Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, April 21, 2026

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

Quorum was present during all committee decisions.

Discussion Items

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.
- 3. Semi-Annual Audit and Education update

  Update on quarter one walk-throughs.
- 1. Approve March Meeting Minutes

  Meeting minutes approved.

Note Items

Approvals

- **Anastasia Zekeridou Update of A Phase 2 Open-Label, Single-Arm, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, in Subjects with Treatment Refractory Stiff Person Syndrome (KYSA-8)**
  Review Type: Update Application
- **Patrick Johnston Update of M-2018-344, A multi-center single arm phase II study to evaluate safety & efficacy of genetically engineered autologous cells expressing anti-CD20 & anti-CD19 specific chimeric antigen receptor in relapsed and/or refractory diffuse large B cell**
  Review Type: Update Application
- **Shannon Fortin Ensign Update of Screen for drivers of glioma invasion**
  Review Type: Update Application
- **Yongjie Zhang Pathomechanistic investigations of C9FTD/ALS and SCA using AAV-mediated mouse models**
  Review Type: Update Application
- **Casey Ager Advances in Lentiviral, AAV, and Transposon Vectors, CRISPR Gene Editing, and Humanized Mouse Models for Immune Research**
  Review Type: Update Application
- **Shannon Fortin Ensign Update of Exploring synergistic proteopathic interactions in mixed pathology dementias**
  Review Type: Update Application
- **Shannon Fortin Ensign Update of Modeling glioblastoma in immunodeficient, immunocompetent, and Alzheimer's mice**
  Review Type: Update Application
- **Yongjie Zhang Update of Investigating genetic modifiers of Frontotemporal Dementia Models**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **John Giudicessi Update of Phase 1/2, First-in-Human, Open-Label, Multicenter Study of NVC-001 (AAV9 Vector Expressing Dominant Negative SUN1) for Safety, Tolerability, and Preliminary Efficacy in LMNA-Related Dilated Cardiomyopathy**
  Review Type: Update Application
- **Yongjie Zhang Update of Evaluating disease mechanisms associated with repeat expansions in C9orf72**
  Review Type: Update Application
- **Yongjie Zhang Update of ASO-mediated therapeutic intervention in C9ORF72 repeat expansion mouse model**
  Review Type: Update Application
- **Shannon Fortin Ensign Update of RCAS-tva Induction of Genetically Altered De Novo Glioblastoma for Measuring Tumor Invasion**
  Review Type: Update Application
- **Shyamal Mehta A Phase 2, Randomized, Double-blind, Sham Surgery-controlled Study of the Efficacy and Safety of Intraputaminal AAV2-GDNF in the Treatment of Adults with Moderate Stage Parkinson's Disease**
  Review Type: New Application
- **Yongjie Zhang Update of ASO-mediated therapeutic intervention in C9ORF72 repeat expansion mouse model**
  Review Type: Update Application
- **Richard Kennedy Update of Assessing immune responses in SARS-CoV2 infected individuals**
  Review Type: Update Application
- **Richard Kennedy Update of Assessment of Immune Responses to Influenza Vaccines**
  Review Type: Update Application
- **Yongjie Zhang Update of Investigating mechanisms of tau proteotoxicity**
  Review Type: Update Application
- **Arkadiusz Dudek Update of 25-002051_RP2-202**
  Review Type: Update Application
- **Richard Kennedy Update of Combination Peptide Vaccine for Zika Virus**
  Review Type: Update Application
- **Richard Kennedy Update of Identification of T and B cell epitopes from poxviruses**
  Review Type: Update Application

- **Khashayarsha Khazaie Update of Epigenetic mechanisms of colorectal cancer tumor promotion by Parvimonas micra**
  Review Type: Update Application
- **Moira Sugrue Update of Liver lesions in congestive hepatopathy and Fontan associated liver disease**
  Review Type: Update Application
- **Chun-Wei Chen Update of Research lab operation - David Chen Lab**
  Review Type: Update Application
- **Yongjie Zhang Update of ASO-mediated therapeutic intervention in C9ORF72 repeat expansion mouse model**
  Review Type: Update Application

Protocols Reviewed

- **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

  Requested change:

  The committee has requested that more information be provided on why the application only mentions KITE-753 and not KITE-363.

  This change will need to be addressed and returned to the IBC prior to final approval of the application.

  The Biological Hazard Application, Bios00002204, for "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" (IRB 26-003413) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of KITE-753, an autologous treatment in which the subject's own T cells, obtained by leukapheresis, are genetically engineered ex vivo, by using a lentiviral construct encoding an anti-CD19 and anti-CD20 chimeric antigen receptor (CAR), to target CD19 and CD20 expression on B-cell 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.

- **Vikas Majithia** 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)

  The Biological Hazard Application, Bios00002194, for "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)" (IRB 26-002067) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of BMS-986353, a CD19-directed cellular immunotherapy that comprises patient-specific autologous CD4+ and CD8+ T-cell populations that have been transduced using a genetically-engineered replication-incompetent, third-generation, self-inactivating (SIN) lentiviral vector encoding a CD19-specific CAR, 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 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.

- **Na Zhao** MicroRNA mediated conversion of human fibroblasts directly to neurons

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing MiR-9/9*-miR-124, MYTL1, NeuroD2, and reverse tetracycline-controlled transactivator to induce cortical-like neurons.

  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

- **Christopher Evans** Update of healing of bone defects using lentivirus and cell therapy

  Modification submitted to include the addition of cell lines BMP2-293, IL-1Ra-293, fLuc-293, CD44-BMP2-iPSCs, Cbh-mtOPG-iPSCs, and Clone 2 iPSCs 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.

  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 BMP2, and luciferase in an animal model.

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

  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.

  BMP2-293

  IL-1Ra-293

  fLuc-293

  CD44-BMP2-iPSCs

  Cbh-mtOPG-iPSCs

  Clone 2 iPSCs

  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.

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

- **Charles Howe** AAVs for manipulating brain cell transgene expression

Modification submitted to include updates to the experimental design and additional genes of interest. The committee reviewed the response to question 2 in section 3.01 and agreed that it does not require additional review.

Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing antigens, calcium reporters, caspase activators, Cre recombinase, Diptheria toxin receptor, Fluorescent proteins, fusion protein tags, granzyme B reporters, interferon pathway genes, luciferase, MHC 1, neurodegeneration genes, T cell activation reporters, and tetraspanin, 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.

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.

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