

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

March 31, 2026

Time: 11:30 a.m.

Location: JA05.110 and web conferencing

Dallas Texas, 75390

IBC Minutes

IBC Attendance March 2026

Noelle Williams, Ph.D.	Bruce Brown, Dr. P.H.
Michael Buszczak, Ph.D.	Jessica Spaniol, JD
Ralph Callicott, D.V.M	Julia Wilkerson, Ph.D.
Don Gammon, Ph.D.	Christopher Sleet, Ph.D.
Robert Orchard, Ph.D.	Kathleen Trindade
Jakub Furmaga, M.D.	Callan Kaut
Mark Thompson	Chad Donelson
Maria Labandeira-Rey, Ph.D.	Audrey Kinser
Ryan Lisk, MPH	

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 March 31, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

The draft minutes from the meeting held on February 24, 2026 were approved unanimously by the members.

Status: February 24, 2026 IBC minutes were approved with minor changes.

Updated Business:

- Registration Closures
- Work holds

Project closures per PI request unless otherwise noted

PI: Yanbin Zheng

- **Title:** PAX/FOXO1 Degron System

PI: Jaehyup Kim

- **Title:** Biotin-ligation

PI: Maria Florian-Rodriguez

- **Title:** A Two-Part, Phase 2, Double-blind, Randomized, Active-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of LBP-EC01 in the Treatment of Acute Uncomplicated Urinary Tract Infection Caused by Drug Resistant Escherichia coli (a.k.a. ELIMINATE trial)

PI: Aimaz Afrough

Title: A Phase 2, Multicohort Open-Label Study of JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA in Subjects with Multiple Myeloma

Work Holds:

PI: Audrey Chang

- **Title:** *Modulation of Cardiac Function by Myosin Light Chain Kinases and Phosphatases*

Recombinant DNA Registration for IBC review and authorization.

PI: John Schoggins

- **Title:** Virus-host interactions
- **Note:** Amendment for addition of:
 - New pathogen strains or recombinants:
 - New recombinant for in vitro use only: Hepatitis C virus intergenotypic chimeras
 - New recombinant of VEEV-TC83
 - New strain: Sendai virus strain 52
 - In vivo work:
 - New in vivo work: Sendai virus
 - New recombinant of previously approved pathogen (VEEV-TC83)
 - New strain of previously approved pathogen (IAV H1N1): Strain A/ California/ 04/2009 pdm09
- **NIH Guideline Section(s):** III-D-1, III-D-3, III-D-4, and III-F-8
- **Project Summary:**
 - This amendment adds:
 - Hepatitis C virus intergenotypic chimeras containing reporter: The chimeric viruses share identical non-structural proteins, while the structural protein coding region has been replaced with structural proteins from additional

genotypes enabling experiments that specifically map phenotypes to HCV structural proteins.

- VEEV-TC83 strain: Add reporter virus to track viral replication and dissemination in vivo in mouse models. Design enables expression of reporter during viral replication while maintaining proper processing of the structural polyprotein. The virus will be used to monitor in vivo replication and dissemination of VEEV TC-83 in mouse model.
- Sendai virus strain: Sendai virus is a rodent parainfluenza virus. The Sendai virus 52 strain will be used to study interferon-mediated antiviral immunity in mice.
- **Pathogen genetically modified: Risk Group 2**
 - New recombinant of Venezuelan equine encephalitis virus, strain TC83
 - New recombinants of Hepatitis C virus: Intergenotypic chimeras based on the JFH-1 genotype
- **Pathogen not genetically modified: Risk Group 2**
 - New strain: Sendai virus, strain 52
 - Addition of in vivo work with: Influenza A H1N1, A/California/04/2009 (H1N1) pdm09
- **Transgenes:** function (source)
 - structural proteins (Hepatitis C virus)
 - self-cleaving element (Thosea asigna virus)
 - reporter (*G. princeps*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human, hamster, non-human primate, dog, and mouse cell lines); bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI is using Sendai and Venezuelan equine encephalitis viruses, zoonotic viruses that 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 virus.
- **Notes:** Production and, as needed, concentration of virus.
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - New in vivo work:
 - IN – Sendai virus
 - New strain/recombinant:
 - IN, SC – VEEV-TC83
 - IN, IT – influenza A H1N1, strain A/California/04/2009 pdm09
 - Note: Lab has also removed in vivo use of lentivirus from this permit.
- **Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures and human and non-human primate cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:

- Inoculation of agent followed by ABSL2 housing
- PPE – Double nitrile gloves, hair bonnet, shoe covers, face masks, disposable white tie-back gown, and eye protection
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 9 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: John Schoggins

- **Title:** Virus-host interactions of Biosafety Level 3 Pathogens
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, III-D-4, and III-F
- **Project Summary:**
 - Use of lentivirus and AAV to modulate gene expression in vitro and in vivo, followed by infection with RG3 viruses to assess effects on viral replication and disease outcomes.
 - Studies focus on identifying host factors that influence viral infection, immune response and pathogenesis using molecular assay and mouse models.
- **Pathogen to be genetically modified: Risk Group 3**
 - CHIKV, La reunion and derivatives
 - SINV/CHIKV Chimera, TR399 (SINV) + LR2006 (CHIKV)
 - SINV/VEEV Chimera, TR399 (SINV) + TrD (VEEV)
- **Pathogen genetically modified by collaborator: Risk Group 2**
 - SARS-CoV-2, mouse adapted MA10 variant (USA-WA1/2020 backbone), infectious Clone (ic2019-nCoV MA10)
- **Pathogen not genetically modified: Risk Group 2**
 - SARS-CoV-2, USA-WA1/2020, Alpha (B.1.1.7), Gamma (P1), Delta (B.1.617.2), Omicron (B.1.1.529)
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: 2nd generation viral vector system uses a 2 plasmid packaging system and is replication incompetent. 2nd generation viral vector systems are known to produce higher titer lentivirus and have better transduction efficiency. We are already approved to work with 2nd generation viral vector system on RDSR-2025-044.
 - Replication incompetent Adeno-associated virus
 - Standard cloning plasmids
- **Transgenes:** function (source)
 - inhibits coronavirus (human)
 - inhibits alphavirus (human)

