Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, August 18, 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, Elitza Theel
Absent:	Hind Fadel, Madiha Fida, Kathleen McNaughton
Mayo Guests:	Dana Good
Guests:	
Duration:	11:30 AM - 1:30 PM

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve July Meeting Minutes

  Meeting minutes approved.
- 5. Incident Investigation

  Incident investigation.
- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

- 6. IBC Membership Update

  Membership update.

- 4. Gain of Function Update

  Update on the gain of function policy from the USG.

- 3. Discuss Access to ABSL2 Suite for Non-BSL2 work (IVIS Imaging)

  Lab member not listed on BSL2 application anymore had access to BSL2 suite. Tried to bring animals out of suite, stopped by DCM. Would like memo/opinion on non hazardous work being done in BSL2 area.

  IBC committee endorses the recommendation that non-hazardous work being conducted in the ABSL2 suite is not allowed. If extenuating circumstances arise, IBC and DCM approval is required prior to use if the space in this capacity.

Note Items

Approvals

- **James Allen Modeling human disease with transgenic zebrafish**
  Review Type: Approved with Modification
- **Munemasa Mori Update of Development and analyses of A Novel Approach to Regenerate Functional Lungs**
  Review Type: Update Application
- **Brian Searle Studying Splice Isoforms in Glioblastoma Patients**
  Review Type: New Application
- **Svetomir Markovic Update of Myeloid Reprogramming Strategies in Models of Cancer Using Non-Coding DNA as Immunostimulatory Material**
  Review Type: Update Application
- **Faheem Guirgis EM Translational Sepsis Research Project**
  Review Type: New Application
- **Hu Zeng Update of Metabolic regulation of humoral immunity**
  Review Type: Update Application
- **Atta Behfar Update of Use of PEP and viral vectors**
  Review Type: Update Application
- **Virginia Shapiro Update of Viral Vectors**
  Review Type: Update Application
- **Lisa Boardman Investigation of Colorectal Cancer via Organoids, Telomere Lengths, and Micro- and Nano-Plastics (MNPs)**
  Review Type: New Application
- **Brin Freund Update of A Multi-center, Phase 1/2a, First-in-human (FIH) Study Investigating the Safety, Tolerability, and Efficacy of AMT-260 in Adults with Unilateral Refractory Mesial Temporal Lobe Epilepsy Administered via MRI-guided Convection-enhanced Delivery (C**
  Review Type: Update Application
- **Taxiarchis Kourelis Update of CA0881005**
  Review Type: Update Application
- **Matthew Schellenberg Update of Delivery of Genes Encoding DNA Repair Proteins using Lentivirus**
  Review Type: Update Application
- **Daniel Saris Update of Observing mitochondrial transfer between mesenchymal stem cells and autologous cells**
  Review Type: Update Application
- **Zvonimir Katusic Update of Function of amyloid precursor protein in brain vascular endothelial cells**
  Review Type: Update Application
- **Tamas Ordog Epigenetics of the Gastrointestinal System**
  Review Type: Update Application
- **Robin Patel Update of General protocol for in vivo (animal) Infectious Diseases Research Laboratory projects.**
  Review Type: Update Application
- **Shizhen Zhu Update of Zebrafish as a Model to Study Oncogenes and Tumor Suppressors in Cancer**
  Review Type: Update Application

Protocols Reviewed

- **Jithma Abeykoon** The Biological, Prognostic and Therapeutic Implications of genetic alterations involving DNA damage repair and replication stress pathways in Mantle Cell Lymphoma

  Requested changes:

  1. In section 5.02, please add more detail on how the construct will be generated for the adenovirus.

  2. In section 2.02 question 3, please add more detail on which cell lines will be used with which viral vector as well as reasoning to use either the lentivirus or adenovirus for a specific cell line.

  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 adenovirus expressing ATM, CCND1, or POLQ 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 ATM, CCND1, or POLQ 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

- **Julio Chavez** A Phase 1/2, open-label, multicenter study of UB-VV400 in combination with rapamycin in relapsed or refractory CD22-positive B-cell malignancies

  The Biological Hazard Application, Bios00002301, for "A Phase 1/2, open-label, multicenter study of UB-VV400 in combination with rapamycin in relapsed or refractory CD22-positive B-cell malignancies" (IRB 26-004874) has been approved.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of a UB-VV400, a type of gene therapy designed to help the immune system fight cancer. It uses modified, inactive

pieces of a virus (lentivirus) to deliver genetic material to certain immune cells in the body 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, Scottsdale, and Jacksonville locations.

Infection Prevention and Control has determined that standard precautions are appropriate for this trial. Please ensure staff review section 10 of the Product Administration Manual for the Occupational exposure treatment guide.

Informed Consent documentation is adequate.

- **Margot Cousin** Developing patient-derived cell culture models using lentiviral transduction

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing bla, enhanced GFP, NEUROG2, pac, and reverse tetracycline transactivator.

  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

- **Yuting Huang** Regulated in situ immunotherapy: Engineering controllable liver-directed gene therapy for safe and durable cancer immunotherapy

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of non-viral recombinant or synthetic DNA plasmids expressing Caff-IL6BR/C-STAR, CD19/CD3 Bispecific engager, CEA/CD3 Bispecific T cell engager, Claudin18.2/CD3 Bispecific T cell engager, EF-1 promoter, EpCAM/CD3 Bispecific T cell engager, GCC(GUCY2C)/CD3 Bispecific T cell engager, GFP, GPC3/CD3 Bispecific T cell engager, HER2/CD3 Bispecific T cell engager, iCasp9, Mesothelin/CD3, miniXon, MUC-1/CD3 Bispecific T Cell engager Bispecific T cell engager, MUC17/CD3 Bispecific T cell engager, NanoLuc/NLuc, SNIPR, Tc45 aptazyme, Y387 pA regulator in an animal model.

  The IBC recommends standard precautions (lab coat, gloves, safety glasses) for the liver perfusion studies.

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

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- **David Lott** Evaluation of antifibrotic therapies for the treatment of vocal fold scarring

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of siRNA molecules encapsulated in synthetic nanoparticles in an animal model.

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

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- **Rahmi Oklu** Porcine Model of Infected Aneurysm Creation and Treatment

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of *Escherichia coli* (*E. coli*) expressing GFP in an animal model.

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

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- **Subhadeep Roy** Oligonucleotide Therapeutics Knockdown

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotide (ASO) and small-interfering RNA (siRNA) in an animal model.

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

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- **Laura Rogers** Update of Genetic modification of cells using replication-deficient retroviral and viral vectors

  Modification submitted to include the use of LCMV and influenza.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of Lymphocytic Choriomeningtis Virus (LCMV) Lab-adapted Strain Armstrong and Influenza Virus - PR8 Strain (laboratory and mouse adapted strain) 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 genes of interest AAK1, antibiotic resistance, ASTN2, bioluminescent reporters, CFHR, CRTC3, EGFR, Envelope proteins, epitope tags, fluorescent proteins, GPATCH8, NFU1, or PPP2R2D in an animal model.

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

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OK Cancel