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

May 26, 2026
Time: 11:30 a.m.
Location: JA05.110 and web conferencing
Dallas Texas, 75390

IBC Minutes

IBC Attendance May 2026

Noelle Williams, Ph.D.	Bruce Brown, Dr. P.H.
Michael Buszczak, Ph.D.	Julia Wilkerson
Jakob Furmaga, M.D.	Jessica Spaniol, J.D.
Don Gammon, Ph.D.	Mark Thompson
Robert Orchard, Ph.D.	Callan Kaut
Ralph Callicott, D.V.M.	Chad Donelson
Danielle Robertson, O.D.	Audrey Kinser
Maria Labandeira-Rey, Ph.D.	
Ryan Lisk, MPH	

Notification to IBC Members and Guests

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

IBC Conflict of Interest Policy reminder

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

Call to Order and Approval of Minutes

Quorum was obtained: A regular meeting of the UT Southwestern IBC was called to order at 11:30 a.m. on May 26, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

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

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

Updated Business:

Project closures per PI request unless otherwise noted.

PI: Kimberly Reynolds

- **Title:** Evolution of metabolic systems

PI: Noelle Williams

- **Title:** Evaluation of novel compounds targeting ribosome biogenesis as cancer therapeutics

PI: Xiaochen Bai

- **Title:** Molecular mechanisms of Receptor Tyrosine Kinase activation from high-resolution cryo-EM structural analysis

New Business:

Reviews

Recombinant DNA Registration for IBC review and authorization.

PI: Emre Turer

- **Title:** Intracellular Bacteria uptake
- **Note:** New
- **NIH Guidelines Section(s):** III-E
- **Project Summary:**
  - Growth and infection of cell lines to visualize intracellular bacteria uptake.
- **Pathogens previously genetically modified: Risk Group 2**
  - *Salmonella enterica* serovar Typhimurium, strain SL1344
  - *Listeria monocytogenes*, strain LS810
- **Transgenes:** function (source)
  - fluorescent marker (*A. victoria*)
- **Host:** Mammalian (established mouse and human cell lines)
- **Zoonotic Potential:** The PI is using *Salmonella enterica* and *Listeria monocytogenes* genetic variants, mutants, and clones that could affect livestock animals which may result in an economic impact according to APHIS. All laboratory personnel must avoid contact with livestock for 5 days following work with active agents.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
  - In-Vitro Procedures:
    - BSL1 – Standard molecular biology procedures
    - BSL2 – Cultivation and manipulation of pathogen stocks and cultures, and human cell lines when procedures involve the production of aerosols and splashes
    - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:

- No safety concerns.

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

Recombinant DNA Registration for IBC review and authorization.

PI: Robert Orchard

- **Title:** Orchard Lab Virus Protocol
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, III-D-3, III-E-1, and III-F-8
- **Project Summary:**
    - Investigation of how specific host (eukaryotic) factors influence viral replication in mammalian cell lines by experimentally infecting cells and measuring viral growth.
    - It uses a combination of engineered and naturally derived viruses, along with genetic manipulation of host cells, to evaluate mechanisms that either promote or restrict viral replication.
    - Application of selective pressure to viruses to study adaptation and emergence of variants capable of overcoming host resistance.
- **Pathogens genetically modified: Risk Group 2**
    - Coxsackievirus B3, strain H3
    - Human Norovirus, strains Norwalk, U201, MD145
    - Murine Norovirus, strains, MNV1, MNV3, WU23, CW3, CR6
    - Influenza A, strain A/PR/8/34
    - Influenza A, strain A/WS/33
    - Influenza B, strain B/Yamagata/88
    - Vesicular stomatitis virus (VSV), serotypes Indiana (*luc*, *gfp*)
    - Vesicular stomatitis virus (VSV), ΔM51R*gfp*
    - Venezuelan equine encephalitis virus, strain TC-83 GFP (subtype IA/B)
    - Sindbis virus, strain SINV-GFP
    - Recovirus, strains Tulane, FT7, FT285, MO/TG30
    - Enterovirus, subspecies D68, strains Fermon, USA/US/MO/14-18947, US/MO/18949, USA/MN/1989-23220, USA/2018-23088, US/IL/14-18956, USA/USA/IL/2018-23252, USA/WI/2009-23230
    - Aichi virus
    - Human Enterovirus, subspecies A-71, strains Tainan/4643/1998, MP4
    - Vaccinia virus, strain Western Reserve
    - Lymphocytic choriomeningitis virus (LCMV), strain r3LCMV-GFP
- **Pathogen not genetically modified: Risk Group 2**
    - Coxsackievirus B3, strain H3
    - Reovirus, strains T3D, T3L
    - Murine Hepatitis virus, strains MHV3-A59, MHV3-JHM
    - Feline Calicivirus, strains Urbana, I-9
    - Porcine Sapovirus, strain Cowden
    - Enterovirus, subspecies D68, strains Fermon, USA/US/MO/14-18947, US/MO/18949, USA/MN/1989-23220, USA/2018-23088, US/IL/14-18956, USA/USA/IL/2018-23252, US/IL/14-18952, USA/WI/2009-23230, USA/2020-23335, USA/2009-23228, USA/2020-23336, USA/2020-23334

