

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

September 29, 2026

Time: 11:30 a.m.

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

IBC Minutes

IBC Attendance September 2026

Noelle Williams, Ph.D.	Mark Thompson
Ralph Callicott, D.V.M.	Ryan Lisk, MPH
Bart Carter, D.V.M.	Bruce Brown, Dr. P.H.
Benjamin Ohlstein, M.D., Ph.D.	Jessica Spaniol, J.D.
Robert Orchard, Ph.D.	Kayle Cirrincione
Michael Reese, Ph.D.	Tomce Runcevski, Ph.D.
Don Gammon, Ph.D.	Callan Kaut
Chun-Li Zhang, Ph.D.	Chad Donelson
Michael Shiloh, M.D., Ph.D.	Audrey Kinser
Jakub Furmaga, M.D.	

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 September 29, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

The draft minutes from the meeting held on August 25, 2026 were approved unanimously by the members.

Status: August 25, 2026 IBC minutes were approved with minor changes.

Updated Business:

- Registration Closures
- Work holds

New Business:

Updated Business:

PI: Michael Rosen

- **Title:** The study of mechanisms by which the properties and interactions of individual molecules give rise to cellular architecture and function, relating molecular scales to cellular scales of organization.
- **Permit Status:**
 - In October 2025, the IBC approved an amendment with a stipulation.
 - Amendment:
 - Addition of non-genetically modified simian virus 40, strain Pa-57.
 - Stipulation:
 - Submission of assay results.
- **Update:**
 - Lab wishes to withdraw the amendment for the addition of procedures with SV40.
 - IBC approval will be updated to storage only of SV40.
 - If the lab seeks to conduct any procedures other than storage with SV40, an amendment will be submitted and approved by the IBC prior to beginning this work.

PI: Hans-Christian Reinecker

- **Title:** Mechanisms of mucosal host defense
- **Registration Number:** RDSR-2026-089
- **Update:**
 - The lab has provided the requested clarification of the proposed microscopy work and the associated SOPs.

New Business:

Project closures per PI request unless otherwise noted

PI: Noelle Williams

- **Title:** Evaluation of sugars in urine as a biomarker for gastrointestinal barrier dysfunction

Reviews

Recombinant DNA Registration for IBC review and authorization.

PI: Peter Tsai

- **Title:** Cerebellar Contribution to Neurodevelopment Disorders
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1, and III-F-8

- **Project Summary:**
 - Investigates how the cerebellum regulates cognition and behavior, and how cerebellar dysfunction contributes to neurodevelopmental and neurobehavioral disorders using genetically modified animal models, optogenetics, and DREADD-based neuronal manipulation.
 - Uses adeno-associated viral (AAV) vectors, fluorescent reporters, and modified rabies virus systems to map and characterize cerebellar neural circuits, including specific neuronal inputs and outputs, through cell type-restricted viral tracing approaches.
 - Employs lentiviral-mediated gene knockdown and primary neuronal cell culture assays to study the molecular and cellular functions of genes involved in cerebellar networks, including the production of recombinant lentiviral vectors in HEK293T cells.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Replication incompetent Adeno-associated virus
 - Replication deficient, EnvA pseudotyped, 2nd generation, delta-G Rabies Virus
- **Transgenes:** function (source)
 - Fluorescent markers (*Discosoma sp.*)
 - Fluorescent marker (*A. victoria*)
 - Recombinase (P1 bacteriophage)
 - Inhibits neuronal activity (human)
 - Muscarinic receptor (human)
 - Regulates TSC2 (mouse)
 - Light driven proton pump (*C. reinhardtii*)
 - Light driven proton pumps (*Halobacterium*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines, primary mouse and rat cell lines); bacteria (*E. coli* K12)
- **Notes:**
 - Production and purification of Lentivirus.
 - Use of ready-to-use AAV and G-deleted Rabies viral stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Stereotaxic intracranial – Lentivirus, AAV, G-deleted Rabies virus
- **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:
 - Stereotaxic intracranial – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE –
 - Animal facility – Yellow gown, nitrile gloves, eye protection

- Animal facility – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- Animal facility – Yellow gown, nitrile gloves, eye protection
- **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: Zhijian Chen

