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

June 30, 2026
Time: 11:30 a.m.
Location: JA05.110 and web conferencing
Dallas Texas, 75390

IBC Minutes

IBC Attendance June 2026

Noelle Williams, Ph.D.	Ryan Lisk, MPH
Ralph Callicott, D.V.M	Jessica Spaniol
Bart Carter, D.V.M	Julia Wilkerson
Don Gammon, Ph.D.	Erik Soliz
Mark Thompson	Callan Kaut
Michael Shiloh, M.D., Ph.D.	Chad Donelson
Maria Labandeira-Rey, Ph.D.	Audrey Kinser

Notification to IBC Members and Guests

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

IBC Conflict of Interest Policy reminder

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

Call to Order and Approval of Minutes

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

The draft minutes from the meeting held on May 26, 2026 were approved unanimously by the members.

Status: May 26, 2026 IBC minutes were approved with minor changes.

Updated Business:

Project closures per PI request unless otherwise noted.

PI: Chien-Ting Wu

- **Registration number:** PSR-2023-007
- **Title:** Study the infection mechanism of SARS-CoV-2

New Business:

Reviews

Recombinant DNA Registration for IBC review and authorization.

PI: Lawson Copley

- **Title:** In vivo and in vitro differential gene expression of *Staphylococcus aureus*
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-4
- **Project Summary:**
  - Study investigates the molecular mechanisms that influence the occurrence and severity of bone infections in otherwise healthy children.
  - BLI (bioluminescent imaging) *S. aureus* lab acquired strains will be included to obtain a visual understanding of the movement of this agent after it enters the animal.
- **Pathogen genetically modified: Risk Group 2**
  - Methicillin-susceptible *Staphylococcus aureus*, strain UAMS-1 spp:lux, clinical isolate MSSA-29
  - Methicillin-resistant *Staphylococcus aureus,* strain USA300 lac:lux, clinical isolate HS-MRSA, clinical isolate MRSA-9
- **Pathogen not genetically modified: Risk Group 2**
  - Methicillin-resistant *Staphylococcus aureus,* clinical isolate MRSA-12
- **Transgenes:** function (source)
  - reporter (*P. luminescens*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Zoonotic Potential:** The PI is using *S. aureus*, 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:** Antibiotic resistance and susceptibility profiles for the clinical isolates have been provided by the lab.
- **Animal Model:** Mouse
- **Route(s) of Administration:** *S. aureus* – intravenous (tail vein)
- **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:
  - Inoculation of agent in a BSC followed by ABSL2 housing
  - PPE –
    - Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face mask, and eye protection
    - Yellow gown, nitrile gloves, and eye protection
    - Hair bonnet, disposable white tie-back gown, double nitrile gloves, shoe covers, face mask, and eye protection
    - Laboratory coat, gloves, and eye protection
- **Training:** 1 individual requires NIH training
- **2025-26 Survey Results:** No deficiencies found

Summary:
- Renewal registration with addition of new core facility for animal imaging.
- Discussion of:
  - Decontamination procedures in newly added core facility.
  - Amount of potential shedding from infected animals.
  - Need for specific route to be followed during animal transport.
  - Use of shared facility for in vitro work.
  - Minor pending updates.
- No other safety concerns.

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations**. These include:** Completion of training, resolution of minor pending comments, and that ARC guidance for specific animal transport route be followed.

Recombinant DNA Registration for IBC review and authorization.

PI: Danielle Robertson

- **Title:** Contact lens-related microbial keratitis
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-4, III-F-8
- **Project Summary:**
  - Studies how *P. aeruginosa* and *S. aureus* cause corneal infections and how bacterial and host cell metabolism influences disease.
  - Employs fluorescent and antibiotic-resistant bacterial strains for imaging and pathogenesis studies.
  - Uses cell culture and animal models (mice and rabbits) to investigate infection mechanisms, inflammation, and potential therapies.
- **Pathogens to be genetically modified: Risk Group 2**
  - *Pseudomonas aeruginosa*, strains listed below
  - *Staphylococcus aureus*, strains listed below
- **Pathogens previously genetically modified: Risk Group 2**
  - *Pseudomonas aeruginosa*, strain PAO1-GFP
  - Methicillin sensitive *Staphylococcus aureus*, strains RN6390, SH1000
- **Pathogens not genetically modified: Risk Group 2**