    - Human Enterovirus, subspecies A-71, strains Tainan/4643/1998, MP4
    - Human Norovirus, strains Norwalk, U201, MD145
    - Human Norovirus, untyped clinical strains
    - Murine Norovirus, strains, MNV1, MNV3, WU23, CW3, CR3, CR6, CR7, S99
    - Vesicular stomatitis virus (VSV), serotype Indiana
    - Recovirus, strains Tulane, FT7, FT285, MO/TG30
    - Human Sapovirus, strain GII.3-AK11
    - Human Sapovirus, untyped clinical strains
    - Vaccinia virus, strain Western Reserve
    - Venezuelan equine encephalitis virus, strain TC-83
    - Chikungunya virus, strain 181/25
    - Sindbis virus, strains 80-2449, EgAr 339
    - Aichi virus
    - Lymphocytic choriomeningitis virus (LCMV), strains Armstrong, Clone 13
    - Human Parechovirus A Type 2, strain Williamson
    - Simian Rotavirus, strain SA11
- **Vectors:** (source)
    - Mammalian expression plasmids
    - Bacterial expression plasmids
    - Standard cloning plasmids
- **Transgenes:** function (source)
    - Complete viral genomes to generate viable virus upon transfection
    - Capsid (Murine norovirus, EV-D68)
    - RNA replication (Murine norovirus)
    - Proteases, polymerases, non-structural proteins (Murine norovirus)
    - Protease (Human Norovirus)
    - GP33, marker (LCMV, chicken)
    - Reporters (*B. lanceolatum, O. gracilirostris, A. victoria, S. pyogenes*)
    - Ligases (human)
    - Recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human, mouse, pig, non-human primate; established cell lines: human, mouse, pig, non-human primate, canine; primary cell lines – human); bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI is using VSV, a zoonotic virus that affects livestock animals which may result in an economic impact according to APHIS. All laboratory personnel must avoid contact with livestock for 5 days following work with active VSV.
- **Notes:** Production, purification, and concentration of virus.
- **Animal Model:** Mouse
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks, cultures and human cell lines when procedures involve the generation of aerosols and splashes

        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Oral gavage – Inoculation of agent followed by ABSL2 housing
        - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** No deficiencies found

Summary:
- As part of this renewal, the lab has added an attenuated Vesicular stomatitis virus (VSV) mutant
- The IBC will be notified of any Murine norovirus mutations that result in the overcoming of host restrictions.

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations**. These include:** IBC must be notified of any mutants with enhanced properties

Recombinant DNA Registration for IBC review and authorization.

PI: Tiffany Reese

- **Title:** Autophagy a Novel Antiviral Host Defense Pathway
- **Note:** Renewal with the additional in vitro Lentiviral vector work
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
    - This project examines how the host autophagy pathway influences infection by herpes simplex and Sindbis viruses, including how viral strains counteract this defense mechanism to enhance neurovirulence.
    - It uses viral vector systems and engineered cell lines to manipulate gene expression and evaluate the role of specific host factors in infection outcomes.
    - A central approach is generating and modifying cells (via CRISPR and viral transduction) to assess how loss or alteration of host genes impacts viral replication and host–virus interactions.
- **Pathogen previously genetically modified: Risk Group 2**
    - Sindbis virus, strain SVIA
- **Pathogen not genetically modified: Risk Group 2**
    - Herpes simplex virus 1, strain 17
    - Sindbis virus, strain SVIA
- **Vectors:** (source)
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
    - Amphotropic Baculovirus
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - Autophagy regulation protein (human)
    - Protein enabling kinases (human)
    - Protein enabling GTPase binding (human)
    - RNA binding (human)
    - Fluorescent markers (*Discosoma sp., A. victoria*)

    - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human, non-human primate, canine; established cell lines); insect established cell lines; bacteria (*E. coli* K12)
- **Notes:**
    - Production and purification, and concentration of HSV-1 and Sindbis virus.
    - Baculovirus and Lentivirus will be produced and purified but not concentrated.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
    - Non-stereotaxic intracranial, intraperitoneal – HSV-1
    - Non-stereotaxic intracranial – Sindbis virus
- **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:
        - Non-stereotaxic intracranial, Intraperitoneal – Inoculation of agent followed by ABSL2 housing
        - PPE – Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 12 deficiencies found, all corrected

Summary:
- Lentiviral CRISPR materials have been added to the renewal to target a new gene. Lentivirus will not be concentrated.
- No safety concerns

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

Pathogen Registration for IBC review and authorization.

