

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

August 25, 2026

Time: 11:30 a.m.

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

IBC Minutes

IBC Attendance August 2026

Noelle Williams, Ph.D.	Don Gammon, Ph.D.
Danielle Robertson, O.D., Ph.D.	Tomce Runcevski, Ph.D.
Ralph Callicott, D.V.M	Maria Labandeira-Rey, Ph.D.
Robert Orchard, Ph.D.	Ryan Lisk, MPH
Michael Reese, Ph.D.	Mark Thompson
Michael Shiloh, M.D., Ph.D.	Brittany Hubbard
Benjamin Ohlstein, M.D., Ph.D.	Kayle Cirrincione
Tu Dan, M.D.	Callan Kaut
Jakub Furmaga, M.D.	Chad Donelson
Chun-Li Zhang, Ph.D.	Audrey Kinser

Notification to IBC Members and Guests

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

IBC Conflict of Interest Policy reminder

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

Call to Order and Approval of Minutes

Quorum was obtained: A regular meeting of the UT Southwestern IBC was called to order at 11:30 a.m. on August 25, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

The draft minutes from the meeting held on July 28, 2026 were approved unanimously by the members.

Status: July 28, 2026 IBC minutes were approved with minor changes.

Updated Business:

- Registration Closures
- Work holds

Project Closures per PI request

PI: Walter Petroll

- **Title:** Assessment of Corneal Fibroblast Biomechanical Behavior

PI: Yucel Akgul

- **Title:** Muscle Fat Grafting

PI: Yuguang He

- **Title:** A Phase 2b; Randomized; Double-masked; Multicenter; Dose-ranging; Sham-controlled Clinical Trial to Evaluate Intravitreal JNJ-81201887(AAVCAGsCD59) Compared to Sham Procedure for the Treatment of Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)

PI: Eunsook Jin

- **Title:** COLSIO Trial: Phase II Randomized, Controlled Trial of Colchicine to Suppress Inflammation and Improve Insulin Resistance in Adults and Adolescents with Obesity

Reviews

Recombinant DNA Registration for IBC review and authorization.

PI: Rose Langsjoen

- **Title:** Development of novel pathogen genomics methods
- **Note:** New. New PI, Safety met with on 4/21/2026.
- **NIH Guideline Section(s):** III-F-8
- **Project Summary:**
 - This project aims to develop novel sequencing methods that can be used in both clinical and research settings to identify, quantify, and characterize RNA and DNA of populations of clinically relevant pathogens.
 - To this end, initial methods will utilize control RNA and DNA constructed in-house from existing viral cDNA clones. These subclones will consist of small segments of BSL-2 alphavirus genomes, amounting to roughly 0.5-6 kilobases of the original 10-12kb genomes; control RNA will be generated by in vitro transcription.
- **cDNA from Risk Group 2 pathogens:**
 - Chikungunya virus, strain 181/clone25
 - Venezuelan equine encephalitis virus, strain TC-83
 - Mayaro virus
 - Sindbis virus, strain AR339
- **Vectors:**
 - Cloning vector
- **Transgenes:** function (source)
 - viral segments (species listed above)

- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI uses nucleic acids from VEEV and Sindbis virus, zoonotic viruses that affect livestock animals which may result in an economic impact according to APHIS. In the case of interstate transport, a USDA permit may be needed for these materials.
- **Notes:** No infectious virus will be present. cDNA from viruses indicated above will be used to clone small segments (less than 50%) of the genome.
- **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:** New PI

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Lenette Lu

- **Title:** Identify Mycobacterium tuberculosis antigens that elicit antibody functions by using Mtb transposon library (Tnseq)
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1
- **Project Summary:**
 - Identification of Mycobacterium tuberculosis antigens that elicit antibody-mediated immune responses using a transposon mutant library and in vitro models of innate and adaptive immune cells.
- **Pathogen: Risk Group 3**
 - *Mycobacterium tuberculosis*, strain H37Rv
- **Vectors:** (source)
 - Transposon
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines: – human, mouse; primary cell lines – human, bone marrow macrophages – mouse)
- **Notes:** The PI indicates: “In transposon mutant libraries, strains contain a transposon that encodes a kanamycin resistance gene and T7 promoters oriented so as to promote transcription into adjacent chromosomal DNA
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**