    - *Pseudomonas aeruginosa*, strains PAO1, PA6206, PA6294, PA6487, PA103, PA19660, K1582, K2467, K3070, AR1270
        - Strains K1582, K2467, K3070 are fluoroquinolone resistant
        - Strain AR1270 is extensively drug resistant, but sensitive to cifederocol
    - Methicillin resistant *Staphylococcus aureus*, clinical isolate strains 491, 509, 597,615, 746
- **Pathogens not genetically modified: Risk Group 2 (Storage Only)**
    - *Pseudomonas aeruginosa*, strain 9027
    - *Serratia marcescens*, strain 13380
    - *Stenotrophomonas maltophilia*, strain 6538
    - *Staphylococcus aureus*, strain 6538
    - *Staphylococcus epidermidis*, strain 35984
- **Vectors:** (source)
    - Bacterial expression plasmids
- **Transgenes:** function (source)
    - Sigma B stress response factor (*S. aureus*)
    - Fluorescent marker (*E. quadricolor*)
    - Fluorescent markers (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines, primary human cell lines); bacteria (*P. aeruginosa*, *S. aureus*)
- **Zoonotic Potential:** The PI is using *Pseudomonas aeruginosa* and *Staphylococcus aureus* 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:**
    - Antibiotic susceptibility profiles have been provided for *P. aeruginosa* strains within the registration.
    - The PI indicates that antibiotic susceptibility testing will be performed prior to initiating experiments with the S. *aureus* clinical isolate strains listed within the registration.
    - The PI indicates that *P. aeruginosa* and *S. aureus* produce toxins, but no work will be performed with these toxins.
- **Animal Model:** Rabbit, mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
    - Mice
        - Routes: Ocular (contact lens, topical to the injured cornea)
        - Agents: Wild type and genetically modified *P. aeruginosa* and *S. aureus*
    - Rabbits
        - Routes: Ocular (contact lens, intrastromal)
        - Agents: Wild type and genetically modified *P. aeruginosa* and *S. aureus*
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures

        - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures, and human materials and cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Mouse – Inoculation of agent in a BSC, followed by ABSL2 housing
        - Rabbit – Inoculation of agent in approved area followed by ABSL2 housing
        - PPE –
            - Animal facility: Blue coat, gloves, eye protection
            - Animal facility: Hair bonnet, double gloves, face mask, white tie-back gown, shoe covers, eye protection
            - Non-animal facility: laboratory coat, gloves, eye protection
- **Training:** All individuals have required training
- **2025-26 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: James Collins

- **Title:** Molecular studies of the human parasite *Schistosoma mansoni*
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, III-D-3, III-D-4, and III-F-8
- **Project Summary:**
    - Study of *Schistosoma mansoni* biology and gene function to identify new drug targets for treating schistosomiasis.
    - Collecting parasite life stages from infected snails and rodents to determine where genes are expressed and whether they are essential for parasite survival.
    - Use of RNA extraction, PCR, cloning, RNA interference (RNAi), and gene reporter assays to investigate parasite gene function and regulation.
    - Express *Schistosoma* proteins in insect and human cell lines for enzymatic, expression, and signaling assays.
    - Test gene knockdown approaches in vitro and in infected mice to evaluate the effects of specific genes on parasite survival and development.
- **Pathogen to be genetically modified: Risk Group 2**
    - *Schistosoma mansoni*, strain NMRI
- **Pathogen not genetically modified: Risk Group 2**
    - *Schistosoma mansoni*, strain NMRI
    - *Schistosoma hematobium*, strain Egyptian
    - *Schistosoma japonicum*, strain Chinese
- **Vectors:** (source)
    - Ecotropic Baculovirus
    - Mammalian expression plasmids

