Institutional Biosafety Committee

Biological Full Committee

Minutes

Tuesday, January 20, 2026

Present:	Henrique Borges da Silva, Marion Curtis, Madiha Fida, Marina Hanson, John Jasker, Richard Kennedy, Daniel Montonye, Suzannah Schmidt-Malan, Russel Sinor, Melanie Swift, Elitza Theel
Absent:	Richard Chichester, John Copland, Hind Fadel, 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 December Meeting Minutes

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

  Consent agenda (note items) approved.

Note Items

Approvals

- **Robin Patel Update of General protocol for in vivo (animal) Infectious Diseases Research Laboratory projects.**
  Review Type: Update Application
- **Tsuneya Ikezu Update of Investigation of Alzheimer's disease and related dementia in animal models and human samples**
  Review Type: Update Application
- **Tanios Bekaii-Saab Update of BNT122-01, A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following**
  Review Type: Update Application
- **Gloria Kim Update of Using lentivirally transduced cells for cellular immunotherapies**
  Review Type: Update Application
- **Yi Lin Update of Genetic manipulation of primary cells and cell lines to facilitate preclinical studies on the effects of myeloid cells in cancer**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **Saranya Chumsri Update of BC-IMT-04**
  Review Type: Update Application
- **Taxiarchis Kourelis Update of KT-US-679-0788: A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel (Anito-cel) Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma**
  Review Type: Update Application
- **Enis Kostallari Update of Pathobiology of liver fibrosis**
  Review Type: Update Application

Protocols Reviewed

- **Krishna Bhat** Monosynaptic retrograde tracing of neuronal circuitry using EnvA-Pseudotyped, G-deleted Rabies Virus (CVS-N2c)

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of modified rabies virus that is replication-deficient, pseudotyped with EnvA, and lacks the glycoprotein gene (G-deleted), allowing infection only of TVA-expressing starter cells (TVA is the receptor for EnvA); Helper virus (AAV8-TC66T-2A-mRuby3-2A-OG) encodes TVA receptor (to allow specific infection from modified rabies virus pseudotyped with EnvA), mRuby3 reporter, and deleted rabies glycoprotein in an animal model.

  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.

  Work with Biosafety to obtain an interstate transport permit for the modified rabies virus.

  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.

  Prior to working with the modified rabies virus, it is highly recommended that staff members contact Employee/Occupational Health Services to review an employee's immunization status and any health-related concerns. When appropriate, immunizations will be made available at no cost to the employee. Employees who wish to have an evaluation or supervisors who have a list of employees who wish to have an evaluation should send an email with name, employee ID, and toxin/organism of concern to swift.melanie@mayo.edu.

  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.

- **Alfred Doyle** B. infantis as a therapeutic for EoE

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of *Bifidobacterium infantis* in an animal model.

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

  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.

- **John Giudicessi** 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

  The Biological Hazard Application, Bios00002155, for "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" (IRB 25-012806) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of NVC-001, a recombinant, non-replicating, single-stranded AAV9 vector, and expresses dnSUN1, 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 only. If the enrollment of patients at Mayo Clinic Phoenix 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.

- **Thomas Grys** Investigation of clinical isolates of Coccidioides spp. species to measure spherulation, volatile organic compounds, and reactivity in novel diagnostic assays

Subject to Laboratory Biosafety Level 3 provisions and practices for research involving the study of *Coccidioides* spp.

As outlined in the application approval is granted to observe spherule growth in BSL2+ mycology area. Please ensure that samples are transported in double containment and remain sealed at all times.

Section III-D-3-b. Experiments involving the use of infectious or defective Risk Group 3 viruses.

All samples in the biosafety level 3 lab and those items that may be potentially contaminated must be inactivated prior to removal from the suite.

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.

- **Tambi Jarmi** Engineering Immune-Silent Human Kidneys Using Lipid Nanoparticle–Delivered CRISPR: From Cell Culture to Organ-on-a-Chip to Whole Organ

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of CRISPR-Cas9 deletion of HLA.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the use of ex vivo human kidneys.

