Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, June 16, 2026

Present: Henrique Borges da Silva, Richard Chichester, John Copland, Marion Curtis, Marina Hanson, John Jasker, Richard Kennedy, Suzannah Schmidt-Malan, Russel Sinor, Melanie Swift, Elitza Theel

Absent: Hind Fadel, Madiha Fida, Kathleen McNaughton, Daniel Montonye

Mayo Guests:

Guests:

Duration: 11:30 AM - 1:30 PM

Minutes approved

Quorum was present during all committee decisions.

Discussion Items

- 3. Document Review: Recombinant DNA and Infectious Agent Policy and Procedure

  Documents approved.
- 4. NIH Modernization Update

  NIH Modernization Update
- 1. Approve May Meeting Minutes

  Meeting minutes approved.

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

Note Items

Approvals

- **Yi Lin Update of 90009530LYM1001, A Phase 1b Multicenter, Open-Label, Study of JNJ-90009530, an Autologous Anti-CD20 CAR-T Cell Therapy in Adult Participants With Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma**
  Review Type: Update Application
- **Pankaj Pasricha Update of Mechanisms and therapies for visceral pain and dysfunctions in disease models**
  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
- **Michael Barry Update of Genetic Vaccines**
  Review Type: Update Application
- **Carlos Mantilla Effective therapies for treatment of spinal cord injury and aging**
  Review Type: Update Application
- **Arkadiusz Dudek Update of 25-002051_RP2-202**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **Pamela McLean Update of Alpha-synuclein and tau in neurodegeneration**
  Review Type: Update Application
- **Zachary Resch Update of Lentivirus work MN BB 3rd floor**
  Review Type: Update Application
- **Taxiarchis Kourelis Update of KT-US-679-0788: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel (Anito-cel) Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma**
  Review Type: Update Application
- **Michael Kattah Update of Genetic regulation of epithelial injury in ulcerative colitis**
  Review Type: Update Application
- **Patricia Simner Update of Characterization of multidrug-resistant bacteria**
  Review Type: Update Application
- **Lauren Dalvin Update of Mechanisms of Uveal Melanoma Pathogenesis**
  Review Type: Update Application

Protocols Reviewed

- **Suman Bose** Developing viral based therapeutics

  Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of third generation engineered lentiviral vectors with selective tropism toward defined immune cell populations 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.

  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

- **Julio Chavez** A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy

  The Biological Hazard Application, Bios00002235, for "A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy" (IRB 26-005979) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of KITE-753 versus axicabtagene ciloleucel (axi-cel), both CAR T cell treatments using a patient's own T cells modified either with a lentiviral or retroviral vector, 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.

- **Yogish Kudva** Phase 1/2 Study to Evaluate the Safety, Tolerability, and Efficacy of SC451, a Hypoimmune Induced Pluripotent Stem Cell (iPSC)-Derived Islet Cell Therapy in Subjects with Type 1 Diabetes (T1D)

  The Biological Hazard Application, Bios00002237, for "Phase 1/2 Study to Evaluate the Safety, Tolerability, and Efficacy of SC451, a Hypoimmune Induced Pluripotent Stem Cell (iPSC)-Derived Islet Cell Therapy in Subjects with Type 1 Diabetes (T1D)" (IRB 26-004063) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of SC451, a hypoimmune, genome-modified iPSC-derived, allogeneic pancreatic islet cell therapy product consisting of insulin-producing beta 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 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.

- **Vikas Majithia** A Phase 1, Multicenter, Open-Label Study of BMS-986553, CD19 In Vivo Chimeric Antigen Receptor (CAR) T Cells, in Participants with Refractory Autoimmune Diseases

  The Biological Hazard Application, Bios00002240, for "A Phase 1, Multicenter, Open-Label Study of BMS-986553, CD19 In Vivo Chimeric Antigen Receptor (CAR) T Cells, in Participants with Refractory Autoimmune Diseases" (IRB 26-004795) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of BMS-986553, an in vivo CAR T cell immunotherapy being developed for the treatment of severe, treatment-resistant, systemic B-cell–driven autoimmune diseases using circRNA encoding an anti-CD19 CAR formulated in CD5-targeted LNPs for selective delivery to T cells following IV administration, 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 Jacksonville location only. If the enrollment of patients at either Mayo Clinic Rochester or 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.

- **Vikas Majithia** A Phase 2, open-label, study to evaluate the efficacy and safety of rapcabtagene autoleucel in patients with active, refractory systemic lupus erythematosus (SLE) or active, refractory lupus nephritis (LN)

  The Biological Hazard Application, Bios00002223, for "A Phase 2, open-label, study to evaluate the efficacy and safety of rapcabtagene autoleucel in patients with active, refractory systemic lupus erythematosus (SLE) or active, refractory lupus nephritis (LN)" (IRB 26-005443) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of YTB323, a CAR-T cell therapy targeting B cells, using a patient's own T cells and modified with a lentiviral vector to target CD19, 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 Jacksonville location only. If the enrollment of patients at either Mayo Clinic Rochester or 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.