- fluorescent marker (*A. victoria*)
- structural protein (VEEV TrD)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines – human, mouse, non-human); bacteria (*E. coli* K12)
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - IV, IN – Lentivirus
 - IM, IP, RO, IN – AAV
 - IN – SARS-CoV-2
- **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-Vitro Procedures in BSL3 facility:
 - Strict Adherence to the current BSL3 SOP Manuals for work involving viruses and cell lines.
 - No viable agent(s) can leave the BSL3 facility without the approval of Safety.
 - PPE – Tyvek Coverall, double gloves, self-contained Battery powdered HEPA-filtered Air Purifying Respirator (PAPR)
 - Disinfection:
 - Vesphene (LpH) Ilse
 - 70% isopropanol to decon surfaces against other bacteria/fungi.
 - Bleach for additional disinfection.
 - Autoclaving for waste disposal.
 - In-Vivo Procedures:
 - IM, IP, RO, IN – ABSL3 inoculation of agent followed by ABSL3 housing.
 - PPE – Tyvek suit, Double gloves, PAPR/CAPR
 - Refer to supplemental document for more information
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 9 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: John Minna

- **Title:** Studies of the Molecular Pathogenesis of Lung Cancer
- **Note:** Renewal

- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - Generation and genetic modification of immortalized normal human bronchial and small airway epithelial cells (HBECs/HSAECs) to study the malignant progression of lung cancer in vitro and in vivo.
 - Use of xenograft mouse models, bioluminescence imaging, irradiation, and drug screening to assess tumor growth, treatment response, and mechanisms of oncogenesis.
 - Genome-wide and targeted genetic screens across patient-derived cancer cell lines to identify oncogenic pathways, biomarkers, and therapeutic targets.
 - Screening of human cell lines in vitro using replication-defective SARS-CoV-2 spike pseudotyped viruses to model viral entry in lung cancer and related cells.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Replication incompetent Retrovirus
 - Replication incompetent, SARS-Cov-2-S glycoprotein pseudotyped, second generation Vesicular Stomatitis Virus
 - Replication incompetent, SARS-Cov-2-S glycoprotein pseudotyped, second generation Mouse leukemia virus (MLV)
 - Mammalian expression plasmids
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - Cell cycle (mouse)
 - Reporter (*Photinus pyralis*)
 - Reporter (*E. coli*)
 - Inhibit tumor suppressor (Simian virus)
 - Tumor suppressors (human)
 - Inactivate form of tumor suppressor (human)
 - Cell signaling (human)
 - Anti-apoptosis (human)
 - Unknown (human)
 - Cell growth (human)
 - Transcription factors (human)
 - Cell cycle control (human)
 - Telomerase (human)
 - Endonuclease (*S. pyogenes*)
 - S glycoprotein (SARS-Cov-2)
- **Oncogenes/Tumor suppressor:** Alteration of genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human; established cell lines: human; See registration for extensive list of established and patient derived cell lines)
- **Notes:**
 - Production and concentration of virus.
 - SARS-Cov-2 spike pseudotyped viruses will be purchased from a vendor.
- **Animal Model:** Mouse

- **Route(s) of Administration:** Subcutaneous, IV (tail vein), intrarenal, intrahepatic, intrapulmonary – modified and non-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, IV (tail vein), intrarenal, intrahepatic, intrapulmonary – Inoculation of modified and non-modified xenografts in a BSC followed by ABSL1 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:** 2 deficiencies found, all corrected

Summary:

- Concerns regarding inconsistent descriptions of the safety practices within the viral vector production SOP document.
- Request for Safety to have a work continuation meeting with the lab to observe the lab’s viral vector production processes.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Work continuation meeting with Safety

Recombinant DNA Registration for IBC review and authorization.

PI: Aakriti Jain

- **Title:** Using cellular models of disease to uncover fundamental principles of lysosomal biology
- **Note:** New. New PI, Safety met with on 2/19/2026.
- **NIH Guideline Section(s):** III-D-3, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Study organelle biology and cellular metabolism.
 - Transduction of cells with lentivirus for the knock-out of endogenous proteins and expression of tagged proteins.
 - Use siRNAs for transient knock-down of target proteins as well as mammalian expression vectors for the transient expression of tagged proteins.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: Continuation of work previously done using this system from postdoctoral work.
 - gRNA vector will be used in combination with cell lines that already express Cas9.
 - Mammalian expression plasmids

- Bacterial expression plasmids
- Standard cloning plasmid
- **Transgenes:** function (source)
 - lipid metabolism (human)
 - lipid trafficking (human)
 - lysosomal proteins (human)
 - amino acid transport (human)
 - nucleoside transport (human)
 - lipid degradation (human)
 - transcriptional factor (human)
 - transmembrane transport (human)
 - fluorescent markers (*Discosoma* sp., *A. victoria*, *B. lanceolatum*)
 - reporter (*P. pyralis*)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); bacteria (*E. coli* K12, BL21)
- **Notes:** Production, purification, and concentration of virus.
- **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 viral 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
- **2025-26 Lab Survey Results:** New PI

Summary:

- No safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Srinivas Malladi

- **Title:** Define Molecular and Cellular Determinants of Metastasis
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Experiments to define drivers and suppressors of metastasis using modification of cell lines to include knockdown or overexpression of candidate genes and labeling.
 - Orally gavage bacteria into healthy mice and monitor in tumor-related studies.
- **Pathogens not genetically modified: Risk Group 1**
 - *Veillonella atypica*

- *Lactobacillus delbrueckii* subspecies *bulgaricus*, strain Lb14
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: 2nd generation is safer than 1st due to the separation of the three plasmids and generally have a higher titer than 1st generation. 2nd generation is used over 3rd generation because 3rd generation system can have a lower titer than 2nd generation.
 - Mutagenesis plasmids
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - transcription factors (human)
 - signaling pathway inhibitor (human)
 - extracellular matrix protein (human)
 - MHC II associated protein (human)
 - serine/threonine kinase (human)
 - DNA repair (human)
 - metabolism protein (human)
 - lipid metabolism (human)
 - fluorescent markers (*A. victoria*, *Discosoma* sp.)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines, primary human and mouse materials); bacteria (*E. coli* K12)
- **Notes:**
 - Production, purification, and concentration of virus.
 - Primary human materials are screened to confirm absence of HIV and Hepatitis A, B, and C viruses.
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - Oral – risk group 1 pathogens
 - IC, IV, SC, MFP, IR, IS, DT, intracardiac, intracarotid artery – xenograft of modified and non-modified cells
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - 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:
 - Risk group 1 pathogens, intracranial xenograft – Inoculation of agent in an approved area followed by ABSL1 housing
 - Xenograft non-stereotaxic routes– Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face mask, and eye protection
- **Training:** All individuals have required training

- **2025-26 Lab Survey Results:** 1 deficiency found, 1 corrected

Summary:

- During the review process, it was noted that there was no specific approval for the in vivo use of *E. coli* strain MP13. The lab indicated that they planned to remove the use of this strain from biosafety and animal protocols.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Removal of *E. coli* MP13 for alignment with animal protocol.