- In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Manipulation of human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - BSL3 – Manipulation and storage of Risk Group 3 agents
- In-Vitro Procedures: BSL3 agents
 - Strict Adherence to the current JA4 BSL3 SOP Manual.
 - 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 Ilse for TB contamination
 - 70% ethanol to decon surfaces against other bacteria/fungi
 - Bleach for additional disinfection
 - Coverage Plus TB for animal areas
 - Autoclaving for waste disposal
- **Medical Surveillance:** All PIs, Project Staff, and ARC Personnel working in the JA4 BSL-3 facility must enroll in the Worker Protection Program and the Tuberculosis Surveillance Program administered by Occupational Health. Access to the BSL-3 laboratory will be revoked for anyone who does not comply with these monitoring programs.
- **Training:** 1 individual requires training
- **2025-26 Lab Survey Results:** 2 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: David Greenberg

- **Title:** Study of Pathogenesis and Novel Therapeutic Approaches to Pathogens in the Immunocompromised Host
- **Note:** Amendment to include a new experimental procedure
- **NIH Guideline Section(s):** III-D-1 and III-F
- **Project Summary:**
- Amendment to study a potential antimicrobial treatment for *Pseudomonas aeruginosa* by expressing a naturally occurring protein and evaluating its effect.
- **Pathogen to be genetically modified: Risk Group 2**
 - *Pseudomonas aeruginosa*, strain PAO1
- **Vectors:**
 - Bacterial expression plasmids
- **Transgenes:** function (source)
 - porin (*P. aeruginosa*)
- **Oncogenes/Tumor suppressor:** None

- **Toxic Genes:** None
- **Host:** Bacteria (*Pseudomonas aeruginosa*)
- **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 bacteria 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:** 28 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: Robert Orchard

- **Title:** Orchard Lab Virus Protocol
- **Note:** Amendment for the addition of Parechovirus molecular clones and replicons.
- **NIH Guideline Section(s):** III-D-1, III-D-3, and III-F-8
- **Project Summary:**
 - Investigating how host cell factors regulate replication of diverse viruses in mammalian cell lines using standard virological assays, including plaque assays, TCID₅₀, and flow cytometry of fixed samples.
 - Adding Parechovirus to ongoing studies of a conserved viral enzyme, using molecular clones (including reporter constructs) to generate wild-type and catalytic mutant viruses and assess the impact of protease mutations on viral replication.
 - Utilizing well-characterized Parechovirus replicon systems to study viral RNA replication independently of virus production, egress, and associated cytotoxic effects.
- **Pathogen genetically modified: Risk Group 2**
 - Parechovirus, strain A1
 - Expressing a reporter
 - Expressing a reporter
 - Expressing a reporter and protease mutations
 - Expressing a reporter and protease mutations
- **Replicons from Risk Group 2 pathogens**
 - Parechovirus, strain A1
 - Expressing a reporter
 - Expressing a reporter and protease mutations
- **Vectors:**
 - Standard cloning plasmid
- **Transgenes:** function (source)
 - Complete viral genome, generates viable virus upon transfection (Parechovirus)

- Protease (Parechovirus)
- Reporter (*O. gracilirostris*)
- Reporter (*B. lanceolatum*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human and non-human primate packaging cell lines; human, mouse, pig, non-human primate, canine established cell lines; primary human cell lines and organoids); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Parechovirus from molecular clones.
- **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 pathogen stocks and human cell lines 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:** No deficiencies found

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: Keisa Mathis

- **Title:** Control of Renal Inflammation in Hypertension and Lupus
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Study how the nervous system communicates with the immune system to control inflammation in the kidney, and how failure of this communication leads to kidney damage and high blood pressure using lupus as the disease model.
 - Use of vector to express genes of interest.
- **Vectors:**
 - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
 - fluorescent marker (*Discosoma sp.*)
 - G-protein coupled receptor (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only
- **Notes:**
 - AAV:

- Use of ready-to-use AAV stocks.
- Human materials:
 - Non-genetically modified human specimens are also utilized. These materials are not screened.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Stereotaxic 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 human materials 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 approved area followed by ABSL1 housing
 - PPE –
 - Animal facility: Yellow gown, nitrile gloves
 - Non-Animal facility: Laboratory coat, gloves, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 5 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: Laura Banaszynski

- **Title:** Histone Variant and Chromatin Regulation
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
 - Investigating how chromatin-associated proteins regulate pluripotency, differentiation, and disease progression using mouse embryonic stem cells and kidney cancer models.
 - Using replication-incompetent lentiviral vectors, shRNA, and CRISPR/Cas9 technologies to express or knockdown genes to assess their roles in chromatin-mediated cellular processes.
 - Producing recombinant histones and chromatin remodeling proteins for in vitro biochemical studies and evaluate how mutations in chromatin-associated factors contribute to clear cell renal cell carcinoma (ccRCC) development and progression.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Bacterial expression plasmids
 - Mammalian expression plasmid
 - Transposon system
 - CRISPR/*cas9* system

- **Transgenes:** function (source)
 - Histone acetyltransferase (mouse)
 - Histone methyltransferase (mouse)
 - Histones (mouse)
 - Chromatin remodeling (*Drosophila*, human)
 - Fluorescent marker (*Discosoma sp.*)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** Alteration of histone acetyltransferase might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging and established cell lines; primary human and mouse cell lines); bacteria (*E. coli* K12, BL21)
- **Notes:** Production, purification, and concentration of Lentivirus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Intrarenal, intraperitoneal – non-modified primary human 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:
 - Intrarenal, intraperitoneal – Inoculation of agent 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
- **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: Jeffrey Woodruff

- **Title:** Cell Culture of human DLD-1 cells
- **Note:** Amendment for the addition of viral vector
- **NIH Guideline Section(s):** III-D-3, III-E-1 and III-F-8
- **Project Summary:**
 - Lentivirus will be used to stably express protein constructs for imaging.
- **Vectors:**

- Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: We are obtaining the lentiviral plasmids from a collaborating lab, which has extensive experience and a well-established track record of using this system.
- **Transgenes:** function (source)
 - histone (human)
 - fluorescent marker (*Discosoma* sp.)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); 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:** 1 individual requires training
- **2024-25 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:

- Discussion of:
 - Centrifugation procedures and decontamination.
 - Live cell imaging procedures.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training, provision of SOP for live cell imaging, and work start meeting with Safety.

Recombinant DNA Registration for IBC review and authorization.

PI: Tamia Harris-Tryon

- **Title:** Microbiota immune system interactions in skin
- **Note:** Amendment for the addition of Lentivirus
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
 - Investigating the role of cutaneous steroid metabolism in skin disease using primary human keratinocytes and sebocytes as in vitro model systems.
 - Generating lentiviral vectors in HEK293T cells to immortalize and perform CRISPR-mediated gene editing of primary keratinocytes and sebocytes, enabling functional studies of genes involved in skin biology and disease.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: The high-titer viral production that second-generation lentiviral systems grant will allow efficient transductions that would limit the number of

times required to generate these second-generation VSV-G pseudotyped lentiviral particles. Moreover, the genome-scale CRISPR knockout (GeCKO) protocol that has been used to successfully knockout genes is well-established within second-generation lentiviral systems. We understand that the risk of assembling replication-competent viral particles substantially increases in preclinical animal models and/or clinical research with second-generation lentiviral systems. We will ensure that these second-generation lentiviruses will only be used for in vitro experiments for basic research purposes within BSL-2 containment.

- CRISPR/*cas9* system
- **Transgenes:** function (source)
 - CRISPR/*cas9* targets: Pending
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging and primary cell lines); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Lentivirus.
- **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:** 6 deficiencies found, all corrected

Summary:

- Discussion of:
 - Safety concerns regarding cell immortalization through oncogene expression with a second-generation Lentiviral vector system
 - Need for the use of a third-generation Lentiviral vector system
 - Pending required updates and requested modifications including intended CRISPR/*cas9* targets
- Investigator required to move to a third-generation Lentiviral vector system
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training, resolution of pending comments and requested updates, use of a third-generation Lentiviral vector system

Recombinant DNA Registration for IBC review and authorization.