- **Isobel Scarisbrick** Use of Antisense Oligonucleotides (ASOs) to study myelin dynamics

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotides targeting F2R to support myeline repair in an animal model.

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

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  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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- **Raquel Yokoda** Mechanisms Regulating YB-1 and YAP in Metastatic Tumor Biology

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing YAP1 or YBX1.

  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

- **Lauren Dalvin** Update of Mechanisms of Uveal Melanoma Pathogenesis

  Modification submitted to include in vivo work and the new aim to utilize immune cell therapies in which they can generate SLC45A2 positive immune cells which will be able to target uveal melanoma cells and prevent/reduce tumor growth and metastasis.

  Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the in vitro study of replication deficient, HIV-1 based lentiviral vector expressing shRNA targeting EGR1, BAP1, GNA11, GNAQ, or hTERT.

  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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Mithun Shah** Update of Pathogenesis of high-risk myeloid neoplasms

  Modification submitted to add in vivo experiments.

  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 shRNA targeting TP53 and TTK.

  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.

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  Lentiviruses and Lentiviral Vector Systems Standard Operating Procedure

- **Bogang Wu** Mechanistic and Therapeutic Investigation of Immune Dysregulation in Cancer and Immune Disorders

  Modification submitted to include the use of LCMV infection model.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of Lymphocytic Choriomeningitis Virus Infection lab-adapted strains Armstrong and Clone 13 to investigate the systemic effects of acute and chronic viral infections 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 to deliver synthetic single-guide RNAs (sgRNAs) into cancer cell lines for CRISPR/Cas9-mediated gene knockout (NFIX) to study gene function in tumor biology in an animal model.

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

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Lentivirus and Lentiviral Vector Systems Guidance

- **Gwen Lomberk** Epigenomics Discovery and Therapeutics

The laboratory has responded to the comments stemming from the IBC.

Subject to Laboratory Biosafety Level 1 provisions and practices for the study of non-viral plasmid amplification and recombinant protein production potentially expressing AURKA, AURKB, AURKC, DNA damage response / repair reporter constructs, ATM, BRCA1, BRCA2, PALB2, Epitope and fusion tags, HP1/CBX (CBX1, CBX3, CBX5), KDM, KMT family, Luciferase, PRMT family, RAS family, Ribosomal proteins (RPL10A), RNA-binding proteins (e.g., G3BP1, G3BP2), Selectable marker genes (e.g., BSD, PuroR, NeoR, HygR), SP/KLF transcription factor family (SP1-SP9; KLF1-17), or SWI/SNF (e.g. ARID1A, ARID1B, SMARCA4, SMARCA2, PBRM1).

Subject to Laboratory Biosafety Level 2 provisions and practices for the study of adenovirus or MMLV potentially expressing AURKA, AURKB, AURKC, DNA damage response / repair reporter constructs, ATM, BRCA1, BRCA2, PALB2, Epitope and fusion tags, HP1/CBX (CBX1, CBX3, CBX5), KDM, KMT family, Luciferase, PRMT family, RAS family, Ribosomal proteins (RPL10A), RNA-binding proteins (e.g., G3BP1, G3BP2), Selectable marker genes (e.g., BSD, PuroR, NeoR, HygR), SP/KLF transcription factor family (SP1-SP9; KLF1-17), or SWI/SNF (e.g. ARID1A, ARID1B, SMARCA4, SMARCA2, PBRM1).

Subject to Laboratory Biosafety Level 2+ provisions and practices for the study of replication deficient, HIV-1 based lentiviral vector potentially expressing AURKA, AURKB, AURKC, DNA damage response / repair reporter constructs, ATM, BRCA1, BRCA2, PALB2, Epitope and fusion tags, HP1/CBX (CBX1, CBX3, CBX5), KDM, KMT family, Luciferase, PRMT family, RAS family, Ribosomal proteins (RPL10A), RNA-binding proteins (e.g., G3BP1, G3BP2), Selectable marker genes (e.g., BSD, PuroR, NeoR, HygR), SP/KLF transcription factor family (SP1-SP9; KLF1-17), or SWI/SNF (e.g. ARID1A, ARID1B, SMARCA4, SMARCA2, PBRM1).

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Lentivirus and Lentiviral Vector Systems Guidance

- **Quinn Peterson** Growth, differentiation and characterization of stem cell and reporter lines

  The laboratory has responded to the comments stemming from the IBC.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of cell lines that were reprogrammed using Sendai virus in an animal model.

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

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OK Cancel