- **Title:** Role of cGAS in immune defense and auto immunity
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-2, III-D-3, III-D-4, III-E, and III-F-8
- **Project Summary:**
 - Investigates innate immune mechanisms and autoimmune disease pathogenesis, focusing on cGAS, TREX1, and related immune signaling pathways to support development of novel treatments, immunotherapies, vaccines, and anti-tumor strategies.
 - Utilizes AAV-CRISPR/Cas9 gene editing, lentiviral vectors, recombinant DNA technologies, protein expression systems, and humanized mouse models to evaluate gene function, immune responses, and therapeutic interventions in infectious disease, autoimmune disease, and cancer models.
 - Employs a range of viral and bacterial research agents, including modified and fluorescently labeled pathogens, to study host-pathogen interactions, immune signaling, vaccine development, and mechanisms of immunity while generating recombinant proteins, plasmids, and engineered cell lines for laboratory research.
- **Pathogens genetically modified by collaborator: Risk Group 2**
 - Herpes simplex virus type 1 (HSV-1), strain T-VEC
 - Vesicular stomatitis virus (VSV), strain Indiana
- **Pathogen previously genetically modified: Risk Group 2**
 - *Listeria monocytogenes*, strains LM10403S WT-Lm-OVA, LM10403S ActA-Lm-OVA
- **Pathogens not genetically modified: Risk Group 2**
 - Respiratory syncytial virus (RSV), strains A2, Long, Line 19
 - Influenza A, strain H1N1 A/PR8/34
 - Sindbis virus, strains NSV, SVNI
 - Sendai virus, strain Hamamatsu
 - Murine leukemia virus (MLV), strain Moloney
 - Murid gammaherpesvirus 68 (MHV68)
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: It remains highly efficient for our specific experimental needs, particularly for cell lines that are difficult to transduce, while we maintain strict biosafety protocols to mitigate the associated risks.

- Replication incompetent Human immunodeficiency virus type 1 (HIV-1)
- Replication incompetent Adenovirus
- Replication incompetent Adeno-associated virus
- Ecotropic Baculovirus
- Mammalian expression plasmids
- Bacterial expression plasmids
- CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Immune response (mouse)
 - Microtubule assembly/stability (human)
 - Immune response (human, mouse)
 - Antigenic immune response (HPV-1)
 - Spike protein (SARS-CoV-2)
 - Intracellular movement (*Listeria monocytogenes*)
 - Antigen (chicken)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
 - Recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Nanoparticles:** yes **Type:** lipid
- **Host:** Mammalian (human and nonhuman primate packaging cell lines, human and nonhuman primate established cell lines, primary murine cell lines); insect (established cell lines); bacteria (*E. coli* K12, *E. coli* B)
- **Zoonotic Potential:** The PI is using VSV, Influenza A virus, Sindbis virus, and *Listeria monocytogenes*, genetic variants, mutants, and clones, zoonotic agents 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 VSV, Influenza A virus, Sindbis virus, and *Listeria monocytogenes* agents.
- **Notes:**
 - Production, purification, and concentration of Lentivirus and Baculovirus.
 - Use of ready-to-use Adenovirus and AAV stocks.
 - HIV-1 LTR-gfp vector retains complete LTRs, tat, and rev, but has a frameshift mutation in env, a ngfr reporter gene in place of nef, and gfp in place of gag, pol, vif, and vpr.
 - Flow cytometry of non-fixed materials: The lab isolates cells from mice and from in vitro work. The timeline for in vitro work is 1 week post transduction.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Intraperitoneal (IP) – AAV
 - Intratracheal, intramuscular, stereotaxic intracranial – Adenovirus
 - Intravenous (IV), intratumoral, intramuscular – mRNA lipid nanoparticles
 - Intravenous (IV) – CAR T-cell allografts
 - Subcutaneous, retro-orbital – non-modified xenografts
 - Intravenous (IV), intraperitoneal (IP), oral gavage – *Listeria monocytogenes*
 - Intravenous (IV), intranasal, retro-orbital – HSV-1

