Preview Minutes

Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, May 19, 2026

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

Minutes approved

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve April Meeting Minutes

  Meeting minutes approved.

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

Note Items

Approvals

- **Sarosh Irani Provision of human biospecimens from patients with neurological diseases (with and without neural autoantibodies) for laboratory based analyses.**
  Review Type: Update Application
- **Mrinal Patnaik Update of Translational Validation of Myeloid-relevant Mutations**
  Review Type: Update Application
- **Julio Chavez A Phase 1/2 Open-label, Multicenter Study Evaluating the Safety and Efficacy of KITE-363 or KITE-753, Autologous Anti CD19/CD20 CAR T-cell Therapies, in Subjects With Relapsed and/or Refractory B-cell Lymphoma**
  Review Type: Approved with Modification
- **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
- **Daniel Tschumperlin Update of Role of immune system in lung injury and repair**
  Review Type: Update Application
- **Jithma Abeykoon 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 Relapsed/Refractory Hematologic Autoimmune Disease**
  Review Type: Update Application
- **Jose Lujan Update of Calcium Imaging/Optogenetics/DBS/FSCV/6-OHDA open field test**
  Review Type: Update Application
- **Sungjune Kim Update of Epigenetic regulation of the immune system**
  Review Type: Update Application
- **Vikas Majithia Update of A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc)**
  Review Type: Update Application
- **Melissa Murray RNA Structure-Guided Discovery for MAPT Exon 10 Splicing Modulators**
  Review Type: New Application
- **Suman Bose Update of Lentivirus production for transforming cell lines**
  Review Type: Update Application
- **Vivek Nagaraja Update of A PHASE 1 STUDY EVALUATING THE SAFETY AND PRELIMINARY EFFICACY OF ALLO-329, A DUAL ANTI-CD19 / ANTI-CD70 ALLOGENEIC CAR T CELL PRODUCT IN AUTOIMMUNE DISEASE (RESOLUTION**
  Review Type: Update Application

Protocols Reviewed

- **Pooja Advani** Overexpressing AMPK in TNBC cell lines through Lentiviral vectors

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing AMPK or knocking down SCD1.

  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.

  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.

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** Gene knockdown using shRNA lentiviral transduction in vitro

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector to knockdownV2R.

  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.

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  Lentivirus and Lentiviral Vector Systems Guidance

- **Megan Dulohery Scrodin** A Phase 1/2, Open-Label, Multi-Center, Dose Escalation, Dose Expansion, and Single Repeat Dose Study of TSRA-196 in Adults With the PiZZ Genotype Who Have Lung and/or Liver Disease Associated with Severe Alpha-1 Antitrypsin Deficiency

  The Biological Hazard Application, Bios00002221, for "A Phase 1/2, Open-Label, Multi-Center, Dose Escalation, Dose Expansion, and Single Repeat Dose Study of TSRA-196 in Adults With the PiZZ Genotype Who Have Lung and/or Liver Disease Associated with Severe Alpha-1 Antitrypsin Deficiency" (IRB 26-003333) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of TSRA 196, an in vivo genome editing investigational product that is synthetically manufactured and consists of 2 chemically modified RNA drug substances (DSs) formulated as LNPs and a formulation buffer, 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.

- **Gwen Lomberk** Epigenomics Discovery and Therapeutics

  In order to ensure that appropriate biosafety risks are identified, containment measures are in place, and the proposed work complies with institutional and regulatory safety guidelines, the IBC has requested additional information to complete review of this study. Please provide further detail on the overall study objectives. In addition, clearly specify which cell lines with which viral vector(s) or methods being used (referencing the gene list in section 5.01). Finally, include a more detailed description of any proposed animal experiments, along with an anticipated timeline.

- **Paul Tang** AAV delivery to pig hearts

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

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

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- **Aaron Johnson** Lentiviral transduction of tumor cell lines

  Modification submitted to include the use of MMLV replication defective vector MIGR1 encoding the rat-ERBB2 ectodomain as a vaccine.

  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 CD19, and eGFP in an animal model.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of replication deficient, MMLV vector expressing EGFRviii aminoterminal peptide-MHCII antigenic peptide chimera in an animal model.

  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.

  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

- **Sundeep Khosla** Update of Targeting Cellular Senescence to Extend Healthspan

  Modification submitted to include the use of anti-sense oligonucleotides in an animal model.

  Subject to Laboratory and animal Biosafety Level 1 provisions and practices for research involving the in vivo study of antisense oligonucleotides against IgG (Fcgrt) 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.

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