Institutional Biosafety Committee

Biological Full Committee

Minutes

Wednesday, August 27, 2025

Present:	Henrique Borges da Silva, Richard Chichester, John Copland, Marion Curtis, Madiha Fida, Marina Hanson, John Jasker, Richard Kennedy, Suzannah Schmidt-Malan, Russel Sinor, Elitza Theel
Absent:	Hind Fadel, Kathleen McNaughton, Daniel Montonye, Melanie Swift
Mayo Guests:	Jeffrey Schmoll
Guests:	Brendan Shea
Duration:	11:30 AM - 1:00 PM

Minutes approved

Quorum was present during all committee decisions.

Discussion Items

- 1. Approve July Meeting Minutes

  Meeting minutes approved.

- 2. Approve Consent Agenda (Note Items)

  Consent agenda (note items) approved.

- 3. Incident Review

  Review of incident report submitted to the NIH.

- 4. Alternative Autoclave Options

  Alternate autoclave options for BSL3 waste. Tabled until September IBC meeting.

Note Items

Approvals

- **John Mills Update of Development of an RT-QuIC assay for diagnosing Creutzfeldt-Jakob Disease (Prion)**
  Review Type: Update Application
- **Zvonimir Katusic Update of Function of amyloid precursor protein in brain vascular endothelial cells**
  Review Type: Update Application
- **Kathryn Knoop Update of Gut Mechanisms of Neonatal Sepsis**
  Review Type: Update Application
- **Virginia Shapiro Update of Viral Vectors**
  Review Type: Update Application
- **John Eaton Update of A Phase 2 Randomized, Double-blind, Placebo-controlled, Parallel Study Evaluating the Safety and Efficacy of LB-P8 in Patients with Primary Sclerosing Cholangitis (PSC)**
  Review Type: Update Application
- **John Copland Combination therapies of SSI4 and sorafenib in ectopic and orthotopic HCC liver models**
  Review Type: Update Application
- **Chun-Wei Chen Update of Research lab operation - David Chen Lab**
  Review Type: Update Application
- **Linda McAllister Update of Lipid nanoparticle mediated nanomedicine delivery**
  Review Type: Update Application
- **Laurence Miller Structural approach to correcting an abnormal servomechanism involved in appetite**
  Review Type: Update Application
- **Tushar Patel Update of Evaluations of therapies for liver disease**
  Review Type: Update Application
- **Autumn Schulze Update of MicroRNA targeted infectious coxsackievirus A21 RNA as oncolytic virotherapy**
  Review Type: Update Application
- **Laurence Miller Update of Receptor mutagenesis**
  Review Type: Update Application
- **Rory Smoot Evaluation of YAP and other common mutations in cholangiocarcinoma and liver regeneration**
  Review Type: Update Application
- **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
- **Hong Qin Update of DEVELOP IMMUNOTHERAPY STRATEGIES AGAINST LYMPHOMA**
  Review Type: Update Application
- **Rafael Fonseca Update of Preclinical Evaluation of Lentiviral Vectors for Oncology Therapy**
  Review Type: Update Application
- **Anthony Windebank Update of Altering MSCs to express NIS and various growth factors.**
  Review Type: Update Application
- **Caitlin Conboy Update of Therapeutic vulnerabilities of ARID1A and PBRM1-deficient cholangiocarcinoma**
  Review Type: Update Application
- **Jian Campian Update of TX103T-RG008: A Phase I, Open-Label, Multiple Dose, Dose-escalation Study to Evaluate the Safety, Tolerability and Antitumor Activity of Anti-B7-H3 CAR-T Cell Injection (TX103) in Subjects with Recurrent or Progressive Grade 4 Glioma**
  Review Type: Update Application
- **Arkadiusz Dudek Update of RPL-003-19, An Open-Label, Multicenter, Phase 1B/2 Study of RP1 in Solid Organ and Hematopoietic Cell Transplant Recipients With Advanced Cutaneous Malignancies**
  Review Type: Update Application
- **Steven OHara Update of Cholangiocyte Pathobiology in Cholestatic Liver Disease**
  Review Type: Update Application

Protocols Reviewed

- **Brian Costello** Clinical Evaluation of Combination Immunotherapy for Renal Cell Carcinoma

  The Biological Hazard Application, Bios00002036, for "Clinical Evaluation of Combination Immunotherapy for Renal Cell Carcinoma" (IRB 25-008524) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of oncolytic virus therapy, VSV-IFNβ-NIS with standard ipilimumab (anti-CTLA4) and nivolumab (anti-PD1) (ipi/nivo) regimen for patients diagnosed with advanced or metastatic renal cell carcinoma (RCC) 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.

