

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
UT SOUTHWESTERN MEDICAL CENTER DALLAS TEXAS**

April 28, 2026

Time: 11:30 a.m.

**Location: JA05.110 and web conferencing
Dallas Texas, 75390**

IBC Minutes

IBC Attendance April 2026

Noelle Williams, Ph.D.	Bruce Brown, Dr. P.H.
Michael Buszczak, Ph.D.	Chun-Li Zhang, Ph.D.
Robert Orchard, Ph.D.	Jakub Furmaga, M.D.
Don Gammon, Ph.D.	Kaylee Cirrincione
Michael Reese, Ph.D.	Julia Wilkerson
Mark Thompson	Callan Kaut
Michael Shiloh, M.D., Ph.D.	Chad Donelson
Maria Labandeira-Rey, Ph.D.	Audrey Kinser

Notification to IBC Members and Guests

All IBC members and guests were notified that this meeting was recorded on audio tape for minute-taking purposes. Recorded copies will be kept by Safety for 90 days from today's date.

IBC Conflict of Interest Policy reminder

- No member of the UT Southwestern Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.
- When a member has a conflict of interest, the member, or other participants, should notify the BSP and IBC Chairperson and may not participate in the IBC review or approval except to provide information if the IBC requests such.
- If you would like a copy of the Institutional Policy, please contact Safety.

Call to Order and Approval of Minutes

Quorum was obtained: A regular meeting of the UT Southwestern IBC was called to order at 11:30 a.m. on April 28, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

The draft minutes from the meeting held on March 31, 2026 were approved unanimously by the members.

Status: March 31, 2026 IBC minutes were approved with minor changes.

Project closures per PI request

PI: Joseph Takahashi

- **Title:** Disrupting effects of parasites on host circadian rhythm and sleep

PI: Kang-Hsin Wang

- **Title:** Pre-clinical pancreatic tumor model for the validation of multimodal image-guided radiation research system

PI: Michael Shiloh

- **Title:** Pathogenesis of SARS-CoV2

PI: Robert Mattrey / Jacques Lux

- **Title:** TRUST Lab Biosafety Permit for manipulation and maintenance of human biologics for in vitro and in vivo experimentation

PI: Ellen Kitchell

- **Title:** A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Human Monkeypox Virus Disease

PI: Mamta Jain

- **Title:** STRIVE Shionogi S-217622 (Appendix E-1); A Multicenter, Adaptive, Randomized, Controlled Trial Platform To Evaluate Safety and Efficacy of Strategies and Treatments for Hospitalized Patients with Respiratory Infections STRIVE Trial 2: Immune Modulation Strategy Trial (IM Strategy)

Approval Lapse:

PI: Larry Anderson

- **Title:** A Phase 1, Multicenter, Open-Label Study of CC-95266 in Subjects with Relapsed and/or Refractory Multiple Myeloma

Reviews

Pathogen Registration for IBC review and authorization.

PI: Markey McNutt

- **Title:** Human Material Registration for the McDermott Center Human Genetics Clinical Core Laboratory
- **Note:** Renewal
- **NIH Guidelines Section(s):** N/A
- **Project Summary:**
 - Generation and banking of immortalized lymphoblast cell lines from human samples using Epstein-Barr virus (EBV).
- **Pathogens:** Risk Group 2
 - Epstein-Barr virus (EBV), Type 1, strain B95-8
- **Host:** Mammalian (primary human cell lines)
- **Notes:**

- This registration is associated with a separate permit, which describes the core facility's handling of primary human materials (blood, lymphocytes, skin fibroblasts) that were acquired from UTSWMC.
- The PI will be producing, purifying, and concentrating virus in the lab.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Cultivation and manipulation of pathogen stocks and cultures, and human cell lines when procedures involve the production of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 1 deficiency was found, all corrected

Summary:

- No major changes in renewal application.
- Pending SOP clarifications and minor updates.
- No other safety concerns.

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations. **These include:** Updates to SOP documents.

Recombinant DNA Registration for IBC review and authorization.