    - Bacterial expression plasmids
    - Standard cloning plasmids
    - dsRNA
- **Transgenes:** function (source)
    - Peptide synthesis (*S. mansoni*)
    - cDNA library, various (*S. mansoni*)
    - RNA library, various (*Schistosoma spp.*)
    - Fluorescent marker (*Discosoma spp.*)
    - Fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines); insect (established cell lines); parasite (*S. mansoni*); bacteria (*E. coli* K12)
- **Notes:**
    - Production, purification, and concentration of Baculovirus.
    - The PI indicates that the *Schistosoma* strains are susceptible to praziquantel.
    - Regarding the in vivo administration location: The PI indicates that schistosomes are too large to be aerosolized. The administration of *Schistosoma* was previously authorized to be conducted in an approved area.
- **Animal Model:** Mouse, *S. mansoni*
- **Route(s) of Administration for mice:**
    - Intravenous (tail vein), IP – dsRNA
    - Percutaneous, IV, IP – *S. mansoni*, *S. hematobium*, *S. japonicum*
- **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:
        - Intravenous (tail vein) – Inoculation of agent in approved area followed by ABSL1 housing
        - Percutaneous, surgical transplantation (hepatic portal) – Inoculation of agent in approved area followed by ABSL1 housing
        - PPE –
            - Animal facility: Yellow gown, nitrile gloves, and eye protection
            - Non-animal facility: lab coat, gloves, eye protection
- **Training:** 5 individuals require training
- **2025-26 Lab Survey Results:** 9 deficiencies found, all corrected

Summary:
- Renewal with no major changes
- 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, notification.

PI: Theodoros Kelesidis

- **Title:** Immunopathogenesis of viral infections
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1
- **Project Summary:**
  - Studies how viral infections drive immune dysfunction, inflammation, and end-organ disease in humans and animal models.
  - Uses H1N1, RSV, rhinovirus, HIV, vaccinia virus, and SARS-CoV-2, to examine host antiviral responses and tissue damage.
  - In vitro infection studies using primary human cells, human and animal cell lines, blood products, serum/plasma, culture supernatants, and murine tissues.
  - Conducts animal studies with virus-infected mice and process tissues/fluids for downstream molecular and immunologic assays.
  - Uses GFP/luciferase-tagged vaccinia virus and GFP-tagged RSV for live-cell imaging and host-pathogen interaction studies.
- **Pathogen previously genetically modified: Risk Group 3 (BSL2 enhanced)**
  - Human Immunodeficiency virus Type 1 (HIV-1), strain L10R/M46I/L63P/V82T/I84V (ARP-394), M46I/L63P/V82T/I84V
- **Pathogen not genetically modified: Risk Group 3 (BSL2 enhanced)**
  - Human Immunodeficiency virus Type 1 (HIV-1), strains JR-CSF, UG070
- **Pathogens previously genetically modified: Risk Group 2**
  - Murine hepatitis virus, strain A59
  - Respiratory syncytial virus (RSV), strain A2
  - Vaccinia virus, strain Western Reserve
- **Pathogen not genetically modified: Risk Group 2**
  - Influenza A, strain A/PR 8/34 (H1N1)
  - Respiratory syncytial virus (RSV), strain A2
  - Rhinovirus, strains B632 (HRV1B), 11757 (HRV16), 209 (HRV39)
  - SARS-CoV-2, strains hCoV-19/USA/PHC658/2021 (Lineage B.1.617.2; Delta Variant), hCoV-19/USA/GA-EHC-2811C/2021 (Lineage B.1.1.529; Omicron Variant), Isolate hCoV-19/USA/MD-HP01542/2021 (Lineage B.1.351)
- **Transgenes:** function (source)
  - Fluorescent marker (*A. victoria*)
  - Reporter (*Photinus pyralis*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human, canine, and non-human primate packaging cell lines; established human and murine cell lines; primary human cell lines and materials)
- **Zoonotic Potential:** The PI is using Human Influenza A virus and Vaccinia virus, 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 VSV.
- **Notes:**
  - Production, purification, and concentration of viruses, including HIV.