PI: Steven Shabel

- **Title:** Neural activity in animal models of depression
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1, and III-F-8
- **Project Summary:**

- Investigating the neural circuitry underlying reward-related behaviors in rodents using viral vector-mediated gene delivery, optogenetics, calcium imaging, and transgenic mouse models to manipulate and monitor specific neuronal populations.
- Utilizing AAV, G-deleted rabies virus, lentiviral vectors, and HSV to target defined neuronal circuits, express neural activity reporters or effectors, and evaluate the roles of specific genes and pathways in neural function and behavior.
- Analyzing rhesus macaque and post-mortem human brain tissues through immunohistochemistry, confocal imaging, and single-nucleus RNA sequencing to characterize cellular and molecular features of neural circuits across species.
- Uses transgenic mice to target specific neuronal populations in the brain with expression of effectors via AAV (to measure activity, activate, or inhibit these neurons) or to remove genes of interest to assess their role in behavior or neural circuit activity.
- **Vectors:**
 - Replication incompetent Adeno-associated virus
 - Replication incompetent G-deleted, EnvA pseudotyped Rabies virus
 - **Storage only:** Replication deficient Herpes Simplex 1 virus
- **Transgenes:** function (source)
 - Fluorescent reporters (*A. victoria*)
 - Optical inhibition (*Natronomonas pharaonis*)
 - Optical excitation (*Chlamydomonas reinhardtii*)
 - Optical inhibition (*Chlamydomonas reinhardtii*)
 - Calcium indicators (recombinant)
 - Fluorescent reporter (*Discosoma sp*)
 - Voltage indicator (recombinant)
 - DREADDs (human)
 - Transporters (mouse)
 - Neuroinflammation (mouse)
 - Recombinase (*S. cerevisiae*)
 - Tetanus toxin light chain (*Clostridium tetani*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** Tetanus toxin light chain inhibits synaptic transmission but is non-neurotoxic without the heavy chain.
- **Host:** Mammalian (human packaging cell line); bacteria (*E. coli* K12)
- **Notes:**
 - PI will be producing, purifying and concentrating AAV in the laboratory.
 - PI will be using ready-to-use AAV, HSV-1 and G-deleted rabies viral stocks.
 - The lab will be working with human and non-human primate brain tissues.
- **Animal Model:** Rat, mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Stereotaxic intracranial – AAV, G-deleted rabies virus, HSV-1 vector
- **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 – Yellow gown, nitrile gloves, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:

- Discussion of:
 - Locations used for stereotaxic injection procedures
 - Safety concerns regarding work with non-fixed non-human primate brain tissue and the potential for exposure to B-virus
 - Need for the investigator to provide pathogen screening and safety information from the supplier of the non-human primate materials.
 - Need for the investigator to clarify whether the lab is actively acquiring and working with the non-human primate materials.
 - Possible need for additional training related to hazard potential of work with non-human primate materials
- Investigator required to provide:
 - Pathogen screening and safety information from the supplier of the non-human primate materials.
 - Clarification of whether the lab is actively acquiring and working with the non-human primate materials.
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Provision of pathogen screening and safety information from the supplier of the non-human primate materials, clarification regarding status of work with non-human primate materials

Recombinant DNA Registration for IBC review and authorization.

PI: Jerry Shay

- **Title:** Molecular Studies of Aging and Cancer
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-E and III-F
- **Project Summary:**
 - Study of mechanisms underlying cancer initiation, progression, and telomere biology through genetic modification and functional studies in human cell lines, including the use of lentiviral and retroviral vectors.
 - Evaluation of tumor formation and potential cancer therapeutics using humor tumor cell xenograft models in mice.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Replication incompetent VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: Second generation viral vectors yield higher viral titers and have been used safely for decades. They omit accessory genes and the HIV envelope

sequences to ensure biosafety. These vectors use three plasmids and require the viral Tat protein. They also contain a selectable gene sequence for selection in cells. We have a BSL-2 safety cabinet for all experiments that is certified annually. These vectors will be used for basic cell culture research and not for clinical-grade translation. They require fewer plasmids for transfection, compared to 3rd generation vectors thus maximizing efficiency of production. The 2nd generation vectors reduce experimental variability.