PI: Julie Pfeiffer

- **Title:** RNA virus evolution and pathogenesis
- **Note:** Amendment to provide updates to existing experiments with CVB3 and add new experiments with CVB3.
- **NIH Guideline Section(s):** III-D-1, III-D-3, and III-F
- **Project Summary:**
 - Experimental update 1: Mutations conferring increased replication of CVB3 in mouse cells have been identified. These mutations have now been cloned into the CVB3 H3 strain infectious clones, virus has been generated, and the resulting phenotypes are under experimentation.
 - Experimental update 2: Infectious clones of CVB3 strains Nancy and H3 will be generated to produce virus in which viral polymerase amino acid sequences for the Nancy and H3 strains have been swapped. The viruses will be used to study the resulting effect on their ability to replicate at increased temperatures.
- **Pathogens to be genetically modified: Risk Group 2**
 - Coxsackievirus B3, strains Nancy, H3
- **Transgenes:** function (source)
 - Polymerases (Coxsackie virus B3)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:

- BSL1 – Standard molecular biology procedures
- BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures, and human cell lines when procedures involve the generation of aerosols and splashes
- PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 10 deficiencies found, all corrected

Summary:

- No major safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** PI must notify the IBC of mutants with altered properties.

Recombinant DNA Registration for IBC review and authorization.

PI: Don Gammon

- **Title:** Virus-Host Interactions: Identification of Host Antiviral Factors and Viral Immunomodulators
- **Note:** Amendment for addition of new Sendai virus recombinants
- **NIH Guideline Section(s):** III-D-3
- **Project Summary:**
 - Adding strains of Sendai virus in the Fushimi strain background obtained from collaborator.
 - Mutant viruses are expected to be attenuated in their replication in cell culture as lab predicts that their substitution mutations will lead to their strong activation of the FACT-ETS-1 Antiviral Response Pathway pathway.
- **Pathogen genetically modified by collaborator: Risk Group 2**
 - Sendai virus, strain Fushimi
- **Transgenes:** function (source)
 - immune evasion protein (Sendai virus)
 - fluorescent marker (*A. victoria*)
 - reporter (*Gaussia princeps*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human and mouse cell lines)
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 8 deficiencies found, all corrected

Summary:

- Use of mouse virus modified for loss of function mutation in immune antagonism gene, resulting in inability to avoid host immune response.
- No safety concerns.

In favor: All**Opposed:** None**Abstained:** None**Status:** Approved**Pathogen Registration for IBC review and authorization.****PI: Dustin Hancks**

- **Title:** Evolution-guided Studies of Host-virus Interfaces
- **Note:** Amendment for the addition of work with Influenza A virus in vitro and in vivo.
- **Project Summary:**
 - The project focuses on the discovery and characterization of host-virus interfaces via viral infection of cell lines and genetic modification to determine how cellular factors and viral factors impact host outcomes and viral replication.
 - This amendment will focus on investigating the immune response against viral pathogens in vivo using strains of Influenza A virus which will be produced and expanded in the lab for use in transgenic mouse models. The lab will evaluate changes in host response and viral kinetics by harvesting mouse tissue to investigate tissue damage markers and viral replication. Additionally, the lab will also infect cell lines in vitro for follow up experiments and to validate the in vivo work.
- **Pathogens: Risk Group 2**
 - Influenza A, strains A/Puerto Rico/8/1934, A/HKx31
- **Host:** Mammalian (established canine cell lines)
- **Zoonotic Potential:** The PI is using Influenza virus, a zoonotic virus that affects livestock animals which may result in an economic impact according to APHIS. All laboratory personnel must avoid contact with livestock for 5 days following work with active Influenza virus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Routes of Administration:** Intranasal – Influenza A virus
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Cultivation and manipulation of pathogen stocks and cultures, and cell lines when procedures involve the production of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - ABSL2 – Inoculation of agent followed by ABSL2 housing
 - PPE – Hair bonnet, double nitrile gloves, shoe covers face masks, disposable white tie-back gown, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 2 deficiencies found, all corrected

Summary:

- Amendment to add Influenza A strains to study host immune response in vitro and in vivo via mouse models.
- No major safety concerns, but the reviewer requested clarification regarding the transportation procedures for infected animal materials going from the animal facility back to the main lab space.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Clarification of transport procedures for infected animal materials.

Pathogen Registration for IBC review and authorization.