Recombinant DNA Registration for IBC review and authorization.

PI: Kim Orth

- **Title:** Use of mammalian expression plasmids, bacterial expression plasmids, *Yersinia pseudotuberculosis*, *Vibrio parahaemolyticus*, *Burkholderia thailandensis*, and *Arcanobacterium haemolyticum*
- **Note:** Amendment for the addition of *Arcanobacterium haemolyticum* and lab personnel
- **NIH Guideline Section(s):** III-D-1, III-D-2, and III-F-8
- **Project Summary:**
 - Modification of *Arcanobacterium haemolyticum* to express fluorescent markers to monitor the growth and dissemination of cell lines under various tissue culture conditions.
- **Pathogen to be genetically modified: Risk Group 2**
 - *Arcanobacterium haemolyticum*, strain ATCC9345
- **Vectors:** (source)
 - Mammalian expression plasmids
 - Bacterial expression plasmids
 - Bacterial complementation plasmids
- **Transgenes:** function (source)
 - fluorescent marker (*A. victoria*)
 - fluorescent marker (*Discosoma sp.*)
- **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 pathogen stocks or 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
- **2025-26 Lab Survey Results:** 8 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: Andrew Sandstrom**

- **Title:** Characterization of Host Pathogen Interactions
- **Note:** Amendment for the addition of Cowpox virus (CPXV), including viral purification, and generation of mutant viruses.
- **NIH Guideline Section(s):** III-D-1, III-D-3, and III-F-8
- **Project Summary:**
 - Cowpox virus infections of cell lines, including E3 ligase knockouts, to determine how pathogen-encoded enzymatic activities modulate the inflammasome.
- **Pathogen to be genetically modified: Risk Group 2**
 - Cowpox virus, strain Brighton
- **Pathogen not genetically modified: Risk Group 2**
 - Cowpox virus, strain Brighton
- **Vectors:** (source)
 - Mutagenesis plasmids
- **Transgenes:** function (source)
 - E3 ligases (Cowpox virus)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: non-human primate; established cell lines: human, non-human primate; bacteria (*E. coli* K12))
- **Zoonotic Potential:** The PI is using Cowpox 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 Cowpox virus.
- **Notes:** Production, purification, and concentration of Cowpox virus.
- **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
- **2025-26 Lab Survey Results:** 1 deficiency found, corrected

Summary:

- The reviewer recommended that the lab staff working with Cowpox virus have a consultation with Occupation Health.

- No safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** All staff members working with Cowpox virus should have a consultation with Occupation Health.

Recombinant DNA Registration for IBC review and authorization.

PI: Dawn Wetzel

- **Title:** Targeting new therapies for *leishmaniasis*
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, III-D-4, III-E and III-F-8
- **Project Summary:**
 - Studies to determine how *Leishmania* enters, survives, and causes disease in murine macrophages and other phagocytic cells to develop drugs to treat *leishmaniasis*.
 - Promastigote and amastigote stages will be used in research, primarily when electroporating *L. amazonensis* to express desired fluorescent markers.
 - Inoculation of mice with modified and non-modified *Leishmania* strains to evaluate host genetics and potential therapeutics.
 - Use of Baculovirus and *L. tarentolae* to express proteins of interest to study mechanistic studies.
- **Pathogen to be genetically modified: Risk Group 2**
 - *Leishmania amazonensis*, strain P8
- **Pathogen not genetically modified: Risk Group 2**
 - *Leishmania amazonensis*, strain P8
 - *Leishmania tarentolae*, strain Parrot
- **Pathogen: Storage only (Risk Group 2)**
 - *Leishmania viannia* panamensis, strain WR 442, WR120, M2903, Tres Bracos 05/LTB0042, M4147, B0510
 - *Leishmania donovani*, strain LV9, MHOM/SD/62/1S-C12D
 - *Leishmania donovani* Khartoum
 - *Leishmania Mexicana*, clinical isolates
 - *Leishmania major*, strain Friedlin, WR 309/LRC-L251
- **Vectors:** (source)
 - Replication incompetent Baculovirus
 - Standard cloning plasmid
- **Transgenes:** function (source)
 - de-gluamylases (human)
 - facilitates membrane fusion of viral envelope (*D. nucleopolyhedrovirus*)
 - microtubule depolymerizer (*Leishmania* sp.)
 - fluorescent marker (*Discosoma* sp.)
 - fluorescent marker (*A. victoria*)
 - fluorescent marker (*B. laceolatum*)
 - reporter (*Photinus pyralis*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None

- **Host:** Parasite (*L. amazonensis*; established cell lines: mouse; insect (established cell lines); bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI is using *Leishmania spp.*, 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.
- **Notes:** Production, purification, and concentration of Baculovirus.
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - Subcutaneous – *L. amazonensis* (modified and non-modified), *L. viannia*, *L. Mexicana*
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks, cultures, and viral vectors when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Subcutaneous – Inoculation of agent followed by ABSL2 housing
 - PPE –
 - Animal Facility: hair bonnet, double gloves, eye protection, face mask, white tie back gown, shoe covers
 - Imaging Facility: hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- Stipulation for the provision of an Electroporation SOP for review prior to receiving approval
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** The investigator must provide an Electroporation SOP to be reviewed by Safety and an amendment should be completed the following month to capture additional *Leishmania* strains not listed for storage only.

Recombinant DNA Registration for IBC review and authorization.

PI: Xin Li

- **Title:** Immunological response of the host to intestinal mycobiota
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2 and III-F-8
- **Project Summary:**
 - Understanding the molecular and cellular interplay between gut fungi and host lung immunity, with a specific focus on T-cell activation.