- **Arkadiusz Dudek** A Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator’s choice in patients with previously treated, unresectable or metastatic cutaneous melanoma

  The Biological Hazard Application, Bios00002026, for "A Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator’s choice in patients with previously treated, unresectable or metastatic cutaneous melanoma" (IRB 25-007960) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of IMA 203, an autologous T-cell product engineered to express a TCR that is highly specific for a human leukocyte antigen (HLA)-A*02:01-presented targeted peptide sequence (PRAME-004) derived from the PRAME protein, produced by transducing primary T cells collected from the melanoma cancer patients with this 3rd generation lentiviral vector expressing PRAME-004 specific TCR for the treatment of cutaneous melanoma 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, Jacksonville, and Phoenix locations.

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

  Informed Consent documentation is adequate.

- **F Fortuin** XC001-1003

  The Biological Hazard Application, Bios00002040, for "XC001-1003" (IRB 25-003298) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of XC001, containing the recombinant adenovirus AdVEGFXC1, to promote the growth of new blood vessels in the heart.

  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 Phoenix location only. If the enrollment of patients at either Mayo Clinic Jacksonville 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.

- **Navin Gupta** A translational pipeline for personalized genome therapy as precure for inheritable kidney disease

Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of plasmid constructed recombinant adeno-associated virus to deliver base editors (Cas9n-deaminase) and guide RNA to target correction of patients' missense and nonsense mutations and resolve cystogenesis in their PKD organoids.

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

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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.

- **Michael Kattah** Genetic regulation of epithelial injury in ulcerative colitis

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing GFP or BFP to analyze the genes expressed in tissue sections, and culturing the cells that line the intestine to uncover the fundamental mechanisms by which genetic factors contribute to refractory colitis.

  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.

  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.

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  Lentivirus and Lentiviral Vector Systems Guidance

- **B Mark Keegan** A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study of mRNA-1195 Intramuscular Injection in Participants 18 to ≤ 55 Years of Age With Multiple Sclerosis

  The Biological Hazard Application, Bios00002039, for "A Phase 2, Randomized, Observer-Blind, Placebo-Controlled, Dose-Ranging Study of mRNA-1195 Intramuscular Injection in Participants 18 to ≤ 55 Years of Age With Multiple Sclerosis" (IRB 25-007647) has been approved.

  Subject to Laboratory Biosafety Level 1 provisions and practice for research involving the study of mRNA-1195 vaccine against Epstein-Barr Virus to produce an immune response that may prevent or slow down multiple sclerosis 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.

- **Richard Kennedy** Identification of T and B cell epitopes from poxviruses

  Subject to Laboratory Biosafety Level 3 provisions and practices for research involving the study of monkey pox (clade II) to collect peptides from permissive host cells.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of aforementioned peptides that will be synthesized and tested using sera and PBMCs from individuals who recovered from Mpox or who received a relevant vaccine (JYNNEOS or ACAM2000).

  Subject to Laboratory Biosafety Level 1 provisions and practices for research involving the study of aforementioned peptides inactivated (heat: 65C for 30 minutes) and sent to the Proteomics Core for tandem mass spectrometry analysis to identify all eluted peptides and discriminate between those from the host, culture media, and virus.

  This study aligns with Section III-D-3-b 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.

  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.

  Prior to working with Mpox, it is highly recommended that staff members have an up to date Mpox vaccination. 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 Occupational Health Services

  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.