  This study aligns with section III-D 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.

  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.

  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.

- **Michel Toledano** A Phase 1/2a, Open-Label, Dose-Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX319 in Subjects with Primary or Secondary Progressive Multiple Sclerosis

  The Biological Hazard Application, Bios00002151, for "A Phase 1/2a, Open-Label, Dose-Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX319 in Subjects with Primary or Secondary Progressive Multiple Sclerosis" (IRB 25-013975) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of TRX318, an allogeneic, chimeric antigen receptor (CAR) type 1 regulatory (Tr1) T cell drug product (DP) that has been designed to address autoimmune and inflammatory disorders including progressive forms of multiple sclerosis in a clinical trial. TRX319 drug product consists of engineered human CD4+ T cells that recapitulate the major regulatory functions of naturally occurring Type 1 regulatory T (Tr1) cells, a subset of CD4+ regulatory T cells (Tregs). TRX319 is generated by isolating CD4+ T cells from a healthy donor and transducing them with a tricistronic lentiviral vector (LVV) encoding human interleukin (IL)10, a truncated (non-signaling) form of the human nerve growth factor receptor (NGFR) [ΔNGFR, CD271], and CD19-targeting chimeric antigen receptor (CAR).

  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. If the enrollment of patients at Mayo Clinic Scottsdale or Mayo Clinic 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.

- **Suman Bose** Update of Lentivirus production for transforming cell lines

  Modification submitted to include the addition of cell lines NTC1, IMPACT, SSUH, and NTC3 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.

  Subjection to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of a non-viral transposon system (piggyBack or sleeping beauty) 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 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.

  NTC1

  IMPACT

  SSUH

  NTC3

  The committee would like to remind the lab:

  During procedures involving hazardous materials, it is essential to inform other laboratory personnel of the associated risks. Appropriate signage should be displayed, specifying the laboratory conducting the work, the biosafety level, required personal protective equipment (PPE), and any occupational health requirements, if applicable.

  If staff have any concerns regarding ongoing hazardous work, they may contact Employee Occupational Health.

  All surgical procedures involving Biosafety Level 2 or higher agents are required to be conducted within a designated DCM surgical suite. An amendment to the approved biosafety application must be submitted before initiating such work.

  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.

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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.

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

- **Julian Molina** Update of A2B694-101, EVEREST-2

  Modification submitted to include the addition of A2B543 as a new study arm, an autologous T-cell therapy engineered with 2 independent lentiviral viruses.

  The Biological Hazard Application, Bios00001655, for "A2B694-101, EVEREST-2" (IRB 24-000337) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the in vitro study of A2B694, composed of autologous logic-gated Tmod cells transduced with a single lentiviral vector, 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 patient at Mayo Clinic Scottsdale is desired, the laboratory is directed to inform the IBC of the expansion.

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

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

  Informed Consent documentation is adequate.

- **Zachary Resch** Update of Lentivirus work MN BB 3rd floor

  Modification submitted to include updates to the application, namely that measles virus and VSV will be transferred to the Quality Control Laboratory as the VVLP is shutting down.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the in vitro study of measles virus and VSV.

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the in vitro study of replication deficient, HIV-1 based lentiviral vectors to develop cGMP-compliant manufacturing processes.

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

  This study aligns with Section III-D-1-a of the NIH guidelines.

  Prior to working with Measles Virus, it is highly recommended that staff members have an up to date MMR Vaccine. Employee/Occupational Health Services will offer a free review of an employee's immunization status and any health-related concerns. When appropriate, immunizations will be made available at no cost to the employee.
  Employees who wish to have an evaluation or supervisors who have a list of employees who wish to have an evaluation should send an email with name, employee ID, and toxin/organism of concern to swift.melanie@mayo.edu.

  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.

  Lentivirus and Lentiviral Vector Systems Guidance

OK Cancel