- Cytotoxicity and cytokine studies in mouse macrophages exposed to *C. albicans* and fungal RNAs/extracts.
- Allergic airway inflammation models with gut fungi and house dust mite (HDM) or papain-induced lung allergens to determine how gut microbiota modulates lung immune responses and disease.
- **Pathogen to be genetically modified: Risk Group 2**
 - *Candida albicans*, strain SC5314
- **Pathogen not genetically modified: Risk Group 2**
 - *Candida albicans*, strain SC5314
 - *Candida tropicalis*, strain CBS 94
 - *Candida parapsilosis*, strain CBS 604
 - *Aspergillus fumigatus*, strain 6258, 14243
 - *Pichia kudriavzevi*, strain 14243
 - *Debaryomyces hansenii*, strain NRL- Y-1448
 - *Issatchenkia orientalis*, strain 6258, 14243
- **Pathogen not genetically modified: Risk Group 1**
 - *Saccharomyces cerevisiae*, strain S288C
- **Vectors:** (source)
 - Standard cloning plasmids
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - maintain cell elongation (*C. albicans*)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** Yes. A transgene in *Candida albicans* encodes a peptide called candidalysin, which is a weak pore-forming cytolytic peptide toxin. To eliminate this toxin, we will use genetic depletion strategy to delete this transgene from the wild type *Candida albicans*. This genetic deletion strategy will not result in any gain of function. According to our previous findings show that candidalysin does not induce any spontaneous disease in the human and mouse gut.
- **Host:**
 - For rDNA: Fungus (*C. albicans*) bacteria (*E. coli* K12)
 - For *C. albicans*: Mammalian (primary cell lines: mouse)
- **Zoonotic Potential:** The PI is using *Candida albicans*, 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.
- **Notes:**
 - PI notes that non-modified *C. albicans* can produce candidalysin, a weak pore-forming cytolytic peptide toxin.
 - PI indicates that *C. albicans* strains are susceptible to antifungals including fluconazole.
 - PI has indicated that *C. tropicalis* and *C. parapsilosis* do not produce fungal toxins.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**

- Oral gavage – *C. albicans*, *C. parapsilosis*, *C. tropicalis*, *S. cerevisiae*, *D. hansenii*, *I. orientalis*, *P. kudriavzevii*
- Intranasal – allergens (house dust mite (HDM) or papain solution)
- **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
 - In-Vivo Procedures:
 - Oral gavage – Inoculation of agent followed by ABSL2 housing
 - PPE – Hair bonnet, double gloves, eye protection, face mask, white tie back gown, shoe covers
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 5 deficiencies found, all corrected

Summary:

- No safety concerns

Opposed: None

Abstained: None

Status: Approved.

Recombinant DNA Registration for IBC review and authorization.

PI: Tao Yue

- **Title:** Study of tumor, immunology, and tumor immunotherapy
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Use viral vector system to modify gene expression in mammalian cell lines. Inject genetically modified cells into mice to monitor cell growth with or without various treatments.
 - Express proteins in cell lines and *E. coli*.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: This study utilizes a 2nd generation lentiviral packaging system that has been well-established and previously approved for our laboratory's work. The system is replication-incompetent, as the viral structural and envelope genes are supplied in trans, and the transfer vector does not encode additional viral genes required for replication. Will continue to follow all institutional biosafety guidelines for handling lentiviral vectors, including appropriate BSL-2 containment practices and training. The use of this 2nd generation system is necessary to maintain consistency with our previously validated constructs and experimental protocols.
 - Replication incompetent, VSV-G pseudotyped, Retrovirus
 - Mammalian expression plasmid
 - Mutagenesis plasmid

- Bacterial expression plasmids
- CRISPR/cas9 system
- **Transgenes:** function (source)
 - library (human, mouse)
 - T cell receptors (human)
 - cytokine (human)
 - signal-regulatory protein alpha (human, mouse)
 - antibody (human)
 - antibody (human)
 - GTPases (mouse)
 - lipid metabolism proteins (mouse)
 - lipid proteins (mouse)
 - unknown functions (mouse)
 - ubiquitination related proteins (mouse)
 - kinase and kinase related proteins (mouse)
 - immune function proteins (mouse)
 - cell cycle proteins (mouse)
 - organelle associated proteins (mouse)
 - oxidoreductase (mouse)
 - insulin receptor (mouse)
 - leucine zipper (mouse)
 - protease activating protein (mouse)
 - actin binding (mouse)
 - pyrophosphate (mouse)
 - zing finger (mouse)
 - peroxiredoxin (mouse)
 - RNA binding (mouse)
 - cilia protein (mouse)
 - fluorescent markers (*A. victoria*, *Discosoma* sp.)
 - reporter (*P. pyralis*)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines, primary human and mouse materials); bacteria (*E. coli* K12, BL21)
- **Notes:**
 - Production, purification, and concentration of virus.
 - Primary human materials are screened to confirm absence of HIV, hepatitis B and C viruses, and tuberculosis.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - IV, IR, IM, intratibial, intrafemoral, periosteal, right/left flank – allograft of genetically modified cells

- IV, IR, IM, RO, intratibial, intrafemoral, periosteal, right/left flank – xenograft of modified and non-modified materials
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - 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:
 - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
 - Allograft – Inoculation of agent in approved area followed by ABSL1 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:** 7 deficiencies found, all corrected

Summary:

- Discussion of 2nd generation lentiviral system and recommendation for 3rd generation system.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Yuanyuan Zhang

- **Title:** Targeting tumor and normal tissue microenvironment for cancer therapeutics
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Determine the role of tumor microenvironment in lung cancer therapeutic effect and progression using unbiased, large scale CRISPR screen using a comprehensive metabolic library, both in cell culture and in the living animal, to identify metabolic vulnerabilities for therapeutic responses. If essential enzyme or pathway is identified, RNAi techniques may be used to silence expression.
 - Protein expression studies in *E. coli* BL21.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: A 2nd generation lentiviral system is used because it is a well-established and widely validated system compatible with commonly used lentiviral vectors while maintaining a replication-incompetent design.
 - Replication incompetent Adeno-associated virus
 - Note: One backbone contains SB100X
 - Mammalian expression plasmids

- Bacterial expression plasmids
- Mutagenesis plasmid
- CRISPR/cas9 system
- **Transgenes:** function (source)
 - electron transfer protein (human)
 - mitochondrial complex subunit (human)
 - acetyl-CoA-transporter (human)
 - histone demethylase (human)
 - mitochondrial enzyme (human)
 - kinase (human)
 - metabolic enzymes (human, *S. cerevisiae*, *L. brevis*)
 - transposase (synthetic)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established human and mouse cell lines); bacteria (*E. coli* K12, BL21)
- **Notes:** Production, purification, and concentration of virus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - RO – AAV
 - SC, IV, intrathoracic – xenograft of modified or non-modified established cell lines
 - SC, IV, intrathoracic – allograft of modified 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:
 - AAV – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
 - Allograft – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face mask, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 2 deficiencies found, all corrected

