Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, February 17, 2026

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 January Meeting Minutes

  Meeting minutes approved.
- 3. BSL2 General Training

  BSL2 general training ready for review.
- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

Note Items

Approvals

- **Sophie Bakri A Randomized, Partially Masked, Controlled, Phase 2b/3 Clinical Study to Evaluate the Efficacy and Safety of RGX-314 Gene Therapy in Participants with nAMD (ATMOSPHERE)**
  Review Type: Update Application
- **Na Zhao Drug Discovery for Alzheimer's Disease**
  Review Type: Update Application
- **Shyamal Mehta Update of A Phase 1/2a Open-Label Ascending Dose Study to Evaluate the Safety and Effects of LY3884961 in Patients with Parkinson's Disease with at Least One GBA1 Mutation (PROPEL)**
  Review Type: Update Application
- **Marina Walther-Antonio Update of Porphyromonas somerae cellular invasion and upregulation of HIF pathway in endometrial cancer**
  Review Type: Update Application
- **Patricia Simner Update of Characterization of multidrug-resistant bacteria**
  Review Type: Update Application
- **Aaron Johnson Lentiviral transduction of tumor cell lines**
  Review Type: Update Application
- **Yuguang Liu Update of Deciphering microbial-immune cell interaction using single cell approaches**
  Review Type: Update Application
- **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
- **Manreet Kaur Update of A Phase 1/2a Open Label, Dose Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX103 in Subjects with Moderate to Severe Treatment- Refractory Crohn's Disease**
  Review Type: Update Application
- **Gina Razidlo Mechanisms of metastatic invasion**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **Diana Jurk Update of retroviruses and lentiviruses to target genes in the nucleus and in mitochondria**
  Review Type: Update Application
- **Brian Neff Update of A Phase 1/2 Trial of AAVAnc80-antiVEGF Gene Therapy in Individuals with Unilateral Vestibular Schwannoma**
  Review Type: Update Application
- **William Hooten Update of Intravenous administration of AAV8-human cocaine hydrolase to treat cocaine use disorder**
  Review Type: Update Application

Protocols Reviewed

- **Kelly Bailey** In Vivo assessment of Immunobiology in Ewing Sarcoma

  Requested changes:

  1. In section 8, please add BSL2+ for the use of lentivirus.

  2. In section 9, please add this to the Occupational health question:

  In the event of an exposure, the following information must be provided to OHS in order to determine if the post exposure prophylaxis protocol (PEP) is offered:
  1. Describe the experiment at the time of the potential exposure
  2. Tell OHS if the lentiviral vector is replication competent or incompetent
  3. If potentially exposed to cells following transduction, provide date of transduction and number of passages prior to employee exposure
  4. If potentially exposed to a lentivirus by an animal (Bite) following implantation of transduced cells or injection

of virus, provide date of when injection or procedure was performed.
5. Tell OHS if the vector carried an oncogene, tumor suppressor, or cytokine. If none of those, describe the gene insert to the OHS provider.

These changes will need to be addressed and returned to the IBC prior to final approval of the application.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of replication deficient retrovirus to create CAR T cells engineered to recognize and bind to MUC1 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 expressing STAG2 KO in an animal model.

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

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

- **Atta Behfar** Regulating gene expression with lentiviral vectors

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 exogenous genes-of-interest or RNAi molecules (fluorescent protein, HLA-G, MHC_RNA1, programmed death-ligand 1, PRRS_NSP4_3, and resistance gene) in an animal model.

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

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.

Lentivirus and Lentiviral Vector Systems Guidance

- **Yutao Liu** Ocular Genetics and Genomics

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing glaucoma-associated genes, keratoconus-associated genes, miRNAs or TGFb2 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 expressing glaucoma-associated genes, keratoconus-associated genes, miRNAs or TGFb2 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.

  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.

  Lentivirus and Lentiviral Vector Systems Guidance

- **Katherine Nickels** Encoded Endeavor ETX-DS-002

  The Biological Hazard Application, Bios00002168, for "Encoded Endeavor ETX-DS-002" (IRB 25-014857) has been approved.

Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of ETX101, a recombinant, replication-defective adeno-associated virus (AAV) vector designed to express an engineered transcription factor to upregulate expression of endogenous SCN1A in target 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.

- **Mark Truty** Update of Pancreatic Cell Line Knockin and Knockout using Crispr

  Requested Changes:

  1. In section 5.04, please clarify the cell line that you are using is correct, and that the shRNA is appropriate or if it should be removed.

  2. In section 10, please clarify the location of the BCS in the surgical suite suite where the cells are transduced. Animals will undergo implantation in the hood. Is this in the Guggenheim 17 location? And then clarify after the animals undergo implantation, they be transported to the animal biosafety surgical suite in double red bags that this is in Guggenheim 20-08.

  These changes will need to be addressed and returned to the IBC prior to final approval of the application.

  Modification submitted to include the use of lentivirus.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of recombinant Cas9 protein in combination with a sgRNA and template from a nonviral source to insert a GFP-FKBP12 fragment into the N-terminus of the gene into the pancreatic cancer cell line L3.6pl. and to knockout EZH2 in L3.6pl, 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 expressing FAT2 ogether with the green-fluorescent mBaoJin, 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 or BSL2) 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.

Lentivirus and Lentiviral Vector Systems Guidance