PI: Lenette Lu

- **Title:** Immune response to *Mycobacterium tuberculosis*
- **Note:** Amendment for the addition of in vivo work with a previously approved pathogen.
- **Pathogens: Risk Group 2**
    - *Mycobacterium bovis*, strain Bacille Calmette Guerin
- **Project Summary:**
    - This project aims to define how antibodies shape the immune response to *Mycobacterium tuberculosis* and related species by evaluating their effects within innate and adaptive immune systems.

- **Zoonotic Potential:** The PI is using *Mycobacterium bovis* BCG that could affect livestock animals which may result in an economic impact according to APHIS. All laboratory personnel must avoid contact with livestock for 5 days following work with active agents.
- **Animal Model:** Mouse
- **Routes of Administration:** Subcutaneous – *Mycobacterium bovis* BCG
- **Required Training, Procedures, and Containment:**
    - In-Vivo Procedures:
        - Subcutaneous – *Mycobacterium bovis* BCG – Inoculation of agent followed by ABSL3 housing
        - PPE – Tyvek suit, shoe covers, PAPR, double gloves
- **Training:** All individuals have required training
- **2025-26 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: Robert Tower

- **Title:** Metabolism of Heterotopic Ossification, Digit Tip Amputation, Mechanisms of Fracture Repair, The Role of Sensory Nerves in Bone Formation
- **Note:** Amendment for the in vivo use of AAV and personnel updates.
- **NIH Guideline Section(s):** III-D-4, and III-F
- **Project Summary:**
    - Use of animal models and AAV to examine the role of sensory nerve innervation in growth plate development and long bone formation.
- **Vectors:** (source)
    - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
    - fluorescent marker (*Discosoma sp*.)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell line)
- **Notes:** PI will be using ready to use stocks.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Periarticular injection – AAV
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required

- In-Vivo Procedures:
  - Periarticular injection – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
  - PPE – Yellow gown, nitrile gloves, safety glasses
- **Training:** 2 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 required training.

Recombinant DNA Registration for IBC review and authorization.

PI: Vivian Lee-Kim

- **Title:** Genetic determinants of cardiovascular development and disease
- **Note:** Amendment for addition of new lab members and adeno-associated virus for delivery to mice.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
  - Use of AAV for in vivo gene overexpression to assess effects on cellular function.

  Vectors: (source)
  - Replication incompetent Adeno-associated virus
- **Transgenes:** function (source)
  - adaptor protein (human)
  - transcription factor (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** In vivo only - mouse
- **Notes:** Use of ready-to-use AAV.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** IV – AAV
- **Required Training, Procedures, and Containment:**
  - In-Vitro Procedures:
    - BSL1 – Standard molecular biology procedures
    - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
    - PPE – Laboratory coat, gloves, and eye protection are required
  - In-Vivo Procedures:
    - IV – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
    - PPE – Lab coat, nitrile gloves, goggles, surgical mask
- **Training:** 3 individuals require NIH training
- **2025-26 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:

- No safety concerns.

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

Recombinant DNA Registration for IBC review and authorization.

PI: Don Gammon

- **Title:** Virus-Host Interactions: Identification of Host Antiviral Factors and Viral Immunomodulators
- **Note:** Amendment for pathogen addition
- **NIH Guideline Section(s):** III-D-3
- **Project Summary:**
  - Addition of Simian rotavirus wild-type and two previously genetically modified recombinant strains: strain with fluorescent marker and strain with deletion of non-structural protein.
- **Pathogen from collaborator: Risk Group 2**
  - Simian rotavirus, strain SA11
- **Transgenes:** function (source)
  - non-structural protein (Simian Rotavirus)
  - fluorescent marker (synthetic)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human, non-human primate, and mouse cell lines)
- **Notes:** Production, purification, and concentration of virus.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
  - In-Vitro Procedures:
    - BSL1 – Standard molecular biology procedures
    - BSL2 – Biosafety cabinet use during manipulation of pathogen stocks and cultures and human and non-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:** 8 deficiencies found, all corrected

Summary:

- Amendment is for addition of simian rotavirus, which is species restricted.
- No safety concerns.