PI: Andrew Koh

- **Title:** Bacterial and fungal gastrointestinal colonization and dissemination
- **Note:** Amendment
- **NIH Guidelines Section(s):** n/a for this amendment
- **Project Summary:**
 - Study the effect of helminths lysates on immune suppression both in vitro and in vivo in mice model.
- **Pathogens: Non-infectious stage (adult worms) of Risk Group 2 Organism**
 - *Schistosoma mansoni*, strain NMRI
 - Note: *S. mansoni* are frozen at time of receipt.
- **Animal Model:** Mouse for *S. mansoni* lysate.
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures and procedures with non-infectious stage of *S. mansoni*
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 3 deficiencies found, all corrected

Summary:

- Receipt of frozen, dead *S. mansoni* worms of adult, non-infectious stage for preparation of lysate.
- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Beatriz Fontoura

- **Title:** Effects of influenza virus on host mRNA nuclear export
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-2 and III-F
- **Project Summary:**
 - Study of how influenza A disrupts host pre-mRNA splicing and mRNA nuclear export pathways in lung epithelial cells.

- Use of CRISPR/Cas9 systems and recombinant plasmids to evaluate the role of host and viral factors involved in RNA processing and export mechanisms.
- **Pathogen to be genetically modified: Risk Group 2**
 - Influenza virus A
- **Vectors: (source)**
 - Mutagenesis plasmids
 - Standard cloning plasmids
 - CRISPR/*cas9* system
- **Transgenes: function (source)**
 - riboprotein (human)
 - auxin response gene (rice)
 - fluorescent marker (*A. victoria*)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor: None**
- **Toxic Genes: None**
- **Host: Mammalian (established cell lines); bacteria (*E. coli* K12)**
- **Animal Model: In vitro only**
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of vectors and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training: All individuals have required training**
- **2024-25 Lab Survey Results: No deficiencies found**

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Resolution of minor pending comments

Pathogen Registration for IBC review and authorization.

PI: Tamia Harris-Tryon

- **Title:** Microbiota immune system interactions in skin
- **Note:** Amendment for the addition of in vivo work with previously approved pathogens and updates to routes of administration
- **Project Summary:**
 - Updating routes of administration for in vivo work and to include the in vivo administration of pathogens previously approved for in vitro work only.
- **Pathogens: Risk Group 2**
 - *Bacteroides thetaiotaomicron*
 - *Staphylococcus epidermidis*, FDA strain PCI 1200
 - *Enterococcus faecalis*, strain V583

- **Zoonotic Potential:** The PI is using *Staphylococcus epidermidis*, genetic variants, mutants, and clones that could affect livestock animals which may result in an economic impact according to APHIS. All laboratory personnel must avoid contact with livestock for 5 days following work with active agents.
- **Animal Model:** Mouse
- **Routes of Administration:**
 - Oral gavage – *B. thetaiotaomicron*
 - Epicutaneous – *E. faecalis*, *S. aureus*, *S. epidermidis*
 - Intradermal – *S. hominis*, *P. aeruginosa*, *S. pyogenes*
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL2 – Cultivation and manipulation of pathogen stocks and cultures, and cell lines when procedures involve the production of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - ABSL2 – Inoculation of agent followed by ABSL2 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 9 deficiencies found, 1 overdue

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Resolution of survey findings, and resolution of minor pending comments.

Recombinant DNA Registration for IBC review and authorization.

PI: Hao Zhu

- **Title:** Liver cancer and regeneration in mice
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1, III-E-3 and III-F-8
- **Project Summary:**
 - The goal of this project is to manipulate, track and evaluate the growth of human and mouse HCCs.
 - Lentivirus expressing markers will be used to infect HCC cells which will then be injected into immune-compromised mice.
 - AAV will be used in vivo to generate liver cancer models and to do in vivo CRISPR screens.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: The main advantage of a 2nd-generation lentiviral system is practicality; it strikes a good balance between efficiency and simplicity. This system gives higher viral titer, and it's easy to use.
 - Replication incompetent Adeno-associated virus including Method of Somatic AAV-transposon In vivo Clonal Screening (MOSAICS)

- BSL1 – Standard molecular biology procedures
- BSL2 – Biosafety cabinet use during manipulation of viral vectors and human materials when procedures involve the generation of aerosols and splashes
- PPE – Laboratory coat, gloves, and eye protection are required
- In-Vivo Procedures:
 - Viral vectors, transduced cell lines – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Xenograft of non-modified cells – Inoculation of agent in a BSC followed by ABSL1 housing
 - Nucleic acids, implantation of modified zygote/blastocysts – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE –
 - ARC: Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, and eye protection
 - Non-ARC: Laboratory coat, gloves, and eye protection
- **Training:** 2 individuals require NIH training
- **2024-25 Lab Survey Results:** 11 deficiencies found, all corrected

Summary:

- Changes made to renewal application were discussed
- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training and resolution of minor pending comment.

