: Update Application
- **Mark Tyson Update of A Phase 1/2 Study of EG-70 as an Intravesical Administration to Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) and High-Risk NMIBC Patients who are BCG Naïve or Received Incomplete BCG Treatment**
  Review Type: Update Application
- **Laura Rogers Update of Genetic modification of cells using transposons**
  Review Type: Update Application

Protocols Reviewed

- **Craig Horbinski** Cell Culture and Molecular Studies of Human Brain Tumor Models

  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 or knocking down blasticidin-resistance marker, Cas9, ERBB3, MBD1, MBD2, MECP2, Non-targeting scramble sgRNA control, or SOX10 in an animal model.

  This study aligns with sections III-D-4-a of the NIH Guidelines.

  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.

  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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Takahisa Kanekiyo** Antisense oligonucleotide (ASO) therapy for Alzheimer's disease

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotide (ASO) knocking down SFRP1 in an animal model.

  This study aligns with sections III-D-4-a of the NIH Guidelines.

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- **Khashayarsha Khazaie** Flagellin-Targeted CAR-Tregs and Tolerogenic Vaccines for Precision Immune Reset in IBD and Colitis-Associated Cancer Risk Reduction

  Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector and murine stem cell virus expressing CAR-Fla: Synthetic flagellin-specific VHH–CD28–CD3ζ chimeric antigen receptor with P2A-tNGFR in an animal model.

  This study aligns with sections III-D-4-a of the NIH Guidelines.

  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.

  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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Yanyan Lou** V940-014

  The Biological Hazard Application, Bios00002303, for "V940-014" (IRB 26-006596) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of V940, also known as mRNA-4157 or intismeran autogene, is an individualized mRNA-based neoantigen therapy designed to elicit neoantigen-specific T-cell responses against a participant's tumor mutanome 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 and Jacksonville locations. If the enrollment of patients at 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.

- **Elie Naddaf** A Phase 2/3, Open-Label, Randomized, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy, Versus Ongoing SOC Immunosuppressive Therapy in Patients with Generalized Myasthenia Gravis (KYSA-6)

  The Biological Hazard Application, Bios00002320, for "A Phase 2/3, Open-Label, Randomized, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy, Versus Ongoing SOC Immunosuppressive Therapy in Patients with Generalized Myasthenia Gravis (KYSA-6)" (IRB 26-006868) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of KYV-101, a treatment made from a participant’s own T cells. The cells are collected from blood, genetically modified using a 3rd generation lentiviral vector to make a chimeric antigen receptor (CAR) that targets CD19 on B cells, 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. If the enrollment of patients at Mayo Clinic Scottsdale or 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.

- **Anastasia Zekeridou** A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Refractory Neurologic Autoimmune Disease

  The Biological Hazard Application, Bios00002321, for "A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Refractory Neurologic Autoimmune Disease" (IRB 26-009901) has been approved.

Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of CTX112, allogeneic T cells modified with CRISPR/Cas9 and then transduced with viral vector rAAV-138 to insert the anti-CD19 CAR transgene 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 and Jacksonville locations only. If the enrollment of patients at 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 Ackerman** Suppression of Rab11b as a treatment for heart failure

  Modification submitted to include the use of antibody-antisense oligonucleotide conjugate (AOC) targeting Rab11b.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus AAV9 and ASOs, to deliver Rab11b dominant negative form to block Rab11b in cardiomyocytes in an animal model.

  This study aligns with sections III-D-4-a of the NIH Guidelines.

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- **Panagiotis Anastasiadis** Update of Src-family kinases in brain tumor cell migration and proliferation

  Modification submitted to include the use of oncolytic HSV-1 (Imlygic) on melanoma samples.

  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 Ac Green Fluorescence Protein, CRE, eGFP, Firefly luciferase, FYN, GFP, KCTD3, Lyn, mCherry, MPRIP, P120 catenin, PDCD1, PLEKHA7, PLEKHG5, puromycin N-acetyl transferase, src, or Yes1 in an animal model.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of vesicular stomatitis virus, HSV-1, and adenovirus expressing Ac Green Fluorescence Protein, CRE, eGFP, Firefly luciferase, FYN, GFP, KCTD3, Lyn, mCherry, MPRIP, P120 catenin, PDCD1, PLEKHA7, PLEKHG5, puromycin N-acetyl transferase, src, or Yes1 in an animal model.

  The cell lines below are registered with the IBC and have been tested for any recombinant lentivirus. These line(s) have been found negative for recombinant virus in a testing methodology approved by the IBC and therefore approval at BSL1/ABSL1 is approved.

- GBM14 NT-sh
- GBM14 SYX-sh1
- GBM14 SYX sh2
- GBM12 NT-sh
- GBM12 SYX-sh1
- GBM12 SYX-sh2

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-4-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.

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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Kelly Bailey** Update of In Vivo assessment of Immunobiology in Ewing Sarcoma

Modification submitted to include the addition of cell lines A673 Non-Target Transfected, A673 STAG2 Knockout Clone 1, A673 STAG2 Knockout Clone 4, TC71 Non-Target Transfected, TC71 STAG2 Knockout Clone 1, TC71 STAG2 Knockout Clone 4, that have been found negative for recombinant virus in a testing methodology approved by the IBC, with results attached in the application. No additional risk above that for the indicated biosafety level was determined.

The IBC requested documentation for the CAR T cells showing negative results for the replication competent retrovirus. If a downgrade of these cells is still desired, please submit a modification with the requested document.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of replication deficient retrovirus to create CAR T cells engineered to recognize and bind to MUC1 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 STAG2 KO in an animal model.

The cell lines below are registered with the IBC and have been tested for any recombinant lentivirus. These line(s) have been found negative for recombinant virus in a testing methodology approved by the IBC and therefore approval at BSL1/ABSL1 is approved.

A673 Non-Target Transfected

A673 STAG2 Knockout Clone 1

A673 STAG2 Knockout Clone 4

TC71 Non-Target Transfected

TC71 STAG2 Knockout Clone 1

TC71 STAG2 Knockout Clone 4

This study aligns with sections III-D-4-a of the NIH Guidelines.

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.

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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Michael Barry** Update of Cancer Therapeutics

Modification submitted to include the use of AAV vectors complimented with adenovirus vectors expressing reporter genes or therapeutic transgenes like p53 or PD-1-Ig an immune checkpoint inhibitor protein as well as non-viral plasmids expressing Sleeping beauty transposase.

The IBC recommends that staff who are conducting the hydrodynamic injections into mice wear safety glasses and a face shield.

Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing genes of interest as outlined in the application in an animal model.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of adenovirus expressing genes of interest as outlined in the application 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 genes of interest as outlined in the application in an animal model.

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

Animals or cells used with combinations of biological hazards take on the biocontainment controls associated with the highest biocontainment level required.

This study aligns with sections III-D-4-a of the NIH Guidelines.

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OK Cancel