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

Recombinant DNA Registration for IBC review and authorization.

PI: Kathyrn O'Donnell-Mendell

- **Title:** Identification and characterization of genes that promote tumorigenesis
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-2, III-D-3, III-D-4, III-E and III-F
- **Project Summary:**
    - Use of transposon-based mutagenesis screens and viral vector systems in vitro and in vivo to identify genes involved in cancer initiation, progression and metastasis and to characterize the gene function.
- **Vectors:** (source)
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
    - Replication incompetent, 3rd generation Lentivirus
    - Replication incompetent Retrovirus
    - Replication incompetent Adenovirus
    - Bacterial expression plasmids
    - Mammalian expression plasmids
    - Standard cloning plasmid
    - CRISPR/*cas9* system
- **Transgenes:** function (source)
    - membrane protein (human)
    - nuclear receptor coactivator (human, mouse)
    - transposon (mouse)
    - retrotransposon (human, mouse)
    - recombinase (P1 bacteriophage)
    - nuclear receptor (human, mouse)
    - protease (human, mouse)
- **Oncogenes/Tumor suppressor:** PI indicates that alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines); bacteria (*E. coli* K12)
- **Notes:** PI will be producing, purifying and concentrating lentivirus and retrovirus in the laboratory. PI will be using ready-to-use adenovirus stocks.
- **Animal Model:** Mouse
- **Transgenic animals: Yes Generated at UTSW: No GDMO: No**
- **Route(s) of Administration:** Subcutaneous – modified cell lines; Intratracheal, Intranasal – adenovirus, 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
    - In-Vivo Procedures:
        - Intratracheal, Intranasal – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing

        - Subcutaneous – Inoculation of modified cell lines in a BSC followed by ABSL1 housing
        - PPE – ARC facility: Double nitrile gloves, hair bonnet, shoe covers, face masks, disposable white tie-back gown, eye protection
        - PPE – ARC facility: Hair bonnet, disposable jumpsuit, nitrile gloves, shoe covers, face masks, eye protection
- **Training:** 6 individuals require NIH training
- **2025-2026 Lab Survey Results:** 6 deficiencies found, all corrected

Summary:
- Recommendation for use of 3rd generation lentiviral system for in vivo work involving oncogenes.
- No other safety concerns.

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

Recombinant DNA Registration for IBC review and authorization.

PI: Jay Horton
Co-PI: Guosheng Liang

- **Title:** Molecular Basis of Cholesterol Metabolism
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E-1 and III-F-8
- **Project Summary:**
    - The goal of this project is to study the regulation of cholesterol and fatty acid metabolism and determine how changes in this regulation affect cellular function and whole-body cholesterol, fat, and glucose metabolism.
    - Overexpression of genes from the cholesterol synthesis, fatty acid synthesis, and related metabolic pathways.
- **Vectors:** (source)
    - Replication incompetent Adenovirus
    - Replication incompetent Adeno-associated Virus
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
    - Replication competent ecotropic Baculovirus
    - CRIPSR/Cas9 system
- **Transgenes:** function (source)
    - cholesterol and fatty acid synthesis gene transcription (mouse)
    - fatty acid synthesis (mouse)
    - fatty acid biosynthesis (mouse)
    - lipid metabolic process (mouse)
    - serine/threonine kinase (mouse)
    - regulation of cholesterol and fatty acid synthesis (mouse)
    - lipid metabolic process (mouse)
    - fatty acid biosynthetic process (mouse)
    - cardiolipin biosynthetic process (mouse)
    - phospholipid biosynthetic process (mouse)

    - cholesterol synthesis (mouse)
    - triglyceride and phospholipid metabolism (mouse)
    - autophagy, lysophagy, and cell metabolism protein (mouse)
    - fluorescent markers (*Discosoma* sp*., A. victoria*)
    - recombinase (P1 bacteriophage)
    - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human cell lines; primary murine cell lines); insect (established cell lines); bacteria (*E. coli* K12)
- **Notes:**
    - Viral production:
        - Production, purification, and concentration of adenovirus.
        - Production and concentration of AAV.
        - Production of lentivirus and baculovirus.
    - Use of ready-to-use AAV.
- **Animal Model:** Mouse, Rat
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:** Tail vein, retro-orbital – AAV, adenovirus
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
        - PPE –
            - ARC: Yellow gown, nitrile gloves, and eye protection
            - Non-ARC: Laboratory coat, gloves, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 9 deficiencies found, all corrected