- Replication incompetent Retrovirus
- **Transgenes:** function (source)
 - cell cycle (mouse)
 - tumor suppressor (human)
 - reporter (Photinus pyralis, E.coli)
 - p53 inhibition (SV40 virus)
 - cell signaling (human)
 - apoptosis suppressor (human)
 - stemness (human)
 - receptor (human)
 - transcriptional factor (human)
 - cell cycle control (human)
- **Oncogenes/Tumor suppressor:** PI indicates that alteration of various genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines – human); bacteria (E. coli K12)
- **Notes:**
 - PI will be producing, purifying and concentrating virus in the laboratory.
 - Some cell lines are HepB positive, but there is no evidence of infectious HepB production.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Subcutaneous, IV – xenografts
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – 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 – Inoculation of xenografts in a BSC followed by ABSL2 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks
- **Training:** 2 individuals require training
- **2025-26 Lab Survey Results:** 1 deficiency found, 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: Hans-Christian Reinecker

- **Title:** Mechanisms of mucosal host defense
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4, III-E and III-F
- **Project Summary:**
- Investigation of innate immune signaling pathways involved in host defense against viral and bacterial infections, including characterization of candidate immune regulators identified through genomic and transcriptomic analyses using genetically modified cell culture models.
- Evaluation of host immune responses and pathogen host interactions during viral and bacterial infections using in vitro cell culture and mouse models to characterize mechanism of infection and inflammation.
- **Pathogen not genetically modified: Risk Group 2**
 - *Listeria monocytogenes*, strain Gibson
 - *Shigella flexneri*, strain IFO 3306
 - *Salmonella enterica* subspecies *enterica*, serovar Typhimurium
 - *Citrobacter rodentium*, strain CDC 1843-73
 - Influenza A H1N1, strain A/PR/8/34
 - Mammalian orthoreovirus (reovirus) type 1 Lang and type 3 Dearing, clinical isolates
- **Pathogen not genetically modified: Risk Group 2 Mouse Pathogen**
 - *Chlamydia muridarum*, strain Nigg II
- **Vectors:**
 - Replication incompetent Adenovirus
 - Oligonucleotide
 - Mammalian expression plasmids
- **Transgenes:** function (source)
 - ATP binding protein (human)
 - putative G-protein complex (human)
 - transmembrane protein (human, mouse)
 - antigen (human, mouse)
 - toll-like receptor (human, mouse)
 - deacetylase (human)
 - golgi marker (human)
 - peptidoglycan binding activity protein (human, mouse)
 - nucleotide-binding protein (human, mouse)
 - ER protein (human)
 - cytosolic DNA sensing agonist (Vaccinia)
 - fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (production cell line: MDCK, L929; established cell lines: HEK293T, HeLa, Caco2, HCT116, ARPE-19, THP-1, Jurkat, DC2.4, JAWS-II, murine intestinal epithelial; primary cell lines: embryonic stem cells, macrophage – mouse); bacteria (*E. coli* K12 and BL21)
- **Zoonotic Potential:** The PI is using *Listeria monocytogenes* and *Salmonella enterica* 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:** Use of ready-to-use adenovirus stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Oral gavage – *Salmonella*, *C. rodentium*, Reovirus; IN – Influenza; IP, Oral gavage – *Listeria monocytogenes*; RO, tail vein – Adenovirus; IP – Oligonucleotides
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures, 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:
 - RO, tail vein – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - IP (oligonucleotides) – Inoculation of agent in approved area followed by ABSL1 housing
 - Oral gavage, IN, IP – Inoculation of agent followed by ABSL2 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks
- **Training:** 1 individual requires training
- **2025-26 Lab Survey Results:** 16 deficiencies found, all corrected

Summary:

- Investigator required to provide additional details of non-fixed imaging including SOPs with safety and spill response measures.
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training, SOPs uploaded for non-fixed microscopy work, and a safety follow-up of the proposed location.

Recombinant DNA Registration for IBC review and authorization.