- Intranasal – Influenza A, RSV, VSV
- Intravenous (IV) – MLV, VSV
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors, pathogen stocks and cultures, and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Intratracheal, intramuscular – Inoculation of Adenovirus in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Intraperitoneal – Inoculation of AAV in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Subcutaneous, retro-orbital (RO) – Inoculation of non-modified xenografts in a BSC followed by ABSL1 housing
 - Intravenous (IV) – Inoculation of CAR T-cell allografts in approved area followed by ABSL1 housing
 - Intravenous (IV), intratumoral, intramuscular – Inoculation of mRNA lipid nanoparticle in approved area followed by ABSL1 housing
 - Intravenous (IV), intraperitoneal (IP), oral gavage – Inoculation of *Listeria monocytogenes* followed by ABSL2 housing
 - Intravenous (IV), intranasal, retro-orbital (RO) – Inoculation of HSV-1 in a BSC followed by ABSL2 housing
 - Intravenous (IV), intranasal – Inoculation of VSV in a BSC followed by ABSL2 housing
 - Intranasal – Inoculation of RSV, Influenza A in a BSC followed by ABSL2 housing
 - Intravenous (IV) – Inoculation of MLV in a BSC followed by ABSL2 housing
 - PPE –
 - Animal facility: Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
 - Animal facility: Yellow gown, nitrile gloves, eye protection
 - Non-Animal facility: Lab coat, gloves, eye protection
- **Training:** 3 individuals require training
- **2025-26 Lab Survey Results:** 24 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Kartik Rajagopalan

- **Title:** Leptin Signaling in AAV Infection

- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E and III-F
- **Project Summary:**
 - The lab aims to investigate the role of leptin signaling and related inflammatory pathways in the host response to infectious diseases.
 - Use of viral vector mediated gene expression approaches to assess gene function and validate mechanisms identified through genetic knockout studies.
 - Evaluation of post-pathogen interactions and immune responses in mouse models of viral and bacterial infection.
- **Pathogen: Risk Group 2**
 - Influenza A, H1N1, strain A/PR/8/34
 - *Staphylococcus aureus*, strain RN4220, UAMS-1, Wichita
 - *P. aeruginosa*, strain PAO1
- **Vectors:**
 - Replication incompetent Adenovirus
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - transcription factor (mouse)
 - ubiquitin-like protein (mouse)
 - phosphatase (mouse)
 - fluorescent marker (*Discosoma sp.*, *A. victoria*)
 - recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; mouse primary cell lines: hepatocytes; cocker spaniel production cell line); bacteria (*E. coli* K12)
- **Zoonotic Potential:**
 - The PI is using *Pseudomonas aeruginosa* and Influenza A which 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 AAV. Use of ready-to-use AAV and Ad stocks.
 - PI has indicated that Staphylococci agents produce virulence factors, including hemolysins, leukotoxins, and enterotoxins (such as enterotoxin B and toxic shock syndrome toxin), but that no work will be done on these toxins.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - tail vein, RO – Adenovirus, AAV
 - intranasal – Influenza A, *Staphylococcus aureus*, *P. aeruginosa*
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures

- BSL2 – Biosafety cabinet use during manipulation of viral vectors, risk group 2 agents, 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:
 - Tail vein, RO – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Intranasal – Inoculation of agent followed by ABSL2 housing
 - PPE – hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks
- **Training:** 3 individuals require training
- **2025-26 Lab Survey Results:** 12 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Walter Chen

- **Title:** Investigating organellar metabolism in neonatal medicine
- **Note:** New PI, Safety met with on 8/18/2026
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Investigates how mitochondrial and peroxisomal function influences neonatal development, metabolism, and neurological disease using human cell culture and mouse models.
 - Uses viral vector-based gene editing, gene expression, and AAV-mediated recombination approaches to manipulate cellular pathways and evaluate their effects on organellar function, metabolism, and gene regulation.
 - Employs molecular cloning, recombinant DNA techniques, and protein expression in bacterial and mammalian systems to support mechanistic studies of cellular and organellar biology.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: Higher viral titer, more streamlined workflow, less inter-batch variability, compatibility with 2nd generation transfer plasmids.
 - Replication incompetent Retrovirus
 - Replication incompetent Adeno-associated virus
 - Bacterial expression plasmids
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Mitochondrial proteins (human)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)

- Recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines, human established cell lines); bacteria (*E. coli* K12, *E. coli* B)
- **Notes:**
 - Production and purification of Lentivirus and Retrovirus.
 - Use of ready-to-use AAV stocks.
 - Flow cytometry will be performed on non-fixed, viral vector-transduced cells only after they have been cultured for at least 8 days or have undergone a minimum of 4 media changes.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intravenous (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:
 - Intravenous (retro-orbital) – Inoculation of AAV in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - PPE –
 - Animal facility: Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
 - Non-animal facility: gloves, lab coat, eye protection
- **Training:** All individuals have required training
- **2026-27 Lab Survey Results:** New PI

Summary:

- Discussion: The use of a second-generation Lentiviral vector system vs. a third-generation system. The committee recommended the use of a third-generation Lentiviral vector system.
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Recommendation of a third-generation Lentiviral vector system

Recombinant DNA Registration for IBC review and authorization,.