Summary:
- Updates to renewal include addition of baculovirus, on which minor clarifications are needed.
- 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: Josephine Thinwa

- **Title:** Modulation of autophagy regulators in viral pathogenesis
- **Note:** New
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8

- **Project Summary:**
    - The overall goal is to identify key regulators of autophagy and determine how altering this pathway affects viral replication and host defense mechanisms.
    - It relies on recombinant DNA and viral delivery systems to express and modify host genes in cell lines and primary neurons to evaluate their role in infection outcomes.
- **Vectors:** (source)
    - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
    - Replication incompetent Retrovirus
    - Mammalian expression plasmids
- **Transgenes:** function (source)
    - Autophagy receptors (human)
    - Neurodevelopmental kinase (human)
    - Transcription factors (human)
    - Fluorescent markers and reporters (*Discosoma sp. A. victoria, B. lanceolatum*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines: human; established cell lines: human; primary cell lines: mouse); bacteria (*E. coli* K12)
- **Notes:** Production and purification of Lentivirus and Retrovirus.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 2 individuals require NIH training
- **2025-26 Lab Survey Results:** 11 deficiencies found, all corrected

Summary:
- The lab is currently using a 2nd generation Lentiviral system but is seeking to transition to 3rd generation Lentiviral vector systems.
- No safety concerns.

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations**. These include:** Completion of required training.

Recombinant DNA Registration for IBC review and authorization.

PI: Josephine Thinwa

- **Title:** Autophagy a novel antiviral host defense pathway
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-1, III-D-2, and III-F
- **Project Summary:**
    - Study of neuronal response mechanisms focusing on autophagy-mediated viral protein clearance, neuroinflammation, and neuronal survival during Sindbis infection in vitro and in vivo.

- **Pathogen genetically modified by collaborator: Risk Group 2**
    - Sindbis virus, tagged with HA, mCherry and gfp
- **Pathogen not genetically modified: Risk Group 2**
    - Sindbis virus, strain AR339
- **Vectors:** (source)
    - Bacterial expression plasmids
- **Transgenes:** function (source)
    - fluorescent markers (*Discosoma sp., A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines: non-human primate, hamster); bacteria (*E. coli* K12)
- **Animal Model:** Mouse
- **Route(s) of Administration:** Intracranial – Sindbis
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of viral vectors when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
    - In-Vivo Procedures:
        - Intracranial – Inoculation of agent followed by ABSL2 housing
        - PPE – Gown, gloves, glasses
- **Training:** 4 individuals require NIH training
- **2025-26 Lab Survey Results:** 11 deficiencies found, all corrected

Summary:
- Recommendation for use of 3rd generation lentiviral system for in vivo work involving oncogenes.
- No other safety concerns.

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

Recombinant DNA Registration for IBC review and authorization.

PI: Ayaz Najafov

- **Title:** Role of necroptosis and its mediators in anti-tumor immunity, tumorigenesis, systemic inflammatory response syndrome, and tissue necrosis.
- **Note:** Amendment for addition of CRISPR technology
- **NIH Guideline Section(s):** III-D-3, III-E and III-F-8
- **Project Summary:**
    - This project evaluates the role of necroptosis-related genes in tumor development by comparing tumor growth in mouse xenograft models with targeted gene knockouts.
    - It uses gene editing and lentiviral approaches to generate modified cell lines and primary cells to assess how disruption of necroptosis pathways influences tumor progression.
- **Vectors:** (source)

    - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
- **Transgenes:** function (source)
    - Kinases (human)
    - Cell adhesion (human)
    - CRISPR/*cas9* system
- **Oncogenes/Tumor suppressor:** None.
- **Toxic Genes:** None.
- **Host:** Mammalian (packaging cell lines: human; established cell lines: human; canine); bacteria (*E. coli* K12)
    - Production and 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 for the addition of CRISPR materials
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Heidi Jacobe

- **Title:** A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc)
- **Note:** New
- **NIH Guidelines:** III-C
- **Project Summary:**
    - A Phase III study sponsored by Juno Therapeutics Inc/ to evaluate the safety and efficacy of CD-19 targeted CAR T-cell therapy compared to standard of care in individuals with active systemic sclerosis.
- **Product(s):**
    - Autologous T cells genetically modified ex vivo
- **Vectors: (source)**
    - Replication incompetent Lentivirus third-generation, replication-incompetent, self-inactivating (SIN) lentiviral vector
- **Transgenes: (source)**
    - Chimeric antigen receptor (mouse, human)

- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - No occurrences of serious adverse events have been reported:
    - Sponsor has provided safety information:
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)
        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Samuel John
Co-PI: Tracey Wright