PI: William Mike Henne

- **Title:** Henne lab protocol to utilize bacterial, *Drosophila* and mammalian plasmids
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4, III-E and III-F-8
- **Project Summary:**
 - Use *Drosophila melanogaster* to study fat biology.
 - Use other hosts to express proteins for biochemical analysis.
- **Vectors:**
 - Standard cloning plasmid
 - Bacterial expression plasmid
 - Mammalian expression plasmid
- **Transgenes:** function (source)

- lipid metabolism (*Drosophila*)
- lipid trafficking (human/synthetic)
- interorganelle tether (yeast)
- fluorescent markers (*A. victoria*, *Discosoma* sp.)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); insect (*D. melanogaster*); yeast (*S. cerevisiae*); bacteria (*E. coli* K12, BL21)
- **Animal Model:** In *Drosophila* only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulation of human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 2 individuals require training
- **2024-25 Lab Survey Results:** 1 deficiency found, all corrected

Summary:

- Discussion of pending updates, which include clarification on production of transgenic flies, disinfection procedures, and plasmids utilized.
- 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: Todd Aguilera

- **Title:** Interrogation and targeting of the immunologic microenvironment in solid tumors.
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
 - Investigating mechanisms that limit antitumor immune responses within the tumor microenvironment and develop therapeutic approaches targeting both immune and tumor cells.
 - Evaluating tumor progression and treatment responses using in vitro and mouse models, including chemotherapy, radiotherapy, immunotherapy, combination therapies, and serial orthotopic tumor implantation.
 - Developing and screening bacteriophage-based molecular expression libraries to identify tumor-targeting molecules, validate selected proteins and peptides for imaging or therapeutic applications, and manipulate candidate genes using overexpression, siRNA/shRNA, and CRISPR/Cas systems.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus

- Justification: We will work to upgrade our lentiviral vector system to a 3rd generation. Current justification is that we rarely produce virus and had not realized we were out of date.
 - Replication incompetent Adenovirus
 - Bacterial/Mammalian expression plasmids
 - Phage libraries of modifications on the coat protein of M13, T4, T7 or lambda phage
 - Lentiviral library with modifications in coat protein
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Receptor tyrosine kinase (mouse)
 - Receptor (mouse)
 - T-cell receptor ligand (mouse)
 - Regulators (mouse)
 - Immunogenicity (chicken)
 - Fluorescent markers (*Discosoma sp.*)
 - Reporter (*Photinus pyralis*)
 - Fluorescent marker (*A. victoria*)
 - Endonuclease (*S. pyogenes*)
 - Recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** Alteration of regulators might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; human and mouse established cell lines); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Lentivirus. Use of ready-to-use Adenovirus stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Subcutaneous, IV (tail vein), intramammary fat pad, intrapancreatic – modified allografts
 - IV (tail vein), IP – bacteriophage
- **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, intramammary fat pad, intrapancreatic – Inoculation of modified allografts in an approved area followed by ABSL1 housing
 - IV – Inoculation of bacteriophage in approved area, mandatory 48h cage change followed by ABSL1 housing
 - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2024-26 Lab Survey Results:** 2 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: David Gau**

- **Title:** Role of actin cytoskeleton on regulation of mitochondria and impact in physiological and pathological contexts
- **Note:** New. New PI, Safety met with on 8/5/2026.
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1, III-F-1 and III-F-8
- **Project Summary:**
 - In this project, goal is to evaluate how perturbation of actin cytoskeletal regulators impacts mitochondria dynamics and how this plays a role in physiological and pathological contexts.
 - Use viral and non-viral gene transfer to alter cell genetic phenotype.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Replication incompetent, VSV-G pseudotyped Retrovirus
 - Replication incompetent Adenovirus
 - Replication incompetent Adeno-associated virus
 - Mammalian expression plasmids
 - siRNA
 - CRISPR/Cas9 system
- **Transgenes:** function (source)
 - actin cytoskeleton regulators (human)
 - anti-apoptotic protein (human)
 - quality control protein (human)
 - fluorescent marker (*Discosoma sp.*)
 - fluorescent marker (*A. victoria*)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** Alteration of gene of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines: human, mouse); bacteria (*E. coli* K12)
- **Notes:**
 - Production of retrovirus.
 - Use of ready-to-use lentivirus, AAV, and adenovirus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - Viral vectors:
 - Intrarenal – AAV
 - Intrarenal – Adenovirus
 - Cell lines:

- Subcutaneous, intrarenal – xenograft of modified and non-modified established human cell lines
- Subcutaneous, intrarenal – allograft of modified established 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:
 - Viral vectors – Inoculation of agent in a BSC followed by 48-hour cage change and 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 – Yellow gown, nitrile gloves, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** New PI

Summary:

- Finalization of BSL-2 facility location is pending.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Confirmation of BSL-2 facility.