Recombinant DNA Registration for IBC review and authorization.

PI: Angelique Whitehurst

- **Title:** To determine how proteins support the tumorigenic environment by using pLKO.1 to express shRNAs for loss of function, pLX to express genes for gain of function, and by using Ad5CMVCre to allow conditional expression in a transgenic mouse.
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - Investigation of tumor vulnerabilities using lentivirus, retrovirus, and plasmids to produce transgenic human cell lines for use in tumor study experiments and mouse models.
 - Use of adenovirus vector in transgenic mice to induce gene expression to study tumorigenesis.
 - Use of bacterial expression plasmids in bacterial cell lines expression of fusion proteins in for the purpose of purification of recombinant protein.
 - Use of siRNA oligo duplexes to transiently knock down proteins of interest in mammalian cells.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Replication incompetent Retrovirus
 - Replication incompetent Adenovirus

- Bacterial expression plasmids
- Mammalian expression plasmids
- Standard cloning plasmids
- siRNA oligo duplexes
- CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Transcription factors (human)
 - Regulates cell cycle (human)
 - Transcription activators (human)
 - Initiates meiotic double stranded breaks (human)
 - Cytochrome c oxidases (human)
 - Regulates activation and differentiation of naive T cells (human)
 - Cancer testis antigen (human)
 - Assists in DNA binding (human)
 - kinase (human)
 - Fluorescent markers (*Discosoma sp.*)
 - Reporter (*Photinus pyralis*)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
 - Recombinase (P1 bacteriophage)
 - Additional transgenes listed in registration application
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established and primary human cell lines; bacteria (*E. coli* K12; *E. coli* B-cell))
- **Notes:**
 - Production and purification of Lentivirus.
 - Purified Retrovirus samples are only being stored in the lab and are not actively being generated or used to modify cell lines described in this registration.
 - Use of ready-to-use Adenovirus stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes **GDMO:** No
- **Route(s) of Administration:**
 - Intraperitoneal, subcutaneous, intramammary, intrapulmonary, intrasplenic, intravenous (portal vein) - modified xenografts
 - Intranasal, intratracheal - adenovirus
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Intranasal, intratracheal – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing

- Intraperitoneal, subcutaneous, intramammary, intrapulmonary, intrasplenic, intravenous (portal vein) – Inoculation of agent in a BSC followed by ABSL1 housing
- PPE –
 - Animal facility - hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
 - Animal facility – yellow gown, nitrile gloves, eye protection
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** 1 deficiency found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training.

Recombinant DNA Registration for IBC review and authorization.

PI: Maralice Conacci-Sorrell

- **Title:** Probing the non-canonical role for cytosolic Myc in driving cancer progression
- **Note:** Renewal
 - In October 2025, an amendment for the addition of in vivo work with plasmid was authorized by the IBC. That amendment was withdrawn, and this renewal does not include this work.
- **NIH Guideline Section(s):** III-D-3, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Exploring novel function of Myc to develop biomarkers for pre-metastatic behavior and therapies to treat Myc-dependent tumors.
 - Genes of interest expressed in mammalian established cell lines.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped Retrovirus
 - Mammalian expression plasmids
- **Transgenes:** function (source)
 - proto-oncogene (human)
 - E3 ubiquitin ligase (human)
 - actin binding protein (human)
 - transcription factors (human)
 - zinc finger (human)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established mouse, rat, and human cell lines); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of virus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes, in core facility **GDMO:** No
- **Route(s) of Administration:**

- Subcutaneous, tail vein – xenograft of non-modified established human cell lines
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE –
 - Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, and eye protection
 - Yellow gown, nitrile gloves, and eye protection
- **Training:** 2 individuals require NIH training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- No major changes in renewal application
- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training.