- **Title:** FT819-201, A Phase 2, Open-Label, Single-Arm Trial of FT819 in Participants With Refractory Moderate-to-Severe Systemic Lupus Erythematosus with Lupus Nephritis
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** Fate Therapeutics, Inc.
- **Project Summary:**
    - A phase 2 trial sponsored by Fate Therapeutics, Inc. to evaluate the efficacy and safety of investigational product in participants with Systemic Lupus Erythematosus.
- **Product(s):**
    - Allogenic T cells genetically modified ex vivo.
- **Vectors:**
    - CRISPR RNA
    - Replication incompetent adeno-associated virus
    - Reprogramming vector backbone

- **Transgenes:**
    - Chimeric antigen receptor
    - Cell reprogramming factors
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - In a Phase I study with this investigational product, treatment-emergent adverse events were reported.
    - Sponsor has provided safety information.
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)
        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - Other: Strict adherence to Children's Medical Center SOPs

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Justin Grodin

- **Title:** A Phase 1b Pilot Trial Evaluating the Safety and Pharmacodynamic Effects of SRD-001 (AAV1-SERCA2a) in Subjects with Heart Failure with Preserved Ejection Fraction
- **Note:** Renewal with change to investigational product dose.
- **NIH Guidelines:** III-C
- **Project Summary:**
    - A Phase 1b study sponsored by Sardocor Corp. evaluating the safety and pharmacodynamic effects of investigational product in subjects with heart failure with preserved ejection fraction.
- **Product(s):**
    - Replication incompetent Adeno-associated Virus
- **Transgenes: (source)**

    - sarcoendoplasmic reticulum calcium transport ATPase isoform (human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - No occurrences of serious adverse events have been reported during the renewal period.
    - Sponsor has provided safety information.
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)
        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - BSL2 – Manipulation of agent in the Pharmacy
        - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Larry Anderson

- **Title:** Phase 1b Dose Expansion Study of NXC-201 for the Treatment of Patients with Relapsed or Refractory AL Amyloidosis
- **Note:** Annual Administrative Renewal – No procedural or personnel changes were noted.
- **NIH Guidelines:** III-C
- **Sponsor:** Nexcella, Inc.
- **Project Summary:**
    - Al phase 1b dose expansion study sponsored by Nexcella exploring the safety and efficacy of NXC-201 in a population of relapsed or refractory AL amyloidosis (AL).
- **Product(s):**
    - Autologous T cells genetically modified ex vivo with replication incompetent retrovirus

for the expression of chimeric antigen receptor recognizing BCMA.

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

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: David Nelson

- **Title:** A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)
- **Note:** Annual Administrative Renewal – No procedural or personnel changes were noted.
- **NIH Guidelines:** III-C

- **Project Summary:**
    - A Phase 3 Randomized Double-blind Study sponsored by Merck Sharp & Dohme to safety and efficacy study to evaluate the addition of V940 to adjuvant pembrolizumab in participants with resectable Stages II-IIIB(N2) NSCLC who did not achieve a pCR after neoadjuvant pembrolizumab with platinum-doublet chemotherapy followed by surgery.
- **Product(s):**
    - Single mRNA encoding up to 34 neoantigens designed to each individual's patient tumor mutanome and HLA type formulated in lipid nanoparticles.
- **Transgenes: (source)**
    - Single mRNA encoding up to 34 neoantigens designed to each individual's patient tumor mutanome and HLA type.
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - No occurrences of serious adverse events have been reported during the renewal period.
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
    - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of a Biosafety Cabinet (BSC), sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.
- **Research Applications:**
    - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as 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:
        - BSL2 – Manipulation of agent in the Pharmacy
        - Other: UTSW Approved SOP for gene transfer project must be followed

Summary: No safety concerns
In favor: All
Opposed: None

Abstained: None
Status: Approved

Recombinant DNA Registration for IBC Review and Authorization.

PI: Susan Iannaccone
Co-PI: Kaitlin Batley

- **Title:** A Phase 3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD)
- **Note:** Annual Administrative Renewal
- **NIH Guidelines:** III-C
- **Project Summary:**
    - A multicenter, phase I/II/III, open-label study sponsored by RegenXBio to evaluate the safety, tolerability, and clinical efficacy of adeno-associated virus (AAV) for the expression of microdystrophin in pediatric subjects with DMD. This part of the overall study is the 2-part phase III study.
- **Product(s):**
    - Replication incompetent adeno-associated virus for the expression of microdystrophin
- **Vectors: (source)**
    - Replication incompetent Adeno-associated virus
- **Transgenes: (source)**
    - cytoskeletal protein
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - No occurrences of serious adverse events have been reported.
    - Sponsor has provided safety information:
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)
        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - BSL2 – Manipulation of agent in the Pharmacy