- BSL2 – The PI will be working with blood and PBMC from HIV-infected patients with suppressed plasma viremia when the downstream experiments do not involve propagation and activation of cells where potentially latent virus can be activated (for example by flow cytometry, PCR, and other immunostaining) at BSL2.
- Enhanced BSL2 – The PI proposes working with blood from HIV-infected patients who have documented viremia at enhanced BSL2 (BSL2 containment with BSL3 practices).
- 8E5, ACH-2, J-Lat, J1.1, and Jurkat E4 cell lines contain integrated, latent HIV-1 proviruses.

- **Animal Model:** Mouse
- **Route(s) of Administration:**
  - Intranasal – Influenza A A/PR 8/34 (H1N1), RSV, Rhinovirus, Genetically modified Vaccinia virus, SARS-CoV-2
- **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
    - Enhanced BSL2 – Cultivation and manipulation of HIV stocks and cultures with BSL3 practices in a BSL2 facility
    - PPE –
      - BSL2 Enhanced Facility – Water resistant gown, double gloves, and eye protection are required
      - BSL1 and BSL2 Facilities – Laboratory coat, gloves, and eye protection are required
  - In-Vivo Procedures:
    - Intranasal – Inoculation of agent in a BSC followed by ABSL2 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:** 5 deficiencies found, all corrected

Summary:
- Discussion of:
  - BSL2 Enhanced locations, practices, and door signage
  - Location and placement of storage equipment
- No other safety concerns

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

Recombinant DNA Registration for IBC review and authorization.

PI: John Beckham

- **Title:** RNA virus pathogenesis and immunopathology
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-4, and III-F
- **Project Summary:**

    - Study of the pathogenies and hose immune response of RNA viruses using in vitro and in vivo models of infection.
    - Use of genetically modified and attenuated viruses to investigate mechanisms that contribute to viral pathogenesis and neuroinflammation.
- **Pathogen to be genetically modified: Risk Group 2**
    - Zika virus, strains PRVABC59, Paraiba_1/2015, Mex-2-81
    - Dengue virus
        - Serotype 1 strain 12150, TH-Sman
        - Serotype 2 strain K0049, 10674, ArA6894
        - Serotype 3 strain US/BID-V1043/2006, V1619/2005
        - Serotype 4 strain 703-4, UIS 497, D85-019
    - LaCrosse virus, lineage 1, strains 78V 13193 (also known as LACV/78/NC-cl), LACV/78/NC-M
    - Venezuelan equine encephalitis virus, strain TC83
    - Oropouche virus – BeAn 19991, Iquitos, Madre de Dios, and Peridoes isolates
- **Pathogen not genetically modified: Risk Group 2**
    - Non-neurotropic lymphocytic choriomeningitis virus (LCMV), strain Armstrong isolate 53b
    - Influenza A virus serotype H1N1 strain A/PuertoRico/8/1934
- **Vectors:** (source)
    - Expression plasmids (CDC Division of Vector-Borne Diseases, NIH/NIAID)
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - sfRNA production mechanisms (West Nile virus, Zika virus, Dengue virus)
    - fluorescent marker (*A. victoria*)
    - putative interferon inhibitor (LaCrosse virus)
    - glycoprotein (LaCrosse virus)
    - phospholipidase D2 inhibitor (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (production cell lines: – non-human primate; established cell lines – hamster; primary cell lines: – mouse, human); insect (production cell lines); bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI is using West Nile virus and Influenza A, 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 West Nile virus.
- **Notes:** PI will be producing, purifying and concentrating virus in the laboratory.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** subcutaneous, intraperitoneal, intracranial (VEEV TC-83 only), and intranasal– Influenza, LCMV, West Nile virus, Dengue virus, Zika virus, Venezuelan equine encephalitis virus, LaCrosse virus
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Manipulation of pathogen stocks and cultures and of human and non-human primate materials when procedures involve the generation of aerosols and splashes

        - BSL2 ENHANCED – Manipulation of virus isolates performed under enhanced containment, within additional PPE (gown, gloves, eye protection, head cover, surgical mask, and show covers) and a supervised training and observation period prior to independent work.
        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Inoculation of agent in BSC followed by ABSL2 housing
        - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, and eye protection
- **Training:** 2 individuals require NIH training
- **2025-26 Lab Survey Results:** 10 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: Kosuke Izumi

