Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, July 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, Melanie Swift, Elitza Theel
Absent:	John Copland, Hind Fadel, Kathleen McNaughton
Mayo Guests:	
Guests:	
Duration:	11:30 AM - 1:30 PM

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve June Meeting Minutes

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

  Consent agenda (note items) approved.
- 3. Incident Review

  Incident review.

Note Items

Approvals

- **Patricia Simner Update of Characterization of multidrug-resistant bacteria**
  Review Type: Update Application
- **Brian Searle Using Mass Spectrometry-Proteomics to Investigate Renal Clearance**
  Review Type: New 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
- **Elie Naddaf Update of A PHASE 1 STUDY OF ANITOCABTAGENE AUTOLEUCEL FOR THE TREATMENT OF SUBJECTS WITH NON-ONCOLOGY PLASMA CELL-RELATED DISEASES**
  Review Type: Update Application
- **Sarah Pickles Update of Evaluating disease mechanisms associated with repeat expansions in C9orf72**
  Review Type: Update Application
- **Sarah Pickles Update of Investigating tau and ApoE4-mediated alterations in oligodendrocyte progenitor cells**
  Review Type: Update Application
- **Evanthia Galanis Update of Oncolytic Therapy**
  Review Type: Update Application
- **Arkadiusz Dudek Update of 25-002051_RP2-202**
  Review Type: Update Application
- **Megan Weivoda Update of Use of lentiviral in multiple myeloma cells**
  Review Type: Update Application
- **Sarah Pickles Update of Investigating genetic modifiers of Frontotemporal Dementia Models**
  Review Type: Update Application
- **Brian Searle Saturation Mutagenesis of Transthyretin**
  Review Type: New Application
- **Tushar Patel Update of Evaluations of therapies for liver disease**
  Review Type: Update Application
- **Wilfried Rossoll Update of AAV-mediated gene delivery in mice**
  Review Type: Update Application
- **Gina Razidlo Mechanisms of metastatic invasion**
  Review Type: Update Application
- **Sarah Pickles Update of Investigating mechanisms of tau proteotoxicity**
  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
- **Patricia Simner Update of Characterization of multidrug-resistant bacteria**
  Review Type: Update Application
- **Sarah Pickles Update of ASO-mediated therapeutic intervention in C9ORF72 repeat expansion mouse model**
  Review Type: Update Application
- **Matthew Starr Update of ACHIEVE-AbbVie M24-528**
  Review Type: Update Application
- **Rafael Fonseca Update of Preclinical Evaluation of Lentiviral Vectors for Oncology Therapy**
  Review Type: Update Application
- **Sarah Pickles Pathomechanistic investigations of C9FTD/ALS and SCA using AAV-mediated mouse models**
  Review Type: Update Application
- **Peter Harris Update of Characterizing the Pathogenicity of Variants of Undetermined Significance in Autosomal Dominant Polycystic Kidney Disease through in vitro Cell Culture**
  Review Type: Update Application
- **Peter Harris Ciliopathy Mutation Mimicking in Bacterial Vectors**
  Review Type: Update Application

Protocols Reviewed

- **James Allen** Modeling human disease with transgenic zebrafish

  Requested change:

  In section 2.02 question 3, please add a statement clarifying that the fish will not have any cell lines that are transduced with lentivirus.

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

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of CRISPR/Cas9 protein or mRNA, as well as guide RNA to knockout pax5, rag2, lck or other allelic dropout regions of interest 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 Akt2, bmi1a, Cas9, CD34, CEBPA, dvl2, DYRK1A, ERG, ETS2, EZH2, FLT3, GFI1, GFP, HIFI1A, HMGN1, HOXA10, HOXA9, IL7R, IRF8, KMT2A, KRASG12D, LMO1, LMO2, mCerulean, mCherry, mDendra2, MECOM, MEIS1, Myc, MYC, notch1a-icn, PU.1, RUNx1, SET, TAL1, TET2, THAP2, or tox 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.

  Animals or cells used with combinations of biological hazards take on the biocontainment controls associated with the highest biocontainment level required.

  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

- **Yan Bi** Understanding pancreatitis mechanisms

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing EGFP, human pancreatic enzymes

or ScFV antibodies, in an animal model.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of herpes simplex virus type 1 (HSV-1), murine gammaherpesvirus 68 (MHV-68), and Epstein–Barr virus (EBV) expressing EGFP, human pancreatic enzymes or ScFV antibodies, 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 EGFP, human pancreatic enzymes or ScFV, 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.

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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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.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Michelle Nguyen** Anti-FAP CAR-T–Enabled Ex Vivo Liver Defibrosis for Organ Rescue

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing Anti-FAP VHH (Clone 455), Anti-FAP VHH (Clone 457), CD247, CD8A, EGFP, mCherry, or TNFRSF9 in an ex vivo human liver perfusion 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-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.

  Due to the note of injection as the route of delivery, 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 for the handling of sharps in the manner described above unless an exemption is on record with the IBC.