PI: Abhimanyu Garg

- **Title:** Genetic and Metabolic Basis of Familial Lipodystrophies
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E and III-F
- **Project Summary:**

- Investigating the genetic and metabolic mechanisms underlying familial lipodystrophies and adipose tissue development.
- Use of viral vector mediated gene expression approaches to evaluate the role of lipid metabolism and adipocyte differentiation pathways in disease pathogenesis.
- **Vectors:**
 - Replication incompetent, non-pseudotyped, Adenovirus
 - Replication incompetent Adeno-associated virus
 - Replication incompetent VSV-G pseudotyped, 3rd generation Lentivirus
 - Replication incompetent, VSV-G/Eco pseudotyped, 4th generation Lentivirus
- **Transgenes:** function (source)
 - modifying enzyme (human)
 - function unknown (mouse)
 - regulator (mouse)
 - energy homeostasis (human)
 - lipid metabolism (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; mouse, hamster, human established cell lines); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Ad and Lenti. Use of ready-to-use AAV and Lenti stocks. PI indicates that transgenic animals were generated by collaborating lab on UTSW campus many years ago.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes **GDMO:** No
- **Route(s) of Administration:** IV – 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:
 - IV – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - JA02 PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 7 deficiencies found, 1 overdue

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Pedro Rosa Neto

Co-PI: Marc Diamond

- **Title:** De novo design of Alzheimer's Disease PET ligand binding sites
- **Note:** New. New PI, Safety met with on 8/11/2026.
- **NIH Guideline Section(s):** III-E and III-F-8
- **Project Summary:**
 - Ligands that image tau pathology in Alzheimer's disease (AD) are currently discovered by trial-and-error screening against scarce human brain tissue. The goal of this project is to remove that bottleneck by engineering small, soluble, single-chain proteins that reproduce the three-dimensional ligand binding pocket found in patient-derived AD tau filaments.
 - Protein sequences are generated entirely in silico. The resulting proteins are designed to be soluble and monomeric, and do not correspond to any natural gene. Because the designs reconstruct the geometry of a tau surface, a small number of positions correspond to human MAPT (tau) residues in the region spanning approximately residues 349 to 362.
 - Recombinant protein production in laboratory *Escherichia coli*.
- **Vectors:**
 - Bacterial expression plasmids
- **Transgenes:** function (source)
 - scaffold (synthetic)
 - clinical tracer binder (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Bacteria (*E. coli* K12, BL21)
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 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: PranavKumar Shivakumar

- **Title:** Pathogenic mechanisms of biliary atresia and liver diseases in children
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**

- Investigation of the pathogenic mechanisms underlying biliary atresia and pediatric cholangiopathies using in vitro organoids models and neonatal mouse models of disease.
- Use of viral infection models to evaluate mechanisms of bile duct and liver injury associated with pediatric liver disease.
- Asses the role of hose genes and signaling pathways in the development of biliary injury, inflammation and fibrosis using gene knockdown and genome editing approaches.
- **Pathogen: Risk Group 2**
 - Reoviridae, S:USA:79:2
- **Vectors:**
 - Replication incompetent Adenovirus
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - oxidase organizer (mouse, human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; non-human primate, human epithelial cells; human cholangiocyte organoids)
- **Notes:** Use of ready-to-use adenovirus.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Intraperitoneal – RRV, Adenovirus
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of viral vectors, risk group 2 agents, 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:
 - Adeno – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - RRV – Inoculation of agent followed by ABSL2 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face mask
- **Training:** 8 individuals require NIH training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- Reviewers discussed appropriate containment measures and husbandry practices for RRV-infected mice. Standard BSL2 housing was determined to be acceptable, consistent with the practices previously used by the laboratory and approved by the committee.
- No other 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: Steven McKnight

