Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, November 18, 2025

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 October Meeting Minutes

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

  Consent agenda (note items) approved.
- 3. AAALAC Site Visit

  AAALAC site visit to Rochester.

Note Items

Approvals

- **Marion Curtis Update of Immunotherapy in ovarian cancer metastasis**
  Review Type: Update Application
- **Taxiarchis Kourelis Update of CA088-1000, A Phase 2, Open-Label, Multicenter Study of BMS-986393, a GPRC5D-directed CAR T Cell Therapy in Adult Participants with Relapsed or Refractory Multiple Myeloma (QUINTESSENTIAL)**
  Review Type: Update Application
- **Christopher Evans Update of Adenovirus and AAV use for Treatment of Critical Size Defect**
  Review Type: Update Application
- **Jose Nativi Nicolau Update of MAGNITUDE: A Phase 3, Multinational, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of NTLA-2001 in Participants with Transthyretin Amyloidosis with Cardiomyopathy**
  Review Type: Update Application
- **Stephen Ansell Update of Modification to R9-177-1/2008: Gene Silencing and delivery using retroviral and lentiviral constructs**
  Review Type: Update Application
- **Matthew Starr Update of RGX-314-3101 Ascent**
  Review Type: Update Application
- **Henrique Borges da Silva Role of extracellular nucleotides in CD8+ T cell immune responses to infection and cancer**
  Review Type: Update Application
- **Richard Vile Update of Oncolytic virus therapy for human brain tumors**
  Review Type: Update Application
- **Aaron Mansfield Update of Preclinical drug testing and assay development for patient-derived tumors in a xenograft model**
  Review Type: Approved with Modification

Protocols Reviewed

- **Kristina Chandra** Reprogramming of human hematopoietic stem cells with Sendai viral vectors

  Requested changes:

  1. In section 1.02, please add where the behavior studies will be conducted.

  2. In section 2.02 question 3, please add that a biohazard sign will be posted to the room while behavior studies are being conducted.

  3. In section 2.02 question 3, please also add how the room will be cleaned and decontaminated after behavior studies are completed.

  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 Sendai virus used to reprogram hematopoietic stem cells 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 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.

- **Ruqin Chen** IFx-Hu2.0 MCC 2021-01 A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF IFx-Hu2.0 AS AN ADJUNCTIVE THERAPY TO PEMBROLIZUMAB IN CHECKPOINT-INHIBITOR NAÏVE PARTICIPANTS WITH ADVANCED OR METASTATIC MERKEL CELL CARCINOMA

  The Biological Hazard Application, Bios00002096, for "IFx-Hu2.0 MCC 2021-01 A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF IFx-Hu2.0 AS AN ADJUNCTIVE THERAPY TO PEMBROLIZUMAB IN CHECKPOINT-INHIBITOR NAÏVE PARTICIPANTS WITH ADVANCED OR METASTATIC MERKEL CELL CARCINOMA" (IRB 25-010588) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of IFx-Hu2.0 pAc/emm55, a recombinant plasmid expression vector containing the S. pyogenes serotype M55 (Isolate A928171) modified cell surface M virulence protein as an antigen 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.

- **Madiha Iqbal** A Phase 2, Open-Label, Randomized Study of Pirtobrutinib and Brexucmphabtagene Autoleucel in Patients with Relapsed or Refractory Mantle Cell Lymphoma

  The Biological Hazard Application, Bios00002119, for "A Phase 2, Open-Label, Randomized Study of Pirtobrutinib and Brexucmphabtagene Autoleucel in Patients with Relapsed or Refractory Mantle Cell Lymphoma" (IRB 25-012737) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of Bruton's tyrosine kinase (BTK) inhibitor, pirtobrutinib, combined with the CAR T cell therapy brexucabtagene autoleucel (brexu-cel) 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, Mayo Clinic Jacksonville, and Mayo Clinic Scottsdale locations.

  Infection Prevention and Control has determined that standard precautions are appropriate for this trial.

  Informed Consent documentation is adequate.

- **Bjorn Oskarsson** Phase 1/2 Investigation Of Novel Experimental Regimen in Amyotrophic Lateral Sclerosis (PIONEER-ALS): An Open-Label, Uncontrolled, Multicenter Study to Assess the Safety and Tolerability of Two Doses of VTx-002

The Biological Hazard Application, Bios00002102, for "Phase 1/2 Investigation Of Novel Experimental Regimen in Amyotrophic Lateral Sclerosis (PIONEER-ALS): An Open-Label, Uncontrolled, Multicenter Study to Assess the Safety and Tolerability of Two Doses of VTx-002" (IRB 25-010905) has been approved.

Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of VTx-002, an rAAV gene therapy vector consisting of an AAV5.2 capsid. VTx-002 carries the transgene expression cassette encoding a humanized anti-TDP-43 antibody fragment in a clinical trial.

Please provide the Certificate of Analysis when available.

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 Phoenix or Mayo Clinic Rochester 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.

- **Davide Povero** Cholangiocarcinoma and ferroptosis

  Requested changes:

  1. In section 2.02 questions 3 and 4, please make sure that the source of the biological agents match to those in sections 5.02 and 5.04.

  2. In section 2.02 question 3, please be more specific on the lentiviral vector you are using.

  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 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus expressing BAP1 and siRNAs encapsulated in lipid nanoparticles (LNPs) used to knockdown OSBPL3, 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 shRNA targeting GPX4 and BAP1 in an animal model.

  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 study aligns with section III-D-4 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 (BSL1 or 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

- **Mustaqeem Siddiqui** A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Relapsed/Refractory Hematologic Autoimmune Disease

  The Biological Hazard Application, Bios00002120, for "A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Relapsed/Refractory Hematologic Autoimmune Disease" (IRB 25-012359) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of CTX112, using human healthy-donor derived T cells that are genetically modified ex vivo using CRISPR-Cas9 gene editing components for the insertion of an anti-CD19 CAR transgene using an adeno-associated virus (rAAV-138) vector to deliver the donor template, 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** Pancreatic Cell Line Knockin and Knockout using Crispr

  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.

  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.

- **Gelareh Mohammadzadeh** Update of Understanding drivers, molecular pathways and the tumor microenvironment for better understanding of brain tumour origins,development and therapeutic paradigms

  Modification submitted to include the use of ICAM1-targetting antisense oligonucleotides (ASOs).

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotides 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 as outlined in the application in an animal model.

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

  Please note that any cell lines must be tested before the IBC can downgrade the biosafety level from BSL-2+ to BSL-1. Contact biosafety@mayo.edu for questions and instructions for a downgrade request.

  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 (BSL1 or 2+) 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.

  Please note the updated language in section 9 for Occupational Health practices following an exposure.

  Lentivirus and Lentiviral Vector Systems Guidance

- **Patricia Simner** Update of Characterization of multidrug-resistant gram-negative bacteria

  Modification submitted to include additional genus of bacteria.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of gram-negative bacteria (including *Acinetobacter baumannii, Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa*) and other similar microbial species not to exceed RG2, associated with clinical infections and/or colonization of patients to understand mechanisms of antimicrobial resistance and/or spread.

  This work aligns with Section Section III-D Experiments that Require Institutional Biosafety Committee Approval Before Initiation of the NIH Guidelines.

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.

If additional precautions should be adhered to, these will be communicated to the lab by the IBC.

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 Vector Hybrids

  The laboratory responded to requests stemming from the IBC, the modification was submitted to remove the viral components of the delivery systems.

  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.