- Other: Approved SOP must be followed

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Larry Anderson

- **Title:** A Phase 1, Multicenter, Open-Label Study of CC-95266 in Subjects with Relapsed and/or Refractory Multiple Myeloma
- **Note:** Renewal
- **NIH Guidelines:** III-C
- **Sponsor:** Juno Therapeutics Inc., a subsidiary of Celegene Corp.
- **Project Summary:**
  - A Phase 1 study sponsored by Juno Therapeutics Inc. to study investigational product in recipients with 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 consultation with Occupational Health is advised for health care workers.
  - No occurrences of serious adverse events have been reported during the renewal period.
  - Sponsor has provided safety information.
  - All health care workers involved in this protocol should observe universal precautions.
  - No special precautions are required for roommates or family members.
- **Research Applications:**
  - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
  - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
  - Minimum Training requirements:
    - Sponsor Training (if applicable)
    - Bloodborne Pathogen Training for individuals listed on the registration
    - IATA Training for individuals shipping infectious samples
    - NIH Guidelines Training for PI
    - PI mediated intra-laboratory training
  - Procedures:
    - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Notification only.

PI: Berge Minassian
Co-PI: Mayank Verma

- **Title:** A Phase 1/2 Open Label Study to Evaluate the Safety and Efficacy of Intrathecally Administered ION283 in Patients with Lafora Disease
- **Note:** Annual Administrative Renewal
- **NIH Guidelines:** III-F-1
- **Project Summary:**
    - First-in-human study to investigate the safety and efficacy of anti-sense oligonucleotide for the treatment of LD.
- **Product(s) Trade Name:**
    - Anti-sense oligonucleotide binding to GYS1 pre-mRNA for recruitment of RNase H1 and degradation of transcript to reduce synthesis of GYS1 protein.
- **Product(s):**
    - Anti-sense oligonucleotide (ASO): Synthetic 20-mer
- **Targeted pre-mRNA:**
    - GYS1, glycogen synthase isoform expressed in the brain and all other organs except the liver
- **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.
    - There have been no new occurrences of serious adverse events in the renewal period.
    - Sponsor has provided safety information.
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as 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:
        - BSL2 – Manipulation of agent in the Pharmacy
        - Other: Children's Health Medical Center approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Notification.

PI: Thomas Kerr

- **Title:** A Dose-Finding, Double-Blind, Placebo-Controlled Phase 2 Study to Evaluate the Efficacy and Safety of GSK4532990 for Steatohepatitis in Adults with Alcohol-related Liver Disease (ALD)
- **Note:** Renewal
- **NIH Guidelines:** III-F-1
- **Project Summary:**
    - A Phase 2 study sponsored by GlaxoSmithKline Research & Development Limited, Inc. to investigate the safety and efficacy of investigational product in adult participants with alcohol-related liver disease.
- **Product(s):**
    - Small interfering RNA interference (siRNA)-based therapeutic composed of synthetic double-stranded siRNA less than 100-mers in length.
- **Transgenes: (source)**
    - Targets hydroxysteroid dehydrogenase mRNA
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
    - A consultation with Occupational Health is advised for health care workers.
    - No occurrences of serious adverse events have been reported during the renewal period.
    - Sponsor has provided safety information.
    - All health care workers involved in this protocol should observe universal precautions.
    - No special precautions are required for roommates or family members.
- **Research Applications:**
    - Biosafety Level 2, (BSL-2) containment, equipment, and practices for all work involving the manipulation of the listed materials at the study location. Manipulation of investigational drug must occur under a certified BSC. All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)

        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - BSL2 – Manipulation of agent in the Pharmacy
        - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

In favor: All
Opposed: None
Abstained: None
Status: Notification only

Recombinant DNA Registration for IBC review and authorization.

PI: Youxing Jiang

- **Title:** Eukaryotic Membrane Protein Structure and Function
- **Note:** Renewal, no major changes
- **NIH Guideline Section(s):** III-D-3, III-E, and III-F-8
- **Project Summary:**
    - This project focuses on expressing and purifying eukaryotic membrane proteins in host cell systems to determine their structure and function using recombinant DNA approaches.
    - It aims to define how organelles interact at a structural level by reconstituting and studying protein complexes involved in mitochondria–ER tethering.
- **Vectors:** (source)
    - Amphotropic Baculovirus
    - Mammalian expression plasmids
    - Bacterial expression plasmids
- **Transgenes:** function (source)
    - Ion channels/transporters (human, mouse)
    - Heat shock protein (human)
    - Fluorescent marker (*A. victoria*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established cell lines: human); insect established cell lines; bacteria (*E. coli* K12, *E. coli* B)
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
    - In-Vitro Procedures:
        - BSL1 – Standard molecular biology procedures
        - BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
        - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training

- **2025-26 Lab Survey Results:** 7 deficiencies found, all corrected

Summary:
- No safety concerns

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

Recombinant DNA Registration for IBC Review and Authorization.