Summary:

- Discussion of pending comment on animal research locations.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Peter Gerhard (Christoph) Zechner

- **Title:** Interrogation of cellular Phosphate Homeostasis
- **Note:** New. New PI, Safety met with on 3/16/2026.
- **NIH Guideline Section(s):** III-D-3, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Identification of the molecular mechanisms that regulate cellular phosphate homeostasis in mammalian cells using lentivirus to achieve loss-of-function or overexpression.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: Constructs obtained from Addgene are frequently packaged in 2nd generation lentivirus. These vectors also need to be used for generating new constructs that need to be directly compared to existing vectors. Wherever possible, 3rd generation lentivirus will be used for new projects.
 - Mammalian expression/standard cloning plasmids
 - Bacterial expression plasmids
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - E3 ligase (human)
 - E2 enzyme (human)
 - protein degradation (human)
 - protein recycling (human)
 - phosphate transport (human)
 - energy stress sensor (human)
 - inositol pyrophosphate related proteins (human)
 - glycolysis protein (human)
 - NADH oxidase (human)
 - endoplasmic reticulum related proteins (human)
 - translation protein (human)
 - small GTPase (human)
 - peroxidase labeling (synthetic)
 - endonuclease (*S. pyogenes*)
 - fluorescent marker (*Zoanthus* sp.)
 - reporters (*P. pyralis*, *Renilla* spp.)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established human and opossum cell lines); bacteria (*E. coli* K12, BL21)
- **Notes:** Production and purification of virus.
- **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 viral 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
- **2025-26 Lab Survey Results:** New PI

Summary:

- No safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Esra Akbay

- **Title:** Use of replication deficient viruses to regulate gene expression in our experiments
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - Study of genes involved in immune evasion and lung cancer progression. Human cancer cell lines will be genetically modified and assessed to study the effects on growth, surface markers, and treatment response in vitro and in vivo.
 - Use of Adenovirus, Lentivirus, and CRISPR technology to knockout and overexpress genes of interest in lung cancer cell lines.
 - Use of mammalian expression plasmids for transient transfection of PDX's, and human and murine cell lines.
 - In vivo, research will be performed with viral vectors and modified/non-modified xenografts, allografts, and PDX samples.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: Based on our previous experience, we observe better yield with 2nd generation plasmids and our protocols are adjusted to this.
 - Replication incompetent Adenovirus
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - MHC regulation (human)
 - nucleic acid sensor (human)
 - stimulates interferon gamma genes (human, mouse)
 - telomerase regulation (human)
 - g protein regulator (human)
 - ceramide synthesis (human)
 - regulates immune system (mouse)
 - activates markers for NK and T cell immunity (mouse)
 - tumor suppressor (human, mouse)
 - fluorescent marker (*A. victoria*)

- endonuclease (*S. pyogenes*)
- recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** The alteration of certain transgenes might result in tumor suppressing effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines: human; mouse; bacteria (*E. coli* K12))
- **Notes:** Production of Lentivirus supernatant. Use of ready-to-use Adenovirus stocks. The PI has confirmed that the following mammalian expression plasmid will only be used for transient transfection of PDX's, and human and mouse cell lines.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Intranasal - Adenovirus
 - Intrapulmonary, Thoracic – Lentivirus
 - Subcutaneous (SC), intratracheal, intrathoracic, intravenous, intrarectal – genetically modified xenografts and PDX samples
 - Intravenous (IV), SC, intratracheal, intrapulmonary, intrarectal – non-modified xenografts, allografts and PDX samples
- **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:
 - Adenovirus, Lentivirus – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Xenografts and PDX samples (genetically modified) – Inoculation of agent in a BSC followed by ABSL1 housing
 - Xenografts, allografts, PDX samples (not-genetically modified) – Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE – Disposable jumpsuit, hair bonnet, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 9 deficiencies found, all corrected

Summary:

- Minor concerns regarding the justification for the use of 2nd generation Lentivirus were remediated by Safety during the meeting.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Brad Pfeiffer

- **Title:** Circuit-Level Mechanisms of Brain Function
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Use rAAV-mediated expression of optogenetic channels (with fluorescent controls) in rodents to control neural activity during learning and memory tasks.
 - Record and manipulate large-scale neuronal populations in awake, freely behaving animals to understand how distributed brain circuits encode and recall spatial memory.
- **Vectors:** (source)
 - Replication incompetent AAV
- **Transgenes:** function (source)
 - fluorescent markers (*A. Victoria*, *coral*)
 - ion channel (*C. reinhardtii*, *H. salinarum*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only (mouse, rat)
- **Notes:** PI will be producing and purifying virus in the laboratory and using ready-to-use stocks.
- **Animal Model:** Mouse, Rat
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intracranial – AAV
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Intracranial – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Lab coat/cloth gown, nitrile gloves, safety glasses, surgical mask
 - Refer to supplemental document for more information
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 17 deficiencies found, all corrected

Summary:

- No safety concerns.

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Zhi-Ping Liu

Co-PI: Jer-Tsong (JT) Hsieh

- **Title:** Using KDM4s inhibitors to treat castration resistant prostate cancer
- **Note:** Amendment to HMSR-2025-023 for the addition of AAV.
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - AAV-shRNA mediated PHF2 knockdown in mouse models of cardiac hypertrophy and assess cardiac outcomes by echocardiography and histology.
- **Vectors:** (source)
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - Histone demethylase (mouse)
 - Fluorescent marker (*B. lanceolatum*)
- **Oncogenes/Tumor suppressor:** Alteration of genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human; established cell lines: mouse; bacteria (*E. coli* K12))
- **Notes:** Production, purification, and concentration of virus AAV.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Retro-orbital – AAV
- **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:
 - Retro-orbital – Inoculation of AAV in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, eye protection
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 8 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: Henry De Belly

- **Title:** Membrane fluidity homeostasis as a critical regulator of Immune cell function
- **Note:** New. New PI, Safety met with on 2/10/2026
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**

- Studies on how membrane mechanics regulate immune cell signaling and migration by using lentiviral overexpression and biosensors.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
- **Transgenes:** function (source)
 - Cytoskeleton regulation (human)
 - Cytoskeletal structure (human)
 - Cadherin cell-cell adhesion (human)
 - Tubby domain (mouse)
 - Tetraspanins (human)
 - mTORC2 signaling (human)
 - Actin regulation (human)
 - PIP2 lipid biosensor (rat)
 - Phosphoinositide kinase (human)
 - Fluorescent marker (*Discosoma sp.*)
 - Fluorescent marker (*B. lanceolatum*)
 - Fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human; established cell lines: human); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Lentivirus.
- **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 viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 2 individuals require NIH training
- **2025-26 Lab Survey Results:** New PI

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: Orson Moe

- **Title:** 1) Klotho and Phosphate in Chronic Kidney Disease: Pathogenesis and Therapeutics, 2) The role of gut bacteria and renal in obesity related kidney disease, 3) Exploration of EpoR Diabodies
- **Note:** Amendment for in vivo research with lipid nanoparticles encapsulated with synthetic mRNA to target Klotho in mice.

- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Assessment of the effects of LNP-encapsulated, non-replicating synthetic mRNA encoding Klotho in mice.
- **Vectors:** (source)
 - Synthetic mRNA encapsulated in lipid nanoparticles (LNPs)
- **Transgenes:** function (source)
 - regulates mineral homeostasis (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Nanoparticles:** yes **Type:** lipid
- **Notes:** PI has confirmed that synthetic mRNA encapsulated lipid nanoparticles will be handled by the collaborator prior to being transported to ARC locations for in vivo inoculations.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Subcutaneous, intraperitoneal, intravenous – lipid nanoparticles encapsulated with mRNA
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Subcutaneous, intraperitoneal, intravenous – Inoculation of lipid nanoparticles encapsulated with mRNA in approved area followed by ABSL1 housing
 - PPE –
 - Animal Facility: yellow gown, eye protection, nitrile gloves
 - Non-animal Facility: lab coat, eye protection, nitrile gloves
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- Minor concerns about the routes of administration described in the submission that were clarified by Safety.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Luke Bartelt

- **Title:** Designing Cell-Type Specific AAV Vectors for Gene Therapy Applications in the Mouse Cerebellum
- **Note:** New. New PI, Safety met with on 2/3/2026.

- **NIH Guideline Section(s):** III-D-4 and III-F-8
- **Project Summary:**
 - Use of putative Purkinje-subtype enhancers with differential accessibility in zebrin-positive or zebrin-negative sub-populations of cells.
 - Use of AAV for in-vivo STARR-seq screens of enhancer reporter libraries.
- **Vector:**
 - Replication incompetent Adeno-associated virus
- **Nucleic acid regions: function (source)**
 - enhancers (mouse)
 - fluorescent marker (*B. lanceolatum*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Bacteria (*E. coli* K12)
- **Notes:** Virus will be produced by the UTSW Viral Vector Core.
 - Dr. Bartelt Lab in vitro:
 - Will insert DNA fragments into AAV plasmids.
 - Will clone AAV plasmids in *E. coli* K12.
 - Core facility:
 - Plasmids will be provided to core facility for AAV production.
 - Dr. Bartelt Lab in vivo:
 - Produced AAV will be returned to the Dr. Bartelt Lab for in vivo use.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intracranial – AAV
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE –
 - ARC: Pending facility designation
 - Non-ARC (pending IACUC approval): Laboratory coat, gloves, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** New PI

Summary:

- No safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Jialiang Wang

- **Title:** Comprehensive investigation of the osteoblast-to-osteocyte transition
- **Note:** Amendment for the in vivo delivery of lipid nanoparticle-encapsulated mRNA
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Establishment of patient-derived osteosarcoma xenografts in immunodeficient mice and evaluation of lipid nanoparticle-encapsulated mRNA therapeutics.
- **Transgenes:** function (source)
 - Osteoblast differentiation (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Nanoparticles:** Yes **Type:** Lipid
- **Notes:**
 - The lipid nanoparticles will be acquired from a collaborator on campus.
 - Patients and patient-derived tumor materials and are screened for the presence of pathogens prior to use.
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - Intravenous – lipid nanoparticle-encapsulated mRNA
 - Subcutaneous, intraosseous – patient-derived xenografts
- **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:
 - Subcutaneous, intraosseous – Inoculation of patient-derived xenografts in a BSC followed by ABSL1 housing
 - Intravenous – Inoculation of lipid nanoparticle-encapsulated mRNA in approved area followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** 6 deficiencies 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: James Brugarolas

- **Title:** Exploring renal cell carcinoma genetics and treatment
- **Note:** Amendment for the addition of LNP-encapsulated mRNA and siRNA for in vivo use.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Use of cell lines and mouse models of renal cancer to study disease biology and treatment response, including evaluation of lipid nanoparticle–delivered mRNA and genetic cargos (e.g., siRNA/miRNA) targeting oncogenic drivers in renal cell carcinoma.
- **Transgenes:** function (source)
 - Reporter (*Photinus pyralis*)
 - Hypoxia response (mouse)
 - Translation factors (mouse)
- **Oncogenes/Tumor suppressor:** Alteration of genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Nanoparticles:** yes **Type:** lipid
- **Notes:** The lipid nanoparticles will be acquired from a collaborator on campus.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Subcutaneous, intraperitoneal, intravenous – lipid nanoparticle-encapsulated mRNA, lipid nanoparticle-encapsulated siRNA
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Subcutaneous, intraperitoneal, intravenous – Inoculation of lipid nanoparticle-encapsulated mRNA, lipid nanoparticle-encapsulated siRNA in approved area followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 12 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: Hani Suleiman

- **Title:** Molecular Determinants of Kidney Podocyte Architecture in Health, Injury, and Recovery
- **Note:** Amendment for addition of AAV in vivo.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**

- Use knockout and transgenic mouse models to study glomerular basement membrane defects and mechanisms of podocyte-based kidney disease.
- Use of AAVs to induce hypertension and examine protein interactions and disease progression under hypertensive stress.
- **Vectors:** (source)
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - silences stabilizer of actin filaments (mouse)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only (mouse)
- **Notes:** PI will be using ready-to-use AAV stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Retro-orbital – AAV
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Retro-orbital – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - PPE – disposable gown, gloves, goggles, face mask
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 8 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: Carol Tamminga

- **Title:** The influence of DG-CA3 mossy fiber terminals on hippocampal activity and psychosis-like behaviors
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - AAV-mediated expression of fluorescent reporters and neuromodulatory receptors to study hippocampal circuitry in mouse models of neuropsychiatric disease.