- **Title:** Molecular analysis of Pallister-Killian syndrome and related disorders
- **Note:** Renewal
- **NIH Guideline Section(s):** III-E and III-F-8
- **Project Summary:**
    - Expression of genes and chromosomal fragments in cell lines.
    - Use of Epstein-Barr virus to immortalize human lymphoblasts.
- **Pathogen not genetically modified: Risk Group 2**
    - Epstein-Barr virus
- **Vectors:**
    - Mammalian expression plasmids
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - centromeric sequences (human)
    - RNA-binding protein (bacteriophage)
    - chromosome segregation protein (human)
    - fluorescent marker (*A. victoria*)
    - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines, primary human cell lines); bacteria (*E. coli* K12)
- **Notes:** Use of ready-to-use 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 and of human materials 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:** 9 deficiencies found, all corrected

Summary:
- Epstein-Barr virus is used to immortalize cells.
- Pending minor updates.
- 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: Deepak Nijhawan

- **Title:** Genetic modification of cell lines using viral vectors and CRISPR
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1 and III-F-8
- **Project Summary:**
    - Use biochemistry and forward genetics to discover protein targets for small molecules with anti-cancer activity.
    - Express or knock out proteins of interest.
- **Vectors:**
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
        - Justification for 2nd generation system: 2nd generation packaging plasmid for producing viral particles. psPAX2 contains a robust CAG promoter for efficient expression of packaging proteins. Requires tat for efficient transcription (tat-dependent LTRs). Fewer plasmids is equal to simpler transfection process.
    - Replication incompetent, ecotropic Retrovirus
    - Mammalian expression plasmids
    - Standard cloning plasmid
    - Bacterial expression plasmid
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - tumor suppressors (human)
    - ribosomal protein (human, mouse)
    - ATPase (human)
    - transcriptional coactivator (mouse)
    - E3 ubiquitin ligase (*Arabidopsis*)
    - fluorescent markers (*A. victoria, Zoanthus* sp., *Discosoma* sp.)
    - endonuclease (*S. pyogenes*)
    - reporters (*P. pyralis, O. gracilirostris*)
    - recombinase (P1 bacteriophage)

- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established mouse and human cell lines; primary mouse cell lines); bacteria (*E. coli* K12, BL21)
- **Notes:** Production, purification, and concentration of lentivirus and retrovirus.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
    - Subcutaneous – xenograft of transduced cells
    - Subcutaneous, intravenous (tail vein) – xenograft of non-modified established cell lines
    - Intravenous (tail vein) – allograft of transduced 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 cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Xenograft – Inoculation of agent in a BSC followed by ABSL1 housing
        - 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:** 1 deficiency found, all corrected

Summary:
- Pending update to add additional route of administration.
- 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: William Prinz

- **Title:** Organelle biogenesis and intracellular lipid homeostasis
- **Note:** Amendment for in vivo use of AAV and LV.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
    - Use of adeno-associated virus and lentiviral vectors in vivo to investigate organelle biosynthesis and intracellular homeostasis.
- **Vectors:**
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
        - Justification: Standard and easy method, used in the past in the lab. We want to maintain consistent yield (quantity and quality) from what we did in the past years.

    - Replication incompetent Adeno-associated virus
    - CRISPR/*cas9*
- **Transgenes:** function (source)
    - lipid trafficking (human)
    - o-mannosyl transferase (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines)
- **Notes:** Production, purification, and concentration of Lentivirus. Use of ready-to-use AAV stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** IV – AAV, LV
- **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
        - PPE – Disposable gown, gloves, safety glasses, surgical mask what is need for the facility, plus eye protection if inoculation will be done within the ARC
- **Training:** All individuals have required training
- **2024-25 Lab Survey Results:** 6 deficiencies found, 2 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: Connie Hsia

- **Title:** Signals for Post-Pneumonectomy Compensatory Lung Growth
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
    - Investigation of mechanisms regulating compensatory lung growth, tissue remodeling, and repair following pneumonectomy and lung injury.
    - Use of recombinant gene plasmid-based gene delivery in vivo to evaluate strategies for enhanced lung repair and protection.
- **Vectors:**
    - Mammalian expression plasmids
- **Transgenes:** function (source)