Recombinant DNA Registration for IBC Review and Authorization.

PI: Saima Kayani

- **Title:** Treatment of Neurological Symptoms of CLN1 Neuronal Ceroid Lipofuscinosis with Intrathecal TSHA-118 (scAAV9.CBh.hCLN1)
- **Note:** New
- **NIH Guidelines:** III-C
- **Project Summary:**
 - An expanded access protocol to explore the treatment potential for individuals with CLN1 Neuronal Ceroid Lipofuscinosis utilizing product manufactured by Taysha Gene Therapies, with financial support from departmental funds, and through organizing sponsor at Rush University Medical Center.
- **Product(s):**
 - Genetically modified adeno-associated virus
- **Transgenes: (source)**
 - lysosomal enzyme (human)
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - No occurrences of serious adverse events have been reported.
 - Sponsor has provided safety information.
 - All health care workers involved in this protocol should observe universal precautions.
 - For roommates or family members, guidance on good hand hygiene is provided.
- **IBC emphasizes:**

- Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of a Biosafety Cabinet (BSC), sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Research Applications:**
 - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - BSL2 – Manipulation of agent in the Pharmacy
 - Other: Approved SOP for gene transfer project must be followed

Summary:

- Discussion of on viral shedding:
 - If information on viral shedding is available
 - Whether shedding data would be collected
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: David Karp

- **Title:** A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19-Targeted NEX-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)
- **Note:** New
- **NIH Guidelines:** III-C
- **Project Summary:**
 - A Phase II study sponsored by June Therapeutics, Inc. to evaluate the efficacy and safety of investigational product in individuals with systemic lupus erythematosus.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with replication incompetent lentivirus

- **Transgenes: (source)**
 - Chimeric antigen receptor (mouse, human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - Occurrences of serious adverse events potentially related to the investigational product have been reported in other studies with this product.
 - Sponsor has provided safety information.
 - All health care workers involved in this protocol should observe universal precautions.
 - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
 - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Research Applications:**
 - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Jessica Garcia

- **Title:** Beyond-9, A Two-Part Open-Label Study Of Regv131-Lnp1265, A Crispr/Cas9-Based Coagulation Factor Ix Gene Insertion Therapy In Participants With Hemophilia B
- **Note:** New
- **NIH Guidelines:** III-C -1
- **Project Summary:**

- A Phase I/II study sponsored by Regeneron Pharmaceuticals, Inc. to evaluate the safety and efficacy of CRISPR/Cas9 based Factor IX gene insertion therapy in individuals with Hemophilia B.
- **Product(s):**
 - Genetically modified adeno-associated virus
- **Transgenes: (source)**
 - Coagulation Factor IX, promoterless gene (human)
 - endonuclease (codon optimized, *S. pyogenes*)
 - albumin (human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with CMC Occupational Health is advised for health care workers.
 - No occurrences of serious adverse events (not at UTSW) have been reported for this investigational drug.
 - Sponsor has provided safety information.
 - All health care workers involved in this protocol should observe universal precautions.
 - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
 - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Benjamin Drapkin

- **Title:** A Phase 1 First-In-Human Study to Investigate the Safety, Pharmacokinetics and Preliminary Efficacy of ML261, an Autologous Anti-DLL3 CAR + CARD11-PIK3R3 Fusion T Cell Therapy, in Participants with Relapsed/Refractory Small Cell Lung Cancer or Select Neuroendocrine

Carcinomas

- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Moonlight Bio, Inc.
- **Project Summary:**
 - A Phase I study sponsored by Moonlight Bio, Inc. to evaluate the efficacy and safety of investigational product in individuals with Relapsed/Refractory Small Cell Lung Cancer or Select Neuroendocrine Carcinomas.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with CRISPR/*cas9* technology and replication incompetent Adeno-associated virus.
- **Transgenes: (source)**
 - *Cas9* and sgRNA ribonucleoprotein complex (human)
 - Chimeric antigen receptor (human)
 - Fusion protein (human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - No occurrences of serious adverse events have been reported
 - All health care workers involved in this protocol should observe universal precautions.
 - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
 - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Research Applications:**
 - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as Medical/Sharps Waste or autoclaved prior to disposal.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:

