Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, December 16, 2025

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

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve November Meeting Minutes

  Meeting minutes approved.
- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.
- 3. CDC Inspection

  DLMP CDC import permit inspection update.

Note Items

Approvals

- **Andrew Limper Update of Pneumocystis carinii animal model**
  Review Type: Update Application
- **Arun Kanakkanthara Update of Effect of various gene loss or overexpression in ovarian cancer**
  Review Type: Update Application
- **Mark McNiven Update of AAV Knockdown or Overexpression in murine animal models**
  Review Type: Update Application
- **Xiaolei Xu Update of Generation of disease models in Killifish**
  Review Type: Update Application
- **Madhusudan Grover Update of Epidemiology and Pathophysiology of Post-Infectious Functional GI Disorders**
  Review Type: Update Application
- **Kristina Chandra Reprogramming of human hematopoietic stem cells with Sendai viral vectors**
  Review Type: Approved with Modification
- **Sarosh Irani Update of Provision of human biospecimens from patients with neurological diseases (with and without neural autoantibodies) for laboratory based analyses.**
  Review Type: Update Application
- **Zhaohui Jin Update of CT041-ST-02, Open-label, multicenter, Phase 1b clinical trial to evaluate the safety and efficacy of autologous anti-claudin18.2 chimeric antigen receptor T-cell therapy in patients with advanced gastric or pancreatic adenocarcinoma**
  Review Type: Update Application
- **Davide Povero Cholangiocarcinoma and ferroptosis**
  Review Type: Approved with Modification
- **Bogang Wu Mechanistic and Therapeutic Investigation of Immune Dysregulation in Cancer and Immune Disorders**
  Review Type: Update Application
- **Loic Deleyrolle Update of Cancer stem cell immunoediting**
  Review Type: Update Application

Protocols Reviewed

- **John Giudicessi** Phase 1, Dose Escalation Trial of RP-A701 in Subjects with BAG3 Variant-Mediated Dilated Cardiomyopathy (BAG3-DCM)

  The Biological Hazard Application, Bios00002096, for "Phase 1, Dose Escalation Trial of RP-A701 in Subjects with BAG3 Variant-Mediated Dilated Cardiomyopathy (BAG3-DCM)" (IRB 25-013813) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of RP-A701, a replication-defective recombinant AAVrh.74 vector containing the human BAG3 gene, 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 Mayo Clinic Scottsdale 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

- **Talal Hilal** A Ph3 Random Controlled Trial of Rondecabtagene Autoleucel,an Autologous, Dual-targeting CD19/CD20 CAR T-Cell Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients With R/R LBCL in the Second-line Setting

  The Biological Hazard Application, Bios00002131, for "A Ph3 Random Controlled Trial of Rondecabtagene Autoleucel,an Autologous, Dual-targeting CD19/CD20 CAR T-Cell Product Candidate, Versus Investigator's

Choice of CD19 CAR T-Cell Therapy in Patients With R/R LBCL in the Second-line Setting" (IRB 25-013559) has been approved.

Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of ronde-cel, which uses a third generation, self-inactivating CD19/CD20 LVV to deliver genes of interest to a participant's T cells ex vivo (via transduction). The LVV uses a single lentiviral construct to deliver a sequence under expression control of an EF1α promoter, 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.

- **Brittni Scruggs** An Open-label, Multicenter Trial to Assess Safety and Efficacy of a Subretinal Administration of AAVB-039 (Celeste)

  The Biological Hazard Application, Bios00002103, for "An Open-label, Multicenter Trial to Assess Safety and Efficacy of a Subretinal Administration of AAVB-039 (Celeste)" (IRB 25-011494) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of AAVB-039, a gene therapy aimed at providing working copies of the ABCA4 gene to retinal 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 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.

- **Paras Shah** An Expanded Access Program of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)

  The Biological Hazard Application, Bios00002127, for "An Expanded Access Program of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG)" (IRB 25-011447) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of cretostimogene grenadenorepvec, a recombinant, conditionally replicating oncolytic adenovirus, in patients with non-muscle invasive bladder cancer (NMIBC) unresponsive to BCG, 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, droplet, and contact precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Mark Tyson** Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer

  The Biological Hazard Application, Bios00002126, for "Expanded Access Use of Recombinant Bacillus Calmette-Guérin in Nonmuscle Invasive Bladder Cancer" (IRB 25-013204) has been approved.

Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of Recombinant BCG, a live, genetically modified BCG immunotherapeutic derived from the Mycobacterium bovis BCG strain Danish, subtype Prague, 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 and Jacksonville locations only. If the enrollment of patients at 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.

Should an exposure or potential exposure to study staff occur, it is recommended for personnel to contact Occupational Health to be evaluated for post exposure follow up.

- **Vamsidhar Velcheti** A PHASE 1/2, FIRST-IN-HUMAN STUDY OF VNX-202 GENE THERAPY IN PATIENTS WITH HER2-POSITIVE CANCER (SENTRY-HER2)

  The Biological Hazard Application, Bios00002096, for "A PHASE 1/2, FIRST-IN-HUMAN STUDY OF VNX-202 GENE THERAPY IN PATIENTS WITH HER2-POSITIVE CANCER (SENTRY-HER2)" (IRB 25-013348) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of VNX-202, a recombinant adeno-associated virus (AAV) vector encoding a bispecific protein, termed GP202, 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.

- **Nilufer Taner** Update of Preclinical development of oligonucleotide therapeutics for ADRD

  Modification submitted to include the use of siRNA, either packaged in lipid nano-particles or not.

  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 tau RD P301S-CFP and tau RD P301S-YFP in an animal model.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotides (ASO) for gene silencing, siRNA, and plasmid constructed recombinant adeno-associated virus expressing genes of interest as outlined in the application in an animal model.

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

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

  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 to handling of sharps in the manner described above unless an exemption is on record with the IBC.

  The laboratory is reminded to use the appropriate animal cage labels (BSL1) in the animal facility for all housed animals associated with this project.

  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.

Employees will be informed by the Principal Investigator, laboratory supervisor, or delegate about the potential for adverse health effects that could occur following an exposure incident and how risks may be controlled to prevent an exposure.

- **Benjamin Wright** Update of Mechanisms and treatments for allergic disease

  Modification submitted to include the use of retrovirus, Murine Stem Cell Virus.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of replication deficient, murine stem cell virus.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing CD28, CD3z, FceR1a, and PLAUR to define the mechanisms of allergic disease and developing targeted treatments.

  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-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.

  Employees will be informed by the Principal Investigator, laboratory supervisor, or delegate about the potential for adverse health effects that could occur following an exposure incident and how risks may be controlled to prevent an exposure.

  Lentivirus and Lentiviral Vector Systems Guidance