PI: Attila Losonczy

- **Title:** In vivo experimental investigations of learning and memory in the mouse brain
- **Note:** Amendment
- **NIH Guideline Section(s):** III-E and III-F-8
- **Project Summary:**
  - Electroporation of plasmid DNA to express various fluorescent protein reporters.
- **Vectors:**
  - Mammalian expression plasmids
- **Transgenes:** function (source)
  - fluorescent markers (*A. victoria, Discosoma* sp.)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (primary human and mouse materials); bacteria (*E. coli* K12)
- **Notes:**
  - Exclusion criteria:
    - Lab indicates that individuals with known neurological infections including HIV and Hepatitis will be excluded, but individuals with neurodegenerative diseases may be included.
  - Transfection of brain sections will occur during electrophysiology. Electrophysiology will be conducted on a microscope outside of a biosafety cabinet.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
  - In-Vitro Procedures:
    - BSL1 – Standard molecular biology procedures
    - BSL2 –
      - Standard procedures: Biosafety cabinet use during manipulation of human materials when procedures involve the generation of aerosols and splashes
      - Electrophysiology: Combination of appropriate personal protective equipment and administrative controls are used.
    - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 2 individuals require training
- **2025-26 Lab Survey Results:** Spaces not yet surveyed

Summary:
- Safety met with the laboratory to discuss procedures.

- No safety concerns.

In favor: All
Opposed: None
Abstained: None
Status: Approved with stipulations**. These include:** Completion of training.

Biosafety Program Monthly Activity Reports

Adjourn Time: 12:17 pm

Addendum:

Owing to unforeseen circumstances, the following project was not addressed during the May 26, 2026 meeting. As a result, a special meeting was convened by the BSO and the IBC Chair on May 27, 2026.

Recombinant DNA Registration for IBC Review and Authorization.

PI: Kevin Courtney

- **Title:** AB-3028-201 Study: An Open-Label, Multicenter Phase 1/2 Study To Evaluate The Safety And Efficacy Of Ab-3028 In Patients With Castration Resistant Prostate Cancer (CRPC)
- **Note:** New
- **NIH Guidelines:** III-C
  Project Summary: A Phase ½ study to evaluate the safety and efficacy of an investigational product in individuals with castration resistant prostate cancer.
- **Product(s):**
  - Autologous T cells genetically modified ex vivo via electroporation to introduce a CRISPR/*cas9* ribonucleoprotein complex and plasmid DNA for the expression of a priming receptor against prostate stem cell antigen (PSCA) and chimeric antigen receptor against prostate-specific membrane antigen (PSMA).
- **Transgenes: (source)**
  - sgRNA and *cas9* complex
  - PrimeR priming receptor (human)
  - Chimeric antigen receptor (human)
  - shRNA-miR module (human)
- **Host:** Human subjects
- **PPE:** Body protection, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
  - A consultation with Occupational Health is advised for health care workers.
  - No occurrences of serious adverse events have been reported
  - All health care workers involved in this protocol should observe universal precautions.
  - No special precautions are required for roommates or family members.
- **IBC emphasizes:**
  - Direct contact, ingestion, autoinoculation and aerosol/droplet inhalation exposure are potential risks. To mitigate these risks the IBC requires the use of sharps protection, and the strict use of PPE. The IBC highly recommends that good hygiene practices be followed during and after the completion of investigational drug manipulation. Hand washing along with the use of PPE will lower the potential for contamination and minimize transmission of the agent.

- **Research Applications:**
    - All equipment used to store, manipulate, or cultivate the investigational drug must be labeled as biohazardous.
    - All liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as hazardous waste.
- **Required Training, Procedures, and Containment:**
    - Minimum Training requirements:
        - Sponsor Training (if applicable)
        - Bloodborne Pathogen Training for individuals listed on the registration
        - IATA Training for individuals shipping infectious samples
        - NIH Guidelines Training for PI
        - PI mediated intra-laboratory training
    - Procedures:
        - Other: UTSW Approved SOP for gene transfer project must be followed

Summary:
- No safety concerns

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