- **Lichun Lu** Finite Element Analysis Guided 3D Printing of Polymeric Composite Scaffolds for Bone Regeneration

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of siRNA that silence noggin protein which regulates the BMP-2 pathway in bone healing.

  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.

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work in an animal model.

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- **Esther Lutgens** Macrophage targeted siRNA loaded apoprotein nanoparticles as therapy for atherosclerosis

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of apolipoprotein nanoparticle (aNP)-loaded siRNA (aNP-siRNA) to target GITR expression in plaque monocytes/macrophages in atherosclerotic mice.

  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.

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- **Svetomir Markovic** Lentiviral transfection in mammalian cell lines

  Subject to Laboratory Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector expressing pHluorin, to create labeled exosomes from cancer cells.

  This study aligns with Section III-D-3-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.

  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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  Lentivirus and Lentiviral Vector Systems Guidance

- **Patricia Simner** Characterization of multidrug-resistant gram-negative 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*) 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.

  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.

- **Bogang Wu** Mechanistic and Therapeutic Investigation of Immune Dysregulation in Cancer and Immune Disorders

  Subject to Laboratory and Animal Biosafety Level 2+ provisions and practices for research involving the study of replication deficient, HIV-1 based lentiviral vector to deliver synthetic single-guide RNAs (sgRNAs) into cancer cell lines for CRISPR/Cas9-mediated gene knockout (NFIX) to study gene function in tumor biology 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

- **Jun Liu** Update of Regulation of Adipose Lipolysis and Relevant Metabolic Processes

  Modification submitted to include the use of Sleeping Beauty transposase and oncogenic plasmids to the liver of C57BL/6J mice.

  Subject to Laboratory and Animal Biosafety Level 2 provisions and practices for research involving the study of adenovirus expressing genes of interest as outlined in the application in an animal model.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of Adeno-Associated virus expressing genes of interest as outlined in the application 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.

  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 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 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.

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- **Nilufer Taner** Update of Preclinical development of oligonucleotide therapeutics for ADRD

  Modification submitted to include the use of KEK293T cells transduced with lentivirus constructs.

  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 tau RD P301S-CFP and tau RD P301S-YFP in an animal model.

  Subject to Laboratory and Animal Biosafety Level 1 provisions and practices for research involving the study of antisense oligonucleotides (ASO) for gene silencing and plasmid constructed recombinant adeno-associated virus expressing genes of interest as outlined in the application 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) 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.

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- **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)

  Modification submitted to provide updated study documents detailing an adverse event from this clinical trial.

  The Biological Hazard Application, Bios00001810, for Dr. Anastasia Zekeridou for "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)" (IRB 24-008546) has been approved.

  Subject to Laboratory Biosafety Level 2 provisions and practices for research involving the study of KYV-101, a chimeric antigen receptor (CAR) T cell therapy.

  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 patient 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.

- **Christian Pfaller** Update of Innate and adaptive immune responses against viral pathogens

  Requested changes:

  1. In section 2.02, question 3, please provide additional information on the details of what you will be doing with the adenovirus and AAV.

  2. In section 2.02, question 3, please clarify if the AAV and adenovirus need to be handled at BSL2/2+ or change to BSL1 and BSL2, respectively.

  3. Please remove the use of the BSL3 facility for COVID studies.

  4. Please update section 9, Occupational Health to capture everything you are doing.

  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 AAV vectors, and Measles Virus-Moraten Strain expressing only NIS, CEA, GFP, or LUC.

  Subject to Laboratory and Animal Biosafety Level **2** provisions and practices for research involving the study of adenoviral vectors, VSV, Influenza A virus, Measles virus, RSV, Human parainfluenza virus type 1 (HPIV1), SARS-CoV-2, and Sendai 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 genes which are listed in the application 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.

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.

The laboratory is reminded to use the appropriate animal cage labels (BSL2+, BSL2, BSL1). Animals exposed to BSI2 or BSL2+ agents must be housed in the animal biosafety suite. 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.

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The laboratory is reminded that if they want to downgrade the lentiviral work from BSL2+ to BSL1, it is required to provide documentation of recombination incompetency.

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