Recombinant DNA Registration for IBC Review and Authorization.

PI: Larry Anderson

- **Title:** Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucel (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma
- **Note:** Renewal. No personnel or procedural changes.
- **NIH Guidelines:** III-C
- **Project Summary:**
 - Expanded access study sponsored by Janssen Research & Development, LLC to explore the efficacy of investigational product in the treatment of multiple myeloma.
- **Product(s):**
 - Autologous T cells genetically modified ex vivo with replication incompetent lentivirus
- **Transgenes:**
 - Chimeric antigen receptor
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A health consultation with Occupational Health is advised.
 - 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 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
 - Refer to supplemental documents for more information

Summary:

- Expanded access study for out of specification product.
- 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: John Schoggins

- **Title:** Virus-host interactions
- **Note:** Amendment for addition of bacterial expression plasmids
- **NIH Guideline Section(s):** III-D-2, III-E and III-F-8
- **Project Summary:**
 - Project aims to define the RNA-binding mechanism of the antiviral factor using purified proteins.
- **Vectors:**
 - Bacterial expression plasmids
- **Transgenes:** function (source)
 - RNA binding antiviral (human, bat)
 - RNA dependent RNA polymerase (yellow fever virus)
 - RNA helicase and protease (yellow fever virus)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Bacteria (*E. coli* K12, BL21)
- **Note on NIH Guidelines:** The transfer of DNA from Risk Group 2 and 3 into nonpathogenic prokaryotes may be performed under BSL2 or the IBC may approve the specific lowering of containment for particular experiments to BSL1.
- **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:** 1 individual requires training
- **2025-26 Lab Survey Results:** 3 deficiencies found, all corrected

Summary:

- The committee discussed the proposed experiments and determined that BSL1 is appropriate.
- 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: Xin Cai

- **Title:** Metabolism of cancer cells
- **Note:** Amendment for addition of in vivo work
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - Determine the in vivo proliferation rate of different cancer cell lines with metabolic gene deletion or over-expression.
- **Transgenic animals:** Yes **Generated at UTSW:** Yes (core facility) **GDMO:** No
- **Animal Model:** Mouse
- **Route(s) of Administration:**
 - Subcutaneous – xenograft and allograft of modified and non-modified established cell lines
- **Required Training, Procedures, and Containment:**
 - In-Vivo Procedures:
 - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
 - Allograft – Inoculation of agent in approved area followed by ABSL1 housing
 - PPE – Yellow gown, nitrile gloves, and eye protection
- **Training:** 1 individual requires training
- **2025-26 Lab Survey Results:** 1 deficiency found, all corrected

Summary:

- Discussion of pending updates, including verification of who will be modifying embryos for the generation of transgenic mice.
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Jinfan Wang

- **Title:** Single-molecule dynamics of cytosolic and mitochondrial translation
- **Note:** Renewal
- **NIH Guideline Section(s):** III-E and III-F-8
- **Project Summary:**
 - Research is focused on the dynamic mechanisms of eukaryotic protein synthesis.
 - Expression and purification of recombinant proteins.
- **Vectors:**
 - Bacterial expression plasmids
 - Insect expression plasmid
 - Yeast expression plasmid
 - Mutagenesis plasmids
 - Standard cloning plasmid
 - CRISPR/Cas9 system
- **Transgenes:** function (source)
 - mitochondrial ribosomal protein (human)
 - ribosomal proteins (human)
 - translation factor (yeast)
 - fluorescent marker (*A. victoria*)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); insect (established cell lines); yeast (*S. cerevisiae*, *S. pombe*); bacteria (*E. coli* K12, BL21)
- **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 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:** 6 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Biosafety Program Monthly Activity Reports

Other Business

Adjourn Time: 12:54 pm