    - erythropoietin growth factor (human, canine)
    - erythropoietin receptor (human, canine, mouse)
    - keratinocyte growth factor (human)
    - keratinocyte receptor (human)
    - fibroblast receptor (mouse)
    - growth factor (human)
    - Klotho cDNA, transmembrane protein (human, mouse)
    - fluorescent reporter *(A. victoria)*
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (rat, mouse); bacteria (*E. coli*: DH5a)
- **Animal Model:** Mouse, Rat
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
    - Inhalation, Subcutaneous, Intravenous – loaded nanoparticles
- **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:
        - Inhalation, Intravenous, Subcutaneous – Inoculation of agent in approved area followed by ABSL1 housing
        - PPE – Laboratory coat, gloves, surgical mask, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 10 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: Benjamin Drapkin

- **Title:** Identifying therapeutic vulnerabilities in small cell neuroendocrine cancer
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3 and III-F
- **Project Summary:**
    - Genetic modification of human lung cancer cells using replication-incompetent lentiviral vectors to identify genes and pathways that drive drug resistance and metastasis.
    - Development of patient-derived xenograft (PDX) models of lung cancer, including small cell lung cancer (SCLC), in immunodeficient NSG mice to evaluate drug responses and tumor progression in vivo.
    - Generate new lung cancer cell lines and establish additional patient-derived xenograft models for translational cancer research.
- **Vectors:** (source)

    - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
    - Standard cloning plasmids
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - Fluorescent marker (*Discosoma sp.*)
    - Fluorescent markers (*A. victoria*)
    - Proto-oncogenes (*human*)
    - Immune regulator (Human)
    - Transcription factors (Human)
    - Tumor Suppressor (Human)
    - Cell cycle regulators (Human)
    - Oncogenes (Human)
    - Transcription factor (*E. coli*)
    - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** PI indicates that alteration of genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; primary human cell lines); bacteria (*E. coli* K12)
- **Notes:** PI will be using ready to use Lentivirus stocks as well as producing, purifying and concentrating Lentivirus in the laboratory.
- **Human materials:**
    - PDX, Blood
- **Animal Model:** Mouse
- **Route(s) of Administration:** subcutaneous implant/injection, intrapulmonary, intracardiac, intracranial injection – PDX
- **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 implant/injection, intrapulmonary, intracardiac – Inoculation of agent in a BSC followed by ABSL1 housing
        - Intracranial injection – Inoculation of agent in approved area followed by ABSL1 housing
        - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks
- **Training:** 3 individuals require training
- **2024-25 Lab Survey Results:** 6 deficiencies found, 1 overdue

Summary:
- Use of a 3rd generation Lentiviral vector system to modify oncogenes and tumor suppressors
- Non-fixed cells will be imaged using a PI-owned microscope
- No other safety concerns

In favor: All
Opposed: None
Abstained: None

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

Recombinant DNA Registration for IBC review and authorization.

PI: Mala Mahendroo

- **Title:** Molecular Mechanisms of Parturition
- **Note:** Amendment for the addition of work with Lentiviral vector
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
    - Use of replication-incompetent lentiviral vectors to achieve stable gene delivery and genetic modification of human cervical cell lines and primary mouse and human cervical organoids.
    - Study gene function and regulation in cervical epithelial models through long-term expression of introduced genes.
    - Use *E. coli* K12 for plasmid cloning, amplification, construct verification, and preparation of lentiviral transfer vectors.
- **Vectors:** (source)
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
        - Justification: A second-generation lentiviral packaging system is used for the following reasons: 1. Established compatibility with the plasmid system in use: The packaging plasmid psPAX2 (Addgene #12260) is a widely validated second-generation construct. It has been extensively characterized in the literature and is the most used packaging plasmid for basic research applications. 2. Sufficient biosafety for in vitro use: All lentiviral work in this project is conducted exclusively in vitro. No animals are directly inoculated with viral vectors. The primary biosafety concern driving the development of third-generation systems, reduced RCL risk for in vivo and clinical applications, is not the limiting factor in this experimental context. The second-generation SIN design, combined with VSV-G pseudotyping on a separate plasmid, provides adequate biosafety for in vitro cell line and organoid transduction under BSL-2 containment.
- **Transgenes:** function (source)
    - ETS transcription factor (mouse)
    - Fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (human packaging cell lines; established human cell lines; primary human and murine 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:** All individuals have required training
- **2024-25 Lab Survey Results:** 10 deficiencies found, all corrected