- Stereotaxic intracranial delivery of viral vectors for neuronal labeling and chemogenic modulation to assess structural and functional changes in targeted brain regions.
- Evaluation of behavioral outcomes, neuronal morphology, and electrophysiological properties to better understand mechanisms underlying altered neural activity and treatment response.
- **Vectors:** (source)
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - fluorescent markers (*Discosoma sp.*, *A. victoria*)
 - recombinase (P1 bacteriophage)
 - DREADD inhibiting neuronal activity (human)
 - glycine receptor (human)
 - activates neuronal activity (*C. reinhardtii*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only
- **Notes:** PI will be using ready-to-use viral stocks.
- **Animal Model:** Mouse
- **Route(s) of Administration:** intracranial – AAV
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors and when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Intracranial – Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, eye protection
 - Refer to supplemental document for more information
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 12 deficiencies found, 4 pending

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization

PI: Xin Cai

- **Title:** Metabolism of cancer cells
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-E-1 and III-F-8
- **Project Summary:**

- Examination of how glucose and TCA cycle metabolism regulate cell proliferation under different nutrient conditions.
- Use of Lentivirus and CRISPR technology to knock out metabolic genes.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: Utilizing these plasmids is necessary to improve infection efficiency for our cells.
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - transcriptional repression (human)
 - metabolic enzyme (human)
 - prodrug activation (human)
 - transaminases (human)
 - dehydrogenases (human)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines: human; mouse); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Lentivirus. The PI has clarified that some metabolic gene over-expression can cause cells to proliferate faster or slower; examples of transgenes being worked with have been provided for proliferation effect studies. However, all of our experiments will be done in either cancerous or immortalized 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 viral 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
- **2025-26 Lab Survey Results:** 1 deficiency 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: Huocong Huang

- **Title:** Targeting Fibroblasts in Mouse Models
- **Note:** New
- **NIH Guideline Section(s):** III-D-4, III-E-1 and III-F-8

- **Project Summary:**
 - Use of CRISPR-modified colorectal and pancreatic cancer models to define the role of cancer-associated fibroblast-related genes in the tumor microenvironment and peritoneal metastasis.
 - Generation of CRISPR/Cas9 knockout cell lines via plasmid transfection.
- **Vectors:** (source)
 - Mammalian expression plasmids
 - CRISPR/cas9 system
- **Transgenes:** function (source)
 - Cancer cell motility (human, mouse)
 - Fibroblast growth (human, mouse)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines: human, mouse; bacteria (*E. coli* K12))
- **Animal Model:** Mouse
- **Note:**
 - Patient-derived xenografts will not be genetically modified.
 - Patient-derived materials were not collected from patients with pathogens such as HIV, HBV, HCV.
- **Route(s) of Administration:**
 - Intraperitoneal – genetically modified xenografts
 - Intraperitoneal, orthotopic (pancreas), subcutaneous – genetically modified allografts
 - Subcutaneous – patient-derived xenografts
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of human cell lines and materials when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Intraperitoneal – Inoculation of genetically modified xenografts in a BSC followed by ABSL1 housing
 - Subcutaneous – Inoculation of patient-derived xenografts in a BSC followed by ABSL1 housing
 - Intraperitoneal, orthotopic (pancreas), subcutaneous – Inoculation of genetically modified allografts in approved area followed by ABSL1 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:** 3 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: Duojia Pan

- **Title:** The hippo signaling pathway in growth control and regeneration
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - Studies on how conserved Hippo signaling pathway regulates mammalian tissue homeostasis, regeneration, and tumorigenesis.
 - Use of AAV in mice to modulate Hippo pathway activity in the liver and to assess effects on growth control and tumor suppression.
 - Comparative studies using Lentivirus modified cancer cells, *Drosophila* transgenics, and unicellular models (*C. owczarzaki*, *S. rosetta*) to broadly characterize the Hippo pathway.
- **Pathogen to be genetically modified: Risk Group 1**
 - *Capsaspora owczarzaki*
- **Pathogen to not be genetically modified: Risk group 1**
 - *Salpingoeca rosetta*, strain BSB-021
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: This expression vector is the only one we could find with strong, stable, and ubiquitous red-fluorescent labeling of our cell lines, so we can use it alongside expression of another gene of interest for location of gene expression in the cell.
 - Replication incompetent Adeno-associated virus
 - Bacterial expression plasmids
 - *C. owczarzaki* expression plasmids
- **Transgenes:** function (source)
 - proto-oncogene (human)
 - transcription factor (mouse)
 - activates kinase (mouse)
 - binds lipids (*D. melanogaster*)
 - tumor suppressor (*D. melanogaster*, mouse)
 - fluorescent marker (*A. victoria*)
 - fluorescent marker (*Discosoma sp.*)
 - fluorescent marker (*B. lanceolatum*)
 - tissue growth regulation (*C. owczarzaki*)
 - protein kinase Hippo (*C. owczarzaki*)
 - regulate cell contractility and cell packing (*C. owczarzaki*)
 - recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** Alteration of certain transgenes might result in tumorigenic or tumor suppressing effects.

- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines: human; insect (*Drosophila melanogaster*); bacteria (*E. coli* K12)
- **Notes:** Production of Lentivirus supernatant. Use of ready-to-use AAV stocks.
- **Animal Model:** Mouse, *Drosophila melanogaster*
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Intravenous (tail vein) – AAV
 - Intravenous (tail vein) – siRNA
 - Intravenous (tail vein), retro-orbital, subcutaneous, intravenous – 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:
 - AAV – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Modified xenografts – Inoculation of agent in a BSC followed by ABSL1 housing
 - siRNA – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 30 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: Aimaz Afrough

- **Title:** A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Janssen Research & Development, LLC
- **Project Summary:** A Phase II study sponsored by Janssen Research & Development, LLC evaluating the impact of changes in the administration of product in different settings.
- **Product(s):**
 - Autologous T-cells genetically modified ex vivo with replication incompetent lentivirus

- **Transgenes: (source)**
 - Chimeric antigen receptor (llama, 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.
 - In this study, no occurrences of serious adverse events have been reported. Serious adverse events 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: Farrukh Awan

- **Title:** A Phase 1b/2 Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bispecific CAR-T Cell Therapy in Adult Participants with B-cell Non-Hodgkin Lymphoma
- **Note:** New

- **NIH Guidelines:** III-C
- **Sponsor:** Janssen Research & Development, LLC
- **Project Summary:** A Phase 1b/2 study sponsored by Janssen Research & Development, LLC to assess the safety and tolerability of investigational product and to evaluate the efficacy based on the overall response rate.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with replication incompetent lentivirus
- **Transgenes: (source)**
 - Chimeric antigen receptor
- **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 have been reported in other studies with this investigational 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: Samuel John

