Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, March 17, 2026

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

Quorum was present during all committee decisions.

Discussion Items

- 3. Supply Chain Distribution Update

  Supply chain management update on package tracking.
- 1. Approve February Meeting Minutes

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

  Consent agenda (note items) approved.

Note Items

Approvals

- **Mark Truty Update of Pancreatic Cell Line Knockin and Knockout using Crispr**
  Review Type: Approved with Modification
- **Michael Barry Update of Genetic Vaccines**
  Review Type: Update Application
- **Roberto Cattaneo Update of Identification of mutations governing measles virus spread in a subacute sclerosing panencephalitis (SSPE) brain**
  Review Type: Update Application
- **Robin Patel Update of General protocol for in vivo (animal) Infectious Diseases Research Laboratory projects.**
  Review Type: Update Application
- **Harmeet Malhi Update of Hepatocyte-derived extracellular vesicles**
  Review Type: Update Application
- **Vikas Majithia Update of Phase 2, Study Of CC-97540, CD19-Targeted NEX-T Chimeric Antigen Receptor (CAR) T Cells, in Participants with Active Systemic Lupus Erythematosus (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids at Least 2 Immunosuppressan**
  Review Type: Update Application
- **Douglas Brownfield Update of Investigation of the cells and molecules of the alveolus**
  Review Type: Update Application
- **Peter Storz Update of Molecular targets for pancreatic cancer**
  Review Type: Update Application
- **Cornelia Weyand Translational Immunology**
  Review Type: Update Application
- **Kelly Bailey In Vivo assessment of Immunobiology in Ewing Sarcoma**
  Review Type: Approved with Modification
- **Patrick McGarrah Update of VYR-VSV2-203, Phase 2 Trial of Voyager V1 (Vesicular Stomatitis Virus Expressing NIS and Human Interferon Beta, VV1), in Combination with Cemiplimab in patients with Hepatocellular Carcinoma, Non-Small Cell Lung Cancer**
  Review Type: Update Application
- **Nicholas Remmes Plasmid DNA Dosimetry**
  Review Type: New Application
- **Fawad Aslam Update of A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis**
  Review Type: Update Application

Protocols Reviewed

- **Talha Badar** A Phase I/II Safety, Dose-Finding, and Pharmacokinetics Study of VNX-101 Gene Therapy in Patients with Relapsed/Refractory CD-19 Positive Hematologic Malignancies

  The Biological Hazard Application, Bios00002186, for "A Phase I/II Safety, Dose-Finding, and Pharmacokinetics Study of VNX-101 Gene Therapy in Patients with Relapsed/Refractory CD-19 Positive Hematologic Malignancies" (IRB 26-001021) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of VNX-101, a combination of a nonreplicating recombinant AAV with a bispecific protein GP101, for the treatment of relapsed/refractory CD-19 positive hematologic malignancies 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.

- **Darren Baker** Lentiviral transduction for stable Cxcr1 and Gpnmb cell line production

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing Cxcr1, GFP, or Gpnmb.

  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.

  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

- **Fouad Chebib** In Vivo AAV and LNP-Mediated CRISPR Delivery for ADPKD Treatment

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing Cy5-labeled mRNA or Pkd1 (Polycystin-1) in an animal model.

  This study aligns with sections III-D-4-a 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 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.

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  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.

- **Fouad Chebib** Gene Therapy Vector Delivery (AAV) in Ex Vivo Human Kidney Perfusion System

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing PD-L1.

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

Due to the note of use of sharps, it is recommended that the laboratory take extra precautions during sharps (needle) usage. 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.

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- **Raymond Iezzi** ATSN-201-1 (Lighthouse)

  The Biological Hazard Application, Bios00002173, for "ATSN-201-1 (Lighthouse)" (IRB 26-000817) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of ATSN-201, which uses a modified AAV vector to delivery a working copy of the RS1 gene to photoreceptors in the retina for the treatment of X-linked retinoschisis, 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 only. If the enrollment of patients at Mayo Clinic Phoenix 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.

- **Terra Lasho** Splicing Effect of YBX1 in CMML

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing AmpR, EGFP, RTetR, or YBK1.

  This study aligns with Section III-D-1-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.

  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

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