Summary:
- Amendment to add production and in vitro use of 2nd generation Lentiviral vectors
- The lab provided detailed SOPs.
- No safety concerns

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

Recombinant pathogen Registration for IBC review and authorization, notification.

PI: Michael Shiloh

- **Title:** Pathogenesis and persistence of *Mycobacterial* Infections
- **Note:** Amendment to add *M. tuberculosis* strains
- **NIH Guideline Section(s):** N/A
- **Project Summary:**
  - Addition of Mtb clinical isolates to study mechanisms of virulence, persistence, and transmission in guinea pig models.
- **Pathogen not genetically modified: Risk Group 3**
  - *Mycobacterium tuberculosis* strains L1-L7, L4.2, L2, clinical stains
- **Note:** New strains are mono-drug resistant
- **Animal Model:** Guinea Pig
- **Route(s) of Administration:**
  - Aerosol, Intranasal, IV– *M. tuberculosis*
- **Required Training, Procedures, and Containment:**
  - In-vitro and in-vivo Procedures: BSL3 agents
    - Strict Adherence to the current JA4 ABSL3 SOP Manual.
    - No viable agent(s) can leave the ABSL3 facility without the approval of Safety.
    - ABSL-3 containment: Manipulation of Risk Group 3 agents
    - Fluids: As authorized by the IBC in 2012; culture liquids known or suspected to contain TB and destined to be removed from and utilized outside the JA4 ABSL-3 facility must undergo double filtration through a 0.2um syringe filter. Once double filtered, the liquids may be removed from the JA4 ABSL-3 facility.
    - PPE: Tyvek Coverall, double gloves, self-contained Battery powdered HEPA-filtered Air Purifying Respirator (PAPR)
    - **Disinfection:**
      - Vesphene IIse 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
    - Glas-Col unit must be used as described in the SOP
    - Bioruptor water bath sonicators must be used as described in the SOP
    - Biotek plate reader must be used as described in the SOP
    - Facility must be surveyed on a semi-annual basis

- **Medical Surveillance:** All PIs, Project Staff, and ARC Personnel working in the JA4 ABSL-3 facility must enroll in the Worker Protection Program and the Tuberculosis Surveillance Program administered by Occupational Health. Access to the ABSL-3 laboratory will be revoked for anyone who does not comply with these monitoring programs.

- **Training:** 3 individuals require NIH 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: Elisabeth Martinez

- **Title:** Effects of Epigenetic Drugs on Cells
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-4, III-E and III-F-8
- **Project Summary:**
  - Ultimate goal is to understand the involvement of epigenetic enzymes in cancers.
  - Cell lines are modified to express epigenetic enzymes.
  - Adenovirus-Cre is used to induce tumor formation in mice.
  - Storage only of materials for currently inactive project.
- **Storage only of pathogen previously genetically modified: Risk Group 2**
  - *Plasmodium falciparum*, strains 3D7, Dd2, NF54, Dd2attB, FCR3-CSA, NF54attB
- **Vectors:**
  - Replication incompetent Adenovirus
  - Mammalian expression plasmids
  - Bacterial expression plasmids
- **Transgenes:** function (source)
  - recombinase (P1 bacteriophage)
  - Jumonji histone demethylases (human, mouse)
  - methytransferase (human)
  - cell cycle regulators (human)
  - nuclear receptors (human)
  - DNA damage repair (human)
  - restriction enzymes (*Arthrobacter*, *S. cerevisiase*)
  - fluorescent markers (*A. victoria*)
  - reporter (*Photinus pyralis*)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:**
  - Expression plasmids: Mammalian (established human, mouse, and rat cell lines; primary mouse and rat cell lines); bacteria (*E. coli* K12, BL21)
  - Adenovirus: In vivo only