- **Title:** Study of Low Complexity Sequence & pEZT-BM subcloning
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-E, and III-F-8
- **Project Summary:**
 - Uses recombinant DNA, baculovirus expression systems, and bacterial cloning techniques to generate and overexpress proteins of interest for biochemical and functional studies.
 - Produces and purifies recombinant proteins, including proteases and tagged fusion proteins, in *E. coli* and insect cell expression systems for downstream protein characterization, cleavage assays, and in vitro analyses.
- **Vectors:** (source)
 - Amphotropic Baculovirus
 - Bacterial expression plasmids
- **Transgenes:** function (source)
 - Hydrogel formation (human)
 - Protease (tobacco etch virus)
 - Protease (human)
 - Fluorescent marker (*A. victoria*)
 - Fluorescent marker (*Discosoma sp.*)
 - Protein expression (*E. coli*)
- **Oncogenes/Tumor suppressor:** Alteration of FUS might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines: HEK293T); insect (established cell lines); bacteria (*E. coli* K12: DH5α, *E. coli* B)
- **Notes:** Production, purification, and concentration of Baculovirus.
- **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:** 14 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: Kevin Williams

- **Title:** Activity dependent regulation of neurons
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4

- **Project Summary:**
 - Uses Cre-dependent adeno-associated viral (AAV) vectors to selectively manipulate neuronal activity through chemogenetic (DREADD) and optogenetic approaches in specific brain cell populations.
 - Employs AAV-mediated expression of neural activity reporters, including GCaMP, combined with in vivo brain injections and fiber photometry to monitor and characterize neuronal function and circuit activity.
- **Vectors:** (source)
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - Inhibits neuronal activity (human)
 - Activates neuronal activity (mouse)
 - Calcium sensors (mouse)
 - Fluorescent marker (*Discosoma sp.*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (mouse)
- **Notes:** Use of ready-to-use AAV.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Stereotaxic intracranial – AAV
- **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:
 - Stereotaxic intracranial – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE –
 - Animal Facility: Yellow gown, nitrile gloves, eye protection
 - Non-Animal facility: Lab coat, gloves, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 7 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: Juan Manuel Povedano Selfa

- **Title:** Identification of chemically-tractable vulnerabilities in cancer
- **Note:** Amendment for the addition of:
 - Adenovirus for in vitro and in vivo use

- Other in vivo work with approved agents
- **NIH Guideline Section(s):** III-D-4 and III-E-1
- **Project Summary:**
 - Use genome editing technologies to modify cell lines.
 - Modified cell lines will be inoculated into animals to investigate the role of the modified genes in vivo.
 - Lentivirus and adenovirus will be used in animal models to investigate the effects in tumor initiation in vivo.
- **Vectors:**
 - Replication incompetent Adenovirus
- **Transgenes:** function (source)
 - recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Adenovirus Host:** Mammalian (established cell lines: murine, human)
- **Notes:** Use of ready-to-use adenovirus stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Subcutaneous – xenograft of modified and non-modified established cell lines, allograft of modified cell lines
 - Intratracheal – lentivirus, adenovirus
- **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:
 - Viral vectors – 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 masks, and eye protection
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** 1 deficiency found, all corrected

Summary:

- Reviewer mentioned pending updates in the application
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Zahid Ahmad

- **Title:** A Phase 1b Single Ascending Dose Study to Evaluate the Safety of VERVE-201 in Patients with Refractory Hyperlipidemia
- **Note:** New
- **NIH Guidelines:** III-C
- **Project Summary:**
 - A first-in-human, open-label, Phase 1b clinical study sponsored by Verve Therapeutics, Inc. evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational product in adults with refractory hyperlipidemia.
- **Product(s):**
 - RNA in lipid nanoparticle
- **Transgenes: (source)**
 - endonuclease and interaction domain (*S. pyogenes*)
 - adenosine deaminase (synthetic)
 - lipid metabolism regulator (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.
 - A treatment-emergency serious adverse event has 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.
- **Research Applications:**
 - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
 - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - BSL2 – Manipulation of agent in the Pharmacy
 - Other: UTSW Approved SOP for gene transfer project must be followed
 - Refer to supplemental documents for more information

Summary:

- Committee considered potential germline effects of the investigational product.
- No other safety concerns.

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Thomas Schlieve

- **Title:** A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia
- **Note:** Renewal. No procedural and minor personnel changes were noted.
- **NIH Guidelines:** III-C
- **Sponsor:** MeiraGTx, LLC
- **Project Summary:**
 - This is a Phase II randomized, double-blind, placebo-controlled, multi-center study sponsored by MeiraGTx, LLC to explore the safety and efficacy of investigational product in adults with radiation-induced xerostomia.
- **Product(s):**
 - Replication incompetent adeno-associated virus
- **Transgenes: (source)**
 - water channel protein (human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A consultation with Occupational Health is advised for health care workers.
 - No 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:**
 - 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

- Manipulation of human specimens in laboratory
 - Other: UTSW Approved SOPs for gene transfer project must be followed
- Refer to supplemental documents for more information

Summary:

- Discussion of:
 - Potential presence of product in collected specimens due to shedding.
 - Intercampus transportation of specimens from collection location to laboratory for processing.
 - Transportation of specimens, which could potentially contain investigational product, must be aligned with institutional transport policy.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Specimen transport procedures aligned with institutional transport policy.