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Lentivirus and Lentiviral Vector Systems Guidance

- **Carrie Schinstock** EXPAND: A Prospective Study to Evaluate the Safety and Efficacy of the 10 GE Xenokidney in Patients with End-stAge ReNal Disease (ESRD)

  The Biological Hazard Application, Bios00002256, for "EXPAND: A Prospective Study to Evaluate the Safety and Efficacy of the 10 GE Xenokidney in Patients with End-stAge ReNal Disease (ESRD)" (IRB 26-005395) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of a recombinant DNA–derived biological product, the 10 GE Xenokidney, which is generated ex vivo by the sponsor through stable genomic modification of donor pigs, 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 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.

- **Mathew Schnorenberg** Myeloid Reprogramming Strategies in Models of Cancer Using Non-Coding DNA as Immunostimulatory Material

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of short synthetic, non-coding double-stranded DNA molecules intended to activate cytosolic DNA sensing through the cGAS-STING pathway 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.

- **Michael Barry** Update of Characterization of filovirus protein functions and host-viral protein interactions

  Modification submitted to update the use of general filovirus proteins.

  The committee discussed and agreed that there are no DURC concerns.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the in vitro study of the filovirus minigenome plasmid is transfected into eukaryotic cells together with expression plasmids (called helper plasmids) for L, VP35, NP and VP30, trVLPs, and if necessary T7 RNA polymerase, leading to expression of the minigenome and formation of minigenome-containing RNP complexes expressing multiple genes of interest (none classified at known or suspected oncogenes or tumor suppressors). Genes of interest include: 2A, Beta-lactamase, bsr, Cas9, Cre, eBFP, FLAG, FLuc, GFP/eGFP, GFP-luciferase, GP (viruses belonging to Filoviridae family), gRNA, HA-tag, Hepatitis delta virus and Hammerhead ribozyme sequences, His-tag, hph, HSP70, HSP90B1, IL-12, IL-15, IL-18, IRES, L (viruses belonging to Filoviridae family): Not expressed from minigenome, microRNA target sequence, Myc-tag, NanoLuc, NP (viruses belonging to Filoviridae family), pac, RBBP6, sGP (viruses belonging to Filoviridae family), Sh ble, Short-hairpin RNAs targeting host genes listed in this application, Small interfering RNAs targeting viral genes listed in this application, SP6pol, Strep-tag, T7pol, Tetracystein-tag, V5-tag, VP24 (viruses belonging to Filoviridae family), VP30 (viruses belonging to Filoviridae family), VP35 (viruses belonging to Filoviridae family), VP40 (viruses belonging to Filoviridae family), VSV-tag, and ZsGreen.

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

  The use of trVLPs is for modeling and characterizing EBOV pathogenesis and life cycle in an animal model. The laboratory has provided sufficient documentation regarding the containment of animals injected with trVLPS.

  As a reminder, should the list of genes change, the laboratory is reminded to modify their Biosafety Application to reflect those changes.

  For the filovirus minigenome, the percentage of the total genome is less than 2/3 of the viral genome in the plasmid. The missing genes involve 4 open reading frames and a portion of the promoter region. As a result, there is no way to get a replication competent virus during the project.

  The committee noted that none of the proposed viruses are transmitted via the airborne route, they must be carried by an insect vector (e.g. mosquito or tick).

  There is no insectary in close proximity to the BSL2 or BSL3 facilities as well as no field study animal in close to the 2 tissue culture rooms where work will be conducted.

  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.

  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 to 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.

- **Michael Barry** Update of Vector Hybrids

  Modification submitted to switch from an 'all in two' system to an 'all in one' system.

  The committee discussed and agreed that there are no DURC concerns.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of non-viral vectors like liposomes, lipid nanoparticles (LNPs) or polyethyleneimine (PEI) to deliver genes of interest including MLV, gag, pol, or CAR, 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. You 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 (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.

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.

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.

- **Michael Barry** Retrovirally-Modified Cells

  Modification submitted to include Simian Foamy Virus.

  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 luciferase or cell surface receptors in an animal model.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of Moloney Murine Leukemia Viral Vector and SFV expressing ras and myc 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. You 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 (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.

  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.

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- **Mukesh Pandey** PET imaging of bacterial infection in gut or topical or surgical implants, cardiac devices and graft infection: An evaluation of novel PET probe

Modification submitted to include the use of H. pylori in a mouse model.

Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of *Acinetobacter baumannii, Klebsiella pneumoniae, Escherichia coli*, *Staphylococcus epidermidis*, methicillin-resistant *Staphylococcus aureus*, *Staphylococcus aureus, Propionibacterium acnes*, *Pseudomonas aeruginosa*, *H. pylori*, and *Enterococcus faecalis* in an animal model.

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 (BSL2) in an approved 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.

As an additional 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.

No additional risk above that for the indicated biosafety level was determined.

OK Cancel