Co-PI: Tracey Wright

- **Title:** FT819-102, A Phase 1 Study of FT819 in B-cell Mediated Autoimmune Diseases
- **Note:** New
- **NIH Guidelines:** III-C-1
- **Sponsor:** Fate Therapeutics, Inc.
- **Project Summary:**
 - A Phase I study for FT819 investigational cell therapy sponsored by Fate Therapeutics, Inc. to assess the safety, efficacy, and tolerability of an investigational product
- **Product(s):**
 - Allogenic T cells, derived from T-cell receptor (TCR), which compromises T-cells, derived from a clonal, T-cell receptor knockout, iPSC line, that expresses a CD19-targeted CAR regulated by the TRAC locus.
- **Current status:** Phase I
- **Vectors: (source)**
 - AAV6 encoding CAR transgene is an Adeno-associated virus serotype 6 vector
 - CRISPR targeting TRAC is RNA
 - Additional recombinant and synthetic nucleic acids were used by the manufacturer to modify FT819 investigational cell therapy.
- **Transgenes: (source)**
 - pCEP4 was used to express certain transgenes
 - Chimeric antigen receptor recognizing CD19, CD28, and CD3-zeta
- **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
 - 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:**
 - All equipment used to store, manipulate, or cultivate the investigational drug must

- be labeled as biohazardous.
- All liquid suspensions, culture waste and unused/unnecessary 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: Strict adherence to Stem Cell Infusion SOP (300.05P Stem Cells Infusion) including verification of identifier on the patients to exactly match the identifier on the product.

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved.

Recombinant DNA Registration for IBC Review and Authorization.

PI: Syed Kazmi

- **Registration Number:** HSGT-2025-033
- **Title:** An Open-label, Phase 1, Multi-Center Master Protocol to Evaluate the Safety and Preliminary Anti-Tumor Activity of TCR-Engineered T cells (KRAS TCRTs) Recognizing KRAS Mutations in Adult Subjects with Unresectable, Advanced, and/or Metastatic Solid Tumors
- **Note:** Amendment updating the clinical protocol to transition to a master protocol with the addition of a new study arm for the investigational drug AZD0240 and updates to the sponsor.
- **NIH Guidelines:** III-C
- **Sponsor:** AstraZeneca Pharmaceuticals LP
- **Project Summary:**
 - A Phase I study master protocol sponsored by AstraZeneca Pharmaceuticals LP to assess the safety, efficacy, and tolerability of an investigational product
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with CRISPR/Cas9 for the expression of T-cell receptor recognizing KRAS G12D-specific TCR and for the knock-out of endogenous TCR loci (TRAC, TRBC1 and TRBC2) and CBLB loci.
- **Current Status:** Phase I
- **Vectors: (source)**
 - CRISPR/Cas9 system: single-stranded gRNA, Cas9 endonuclease
- **Transgenes: (source)**
 - Chimeric antigen receptor recognizing B-cell maturation agent (mouse, human)
- **Host:** Human subjects

- **PPE:** Chemo gown, 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.
 - 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: Benjamin Greenberg

- **Title:** 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
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Tr1X, Inc.
- **Project Summary:**

- A Phase I/II study sponsored by Tr1X, Inc. to assess the safety, efficacy, and tolerability of an investigational product compared to CD19 CAR-T cell therapies.
- **Product(s):**
 - Allogeneic T cells genetically modified ex vivo with replication incompetent Lentivirus
- **Current Status:** Phase I/II
- **Vectors: (source)**
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
- **Transgenes: (source)**
 - Chimeric antigen receptor recognizing CD19 (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.
 - 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.
 - 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 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: Benjamin Greenberg

- **Title:** A Multicenter, Phase 1, Safety and Tolerability Study of CC-97540 (BMS-986353) in anti-Aquaporin 4 Antibody Positive Neuromyelitis Optica Patients
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Bristol-Myers Squibb
- **Project Summary:**
 - A Phase I study sponsored by Bristol-Myers Squibb to assess the safety, efficacy, and tolerability of an investigational product.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with replication incompetent Lentivirus
- **Current Status:** Phase I
- **Vectors: (source)**
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
- **Transgenes: (source)**
 - Chimeric antigen receptor recognizing CD19 (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 have been reported in other studies with this investigational 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 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: Larry Anderson**

- **Title:** A Phase 3 Randomized Study Comparing Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Ciltacabtagene Autoleucel versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible
- **Note:** Annual Administrative Renewal. No procedural or personnel changes were noted.
- **NIH Guidelines:** III-C
- **Project Summary:** A Phase III study sponsored by the European Myeloma Network to compare product with stem cell transplant.
- **Product(s):**
 - Autologous T-cells genetically modified ex vivo with replication incompetent lentivirus
- **Transgenes: (source)**
 - Chimeric antigen receptor (llama, 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 new occurrences of serious adverse events 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.
- **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: Samuel John

- **Title:** AALL1721 CTL019G2201J: A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation (EOC) therapy
- **Note:** Annual Administrative Renewal. No procedural or personnel changes were noted.
- **NIH Guidelines:** III-C
- **Project Summary:** A phase II study sponsored by Novartis Pharmaceuticals to assess the efficacy and safety of product in pediatric and young adult patients.
- **Product:**
 - 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.
 - No new occurrences of serious adverse events 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.
- **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: Strict adherence to Stem Cell Infusion SOP (300.05P Stem Cells Infusion) including verification of identifier on the patients to exactly match the identifier on the product.

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Susan Iannaccone

- **Title:** A Phase I/II Open-label Intraneural Administration of scAAV9/JeT-GAN Into the Vagus Nerve to Determine the Safety and Efficacy for Patients with Giant Axonal Neuropathy (GAN) caused by a Mutation in the GAN gene
- **Note:** Annual Administrative Renewal. No procedural changes and minor changes to personnel were noted.
- **NIH Guidelines:** III-C
- **Project Summary:** A Phase I/II sponsored by Hannah’s Hope Fund for Giant Axonal Neuropathy, Inc. exploring investigational product in the treatment of Giant Axonal Neuropathy.
- **Product(s):**
 - Recombinant adeno-associated virus
- **Transgenes: (source)**
 - optimized GAN sequence (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 during the renewal period.
 - Sponsor has provided safety information.
 - All health care workers involved in this protocol should observe universal precautions.
 - Caregivers and family members are instructed to practice hand hygiene.
- **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

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Biosafety Program Monthly Activity Reports

Adjourn Time: 12:34pm