Recombinant DNA Registration for IBC review and authorization.

PI: Jay Horton

Co-PI: Guosheng Liang

- **Title:** Molecular Basis of Cholesterol Metabolism
- **Note:** Amendment for addition of lipid nanoparticle encapsulating nucleic acids
- **NIH Guideline Section(s):** III-D-4 and III-F-8
- **Project Summary:**
 - Lipid nanoparticles will be used as non-viral delivery vehicles for nucleic acids, including synthetic RNA and plasmid DNA.
 - In some mouse models, guide RNA may be used to direct editing of selected genes.
 - Reporter constructs, including fluorescent reporter plasmids, may be used to assess delivery and transgene expression.
- **Vectors:**
 - Mammalian expression plasmids
 - sgRNA
- **Transgenes:** function (source)
 - cholesterol and fatty acid synthesis gene transcription (mouse)
 - fatty acid synthesis (mouse)
 - fatty acid biosynthesis (mouse)
 - lipid metabolic process (mouse)
 - serine/threonine kinase (mouse)
 - regulation of cholesterol and fatty acid synthesis (mouse)
 - lipid metabolic process (mouse)
 - fatty acid biosynthetic process (mouse)
 - cardiolipin biosynthetic process (mouse)
 - phospholipid biosynthetic process (mouse)
 - cholesterol synthesis (mouse)
 - triglyceride and phospholipid metabolism (mouse)
 - autophagy, lysophagy, and cell metabolism protein (mouse)

- fluorescent markers (*Discosoma* sp., *A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Nanoparticles:** yes **Type:** lipid
- **Host:** Mammalian (established human cell line); Bacterial (*E. coli* K12)
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intravenous (tail vein, retro-orbital) – CRISPR gRNA, plasmid
- **Required Training, Procedures, and Containment:**
 - In-Vivo Procedures:
 - Inoculation of agent in approved area followed by ABSL1 housing
 - PPE –
 - ARC: Yellow gown, nitrile gloves, and eye protection
 - Non-ARC: Lab coat, hand protection, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 11 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: Judy Liu

- **Title:** Molecular and Cellular Pathways in Epilepsy
- **Note:** Amendment
- **NIH Guideline Section(s):** III-E, III-F-1, and III-F-8
- **Project Summary:**
 - Modification of genes of interest in immortalized human cell lines.
- **Vectors:**
 - Mammalian expression plasmids
 - Anti-sense oligonucleotides
- **Transgenes:** function (source)
 - sodium citrate co-transporter (human)
 - fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); bacteria (*E. coli* K12)
- **Note:** The lab will also be using blood which is not screened.
- **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 human materials when procedures involve the generation of aerosols and splashes
- PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 1 individual requires training
- **2025-26 Lab Survey Results:** 7 deficiencies found, 2 pending

Summary:

- Discussion of pending items
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Zhenpeng Qin

- **Title:** Qin Lab Biosafety Permit
- **Note:** Amendment for addition of:
 - Transgenic animals
 - In vivo use of mRNA
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Obtain gene delivery in the brain and spinal cord.
- **Transgenes:** function (source)
 - nitric oxide synthase (mammalian)
 - reporter (*Photinus pyralis*)
 - fluorescent marker (*Discosoma sp.*)
 - recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Intraparenchymal, intrathecal, intravenous, or retro-orbital – mRNA
- **Required Training, Procedures, and Containment:**
 - In-Vivo Procedures:
 - Inoculation of agent in approved area followed by ABSL1 housing
 - PPE –
 - ARC: Yellow gown, nitrile gloves
 - Non-ARC: Lab coat, gloves, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:

- Discussion of pending updates to clarify locations and routes of administration
- No other safety concerns

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations. **These include:** Resolution of minor pending comments.

Biosafety Program Monthly Activity Reports

Other Business

- Policy updates

Adjourn Time: 12:50 pm