- **Notes:**
    - Use of ready-to-use adenovirus stocks.
    - Lab also uses non-modified human lung and metastatic lung tumors in vitro and in vivo. Tumors are only collected from HIV and Hepatitis B and C negative individuals.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes **GDMO:** No
- **Route(s) of Administration**:
    - Intranasal, intratracheal – adenovirus
    - Subcutaneous, intrapulmonary – xenograft of non-modified materials (established cell lines and lung tumors)
- **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:
        - Adenovirus – 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
        - PPE –
            - Yellow gown, nitrile gloves, and eye protection
            - Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face mask, and eye protection
            - Laboratory coat, gloves, and eye protection
- **Training:** 2 individuals require NIH training
- **2024-25 Lab Survey Results:** 4 deficiencies found, all corrected

Summary:
- *Plasmodium* is currently in storage only. Amendment would need to be submitted and approved by the IBC prior to any non-storage use.
- 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: Farrukh Awan

- **Title:** A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 Car T-Cell Product Candidate, Versus Investigator's Choice of CD19 Car T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (PINACLE-H2H)
- **Note:** New
- **NIH Guidelines:** III-C
- **Project Summary:**

- A Phase 3 study sponsored by Lyell Immunopharma, Inc. to evaluate the efficacy and safety of investigational product versus commercially available autologous CAR T-cell therapies.

- **Product(s):**
  - Autologous T cells genetically modified ex vivo with replication incompetent lentivirus
- **Transgenes: (source)**
  - Chimeric antigen receptor (human, mouse)
- **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 in this Phase 3 study.
  - 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 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
  - Refer to supplemental documents for more information

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC review and authorization.

PI: Aparajita Dasgupta
Co-PI: Khuloud Jaqaman

- **Title:** Functional links between cell surface receptor interactions and angiogenic signaling
- **Note:** Renewal
- **NIH Guideline Section(s):** III-E and III-F-8
- **Project Summary:**
  - Studies focus on vascular endothelial cell surface receptors that regulate angiogenic signaling.
  - Use transient transfection systems to overexpress proteins of interest in mammalian cells
  - Have a previously transduced cell line that expresses fluorescent reporter protein.

- **In storage only:**
  - Lentiviral plasmids
- **Modified cell line:**
  - Cell line previously genetically modified
- **Vectors:**
  - Expression plasmids
- **Transgenes:** function (source)
  - receptors (human)
  - extracellular matrix (human)
  - tyrosine kinase (human)
  - adhesion proteins (human)
  - endocytosis proteins (human)
  - cytoskeletal protein (human)
  - angiogenesis proteins (human)
  - fluorescent markers (*Discosoma* sp., *L. hemprichii*, *E. quadricolor*, *A. victoria*, *Dendronephytha* sp., *Echinophyllia* sp.)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (established human and hamster cell lines, primary human 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 human materials when procedures involve the generation of aerosols and splashes
    - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** No deficiencies found

Summary:
- Renewal registration with changes:
  - Modification to PI.
  - Removal of use of lentivirus, as lentiviral plasmids are in storage only. An amendment to this permit would need to be submitted and approved by the IBC prior to any lentiviral production or use.
- 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: Elena Hsieh

- **Title:** Dominant-Negative IL2RB Variants Cause a Novel Form of Immune Dysregulation and Combined Immunodeficiency

- **Note:** New PI, Safety met with on 5/20/2026
- **NIH Guideline Section(s):** III-F
- **Project Summary:** Study of the functional consequences of immune receptor variants using plasmid-mediated gene expression in human cell culture models.
- **Vectors:** (source)
    - Standard cloning plasmids (GenScripts)
- **Transgenes:** function (source)
    - fluorescent marker (*A. victoria*)
    - immune regulation (human)
- **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 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
- **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 and resolution of minor pending comments

Biosafety Program Monthly Activity Reports

Other Business

Adjourn Time: 12:43 pm