- No safety concerns

In favor: All
Opposed: None
Abstained: None
Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Heidi Jacobs

- **Title:** A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucl versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Novartis
- **Project Summary:**
 - A Phase II study sponsored by Novartis to evaluate the efficacy and safety of investigational product in individuals with severe refractory diffuse cutaneous systemic sclerosis.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with replication incompetent Lentivirus.
- **Transgenes: (source)**
 - Chimeric antigen receptor (mouse, human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - Occurrences of serious adverse events potentially related to the investigational product have been reported in other studies with this product.
 - All health care workers involved in this protocol should observe universal precautions.
 - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
 - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Research Applications:**
 - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as Medical/Sharps Waste or autoclaved prior to disposal.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration

- IATA Training for individuals shipping infectious samples
- NIH Guidelines Training for PI
- PI mediated intra-laboratory training
- Procedures:
 - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Justin Grodin

- **Title:** 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 (ATTR-CM)
- **Note:** Annual Administrative Renewal
 - No change to personnel
 - In October 2025, the FDA placed this study on clinical hold (pause to enrollment). Study currently remains on clinical hold.
- **NIH Guidelines:** III-C
- **Project Summary:**
 - A Phase III study sponsored by Intellia Therapeutics, Inc. to evaluate the efficacy and safety of investigational product in adult participants with transthyretin amyloidosis with cardiomyopathy.
- **Product(s):**
 - Lipid nanoparticle encapsulating sgRNA and mRNA
- **Transgenes: (source)**
 - thyroid hormone transport protein (human)
 - endonuclease (*S. pyogenes*)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - Occurrences of serious adverse events (not at UTSW) have been reported during the renewal period.
 - Sponsor has provided safety information.
 - All health care workers involved in this protocol should observe universal precautions.
 - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
 - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of a Biosafety Cabinet (BSC), sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for

contamination and minimize transmission of the agent.

- **Research Applications:**
 - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - BSL2 – Manipulation of agent in the Pharmacy
 - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:

- Discussion of the study status as clinical hold.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Approval contingent upon lift of the study status from clinical hold. Addition stipulation of submission of amendment when study status changes.

Recombinant DNA Registration for IBC review and authorization.

PI: Tao Zou

- **Title:** Leveraging immune mechanisms of self/non-self recognition for lung cancer therapy
- **Note:** Amendment for addition of in vivo work
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Utilize both murine cancer cell line models (genetically modified and unmodified) and human cancer cell line xenograft models (genetically modified and unmodified) to determine whether deletion of specific genes will have impact on the rate of tumor growth, the responsiveness of these tumors to immune checkpoint inhibitor therapy, and the anti-tumor immune response.
- **Animal Model:** Mouse
- **Administration:**
 - Routes: Subcutaneous, intravenous (tail vein)
 - Materials:
 - Xenograft of established human cell lines, genetically modified or non-modified
 - Allograft of murine cells, genetically modified
- **Notes:**

- As previously approved, in vitro established human and murine cell lines are transduced with lentivirus. Gene targets do not include any oncogenes or toxic genes.
- Prior to in vivo use, cell lines are cultured for at least 10 days.
- **Transgenic animals:** Yes **Generated at UTSW:** Yes (Core Facility) **GDMO:** No
- **Required Training, Procedures, and Containment:**
 - In-Vivo Procedures:
 - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
 - Allograft – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, and eye protection
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** New PI not at UTSW at time of last survey

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC notification.

PI: Jing Tian

- **Title:** Mechanism of EPA or glucagon mediated inhibition of SREBP-1 processing
- **Note:** Renewal
- **NIH Guideline Section(s):** III-E, III-F-8
- **Project Summary:**
 - Use of cloning vectors and CRISPR/*Cas9* plasmids via loss-of-function approaches to study how Polyunsaturated fatty acids (PUFAs) or glucagon inhibits SREBP-1 processing.
 - Plasmids will be propagated in *E. coli* K12 and used for CRISPR/*Cas9*-mediated knockout of genes in human cells.
 - Use of transgenic mice to investigate metabolic pathways involved in lipid synthesis.
- **Vectors:** (source)
 - Mammalian expression plasmids
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Negative regulators for SREBP-1 transportation to the nucleus (human)
 - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines; bacteria (*E. coli* K12))
- **Animal Model:** In vitro only
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of human cell lines when procedures involve the generation of aerosols and splashes

- PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 1 deficiency was found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC notification

PI: Dawn Wetzel

- **Title:** Targeting new therapies for *leishmaniasis*
- **Note:** Amendment for the addition of non-modified *L. tropica*, *L. pifanoi*, *L. infantum* for storage only.
- **NIH Guideline Section(s):** N/A; Storage only
- **Project Summary:**
 - *L. tropica*, *L. pifanoi*, *L. infantum*, and additional *Leishmania* strains that have been previously approved will only be stored in the lab and not modified.
- **Pathogen: Storage only (Risk Group 2)**
 - *Leishmania tropica*, strain LRL-L8
 - *Leishmania pifanoi*, strain LtRod
 - *Leishmania infantum*, strain QQ
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - Storage only
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Hijai Regina Shin

- **Title:** Inter-organelle communication in health and disease
- **Note:** Amendment for the addition of in vivo work and updates to personnel.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**

- Addition of administration of xenografts modified with lentiviral vector to study effects of organelle adaptation to environmental changes on cancer progression using transgenic mouse models.
- **Transgenes:** function (source)
 - Organelle integrity (human)
 - Fluorescent markers (*Discosoma sp.*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines)
- **Notes:** Xenografts have been modified in vitro by a previously authorized Lentiviral vector system.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes **GDMO:** No
- **Route(s) of Administration:** Subcutaneous, intravenous (tail vein), intralymphatic – genetically modified xenografts
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Subcutaneous, intravenous (tail vein), intralymphatic – Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** 2 individuals require training
- **2024-25 Lab Survey Results:** 5 deficiencies found, 1 overdue

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training and resolution of survey findings.

Recombinant DNA Registration for IBC review and authorization.

PI: Audrey Chang

- **Title:** Modulation of Cardiac Function by Myosin Light Chain Kinases and Phosphatases
- **Note:** Renewal
- **NIH Guideline Section(s):** III-F
- **Project Summary:**
 - Study of the biochemical regulation of muscle contraction and cardiac function by myosin light chain kinases and phosphatases.

- Use of recombinant plasmids and baculovirus expression systems to characterize enzymes in mammalian and insect cell models.
- **Vectors: (source)**
 - Baculovirus
 - Mammalian Expression plasmid
- **Transgenes: function (source)**
 - kinase (mouse)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell line); insect (established cell line); bacteria (*E. coli* K12)
- **Notes:** PI will be producing, purifying, and concentrating baculovirus in the laboratory.
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 7 deficiencies found, 7 overdue

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Resolution of survey findings

Recombinant DNA Registration for IBC notification.

PI: Felix Nitschke

- **Title:** Cross-correction enabled gene therapy and neurodegenerative diseases
- **Note:** Amendment for the addition of in vivo work with antisense oligonucleotides and personnel updates
- **NIH Guideline Section(s):** III-F-1
- **Project Summary:**
 - Addition of in vitro and in vivo use of potentially therapeutic antisense oligonucleotides (ASO) in studies related to neurological disorders associated with glycogen metabolism.
- **Vectors: (source)**
 - Antisense oligonucleotides (Vendor)
- **Transgenes: function (source)**
 - ASO (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines)
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intracerebroventricular (ICV) – Antisense oligonucleotides (ASO)
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:

- BSL1 – Standard molecular biology procedures
- BSL2 – Biosafety cabinet use during manipulation of human cell lines when procedures involve the generation of aerosols and splashes
- PPE – Laboratory coat, gloves, and eye protection are required
- In-Vivo Procedures:
 - Intracerebroventricular (ICV) – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, eye protection
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training.

Human Materials Registrations Requiring IBC Notification.

Safety has reviewed the submitted Hazard Registrations and determined that all registrations meet the IBC expectations regarding the safe use of Human Materials. Safety will ensure that faculty members are aware of their responsibilities including, but not limited to, the implementation of proper containment and safe practices, and the documented training of staff on the appropriate use, storage, and disposal of Human Material. The approval letter will include regulatory requirements; Safety outreach activities, and contact information specific to exposures, incidents, and/or spills.

Biosafety Program Monthly Activity Reports

Other Business

Adjourn Time: 12:29 pm