

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

July 28, 2026

Time: 11:30 a.m.

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

IBC Minutes

IBC Attendance July 2026

Ralph Callicott, D.V.M	Maria Labandeira-Rey, Ph.D.
Robert Orchard, Ph.D.	Julia Wilkerson
Benjamin Ohlstein, M.D., Ph.D.	Callan Kaut
Michael Reese, Ph.D.	Chad Donelson
Chun-Li Zhang, Ph.D.	Audrey Kinser
Tu Dan, M.D.	Kayle Cirrincione
Tomce Runcevski, Ph.D.	Mark Thompson
Bruce Brown, Dr. P.H.	Jessica Spaniol
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 July 28, 2026 on the UT Southwestern campus in room JA5.110 and via web conferencing.

The draft minutes from the meeting held on June 30, 2026 were approved unanimously by the members.

Status: June 30, 2026 IBC minutes were approved with minor changes.

Updated Business:

- Registration Closures
- Work holds

Project closures per PI request unless otherwise noted

PI: Farrukh Awan

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

PI: Bradley Marple

- **Title:** A randomised, double-blind, parallel group Phase III study to assess the efficacy and safety of 100 mg SC depemokimab in patients with chronic rhinosinusitis with nasal polyps (CRSwNP) – ANCHOR-1 (depemokimAb iN CHrOnic Rhinosinusitis)

PI: Andrew Koh

- **Title:** Gut Microbiome in Amyloidosis Patients

PI: Guo-Min Li

- **Title:** Mechanism of DNA mismatch repair and its role in human diseases

PI: John Schoggins

- **Title:** SARS-CoV-2 clinical samples for research

Notifications

PI: Sarah Shahmoradian

- **Title:** Subcellular imaging of protein aggregation using cryo-fixation and correlative light and electron microscopy
- **Note:** Renewal application
- **NIH Guideline Section(s):** III-E
- **Action:** Letter for Lapse in Approval issued

PI: Raiyan Zaman

- **Note:** New application
- **NIH Guidelines Section(s):** n/a
- **Title:** Non-invasive Detection of Stenosis/Atherosclerotic Plaques/Myocardia Infarction/Aortitis with Multi-mode Imaging Systems
- **Action:** Letter of No Approval issued

Reviews

Recombinant DNA Registration for IBC review and authorization.

PI: Neima Briggs

- **Title:** Mechanisms of Host Immunity to Parasites and Vaccines
- **Note:** New. New PI, Safety met with on 7/13/2026.
- **NIH Guideline Section(s):** III-D-4

- **Project Summary:**
 - The Briggs laboratory investigates the mechanisms that promote protective immunity, immune tolerance, and vaccine-induced protection during helminth infection.
 - The research combines experimental rodent models of helminth infection with immunologic analysis of de-identified human biospecimens.
 - Vaccination and immune-intervention studies may use nonviral nucleic-acid vaccine formulations.
- **Pathogen not genetically modified: Risk Group 2**
 - *Nippostrongylus brasiliensis*, rat-adapted laboratory strain
 - *Trichuris muris*, J strain
- **Human materials not genetically modified, collected from individuals with or without gastrointestinal parasite infection in sites including the United States, Honduras, and Brazil:**
 - Serum/plasma, cryopreserved PBMCs, stool, DNA, RNA
 - Note: For infected samples, screening was conducted to confirm infection with gastrointestinal parasites. Lab indicates individuals are otherwise healthy children and adults with no known bloodborne pathogens.
- **Vectors:**
 - mRNA
- **Transgenes:** function (source)
 - glutathione S-transferase (*N. americanus*, human hookworm)
 - cysteine-rich secreted protein (*N. americanus*)
 - aspartic protease (*N. americanus*)
 - cysteine-rich putatively secreted protein (*T. muris*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Nanoparticles:** Yes **Type:** lipid
- **Host for mRNA:** In vivo only
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Route(s) of Administration:**
 - *N. brasiliensis* – subcutaneous, intradermal
 - *T. muris* – oral gavage
 - mRNA - intramuscular
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures
 - BSL2 – Biosafety cabinet use during manipulations of infectious pathogen stocks and cultures and human materials when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - mRNA – Inoculation of agent in approved area followed by ABSL1 housing
 - Pathogens – Inoculation of agent in BSC followed by ABSL2 housing
 - PPE – Pending facility designation
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** New PI

Summary:

- Discussion of the need for work with infectious parasite stages to occur within a biosafety cabinet rather than on a bench.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training and use of biosafety cabinet during manipulations of infectious parasite stages.

Recombinant DNA Registration for IBC review and authorization.

PI: Stephanie Boisson-Dupuis

Co-PI: Jean-Laurent Casanova

- **Title:** Genetic and Immunologic determinants of Tuberculosis
- **Note:** New PI, OSBC met with on 7/6/2026.
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
 - Study of genetic and immunological determinants of tuberculosis to identify disease-associated genetic variants and define their role in susceptibility to infection.
 - Use of recombinant gene expression and gene transfer approaches in human cell models to evaluate the function effects of candidate variants and their contribution to disease.
- **Pathogen not genetically modified: Risk Group 2**
 - *Mycobacterium bovis*, BCG
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus (Applied Biological Materials Inc.)
 - Replication incompetent Retrovirus (Collaborator)
 - Mammalian expression plasmids (Addgene)
- **Transgenes:** function (source)
 - kinase (human)
 - transcription factor (human)
 - cytokine receptor (human)
 - cytokine (human)
 - intracellular protein (human)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; primary cell lines – human; established cell lines – human, non-human primate;); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration 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 pathogen stocks and cultures, viral vectors, human cell lines, and non-human primate cell lines 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:** New PI

Summary:

- Reviewers expressed concern regarding the shared laboratory space and emphasized the need to ensure all personnel are aware of the activities occurring and hazards present within the space. Reviewers requested that personnel meet with Safety and consult with Occupations Health, as appropriate.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training and meeting with Safety.

Recombinant DNA Registration for IBC review and authorization.

PI: Chien-Ting Wu

- **Title:** Virus Host Interactions
- **Note:** Amendment for addition of SARS-CoV-2 at BSL2, addition of genetic modifications to previously approved RG2 pathogens, and addition of transgenic animals.
- **NIH Guideline Section(s):** III-D-2
- **Project Summary:**
 - Study of host pathogen interactions and antiviral immune response to respiratory pathogens.
 - Amendment to expand studies of respiratory pathogens host-interactions by incorporating additional risk group 2 strains and agents.
- **Pathogen previously genetically modified: Risk Group 2**
 - Murine Sendai virus, strain Z
 - RSV, Washington/20993/1964, JS
 - Influenza A, 2009, H1N1, strain A/California
 - Human Parainfluenza virus (PIV) 1 and 3
- **Pathogen not genetically modified: Risk Group 2**
 - SARS-CoV-2, Omicron subvariant BA.5
- **Transgenes:** function (source)
 - fluorescent marker (*A. Victoria*, *Discosoma sp.*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines – non-human primate; established cell lines – human, murine, canine)
- **Notes:** PI has indicated that SARS-CoV-2 will be fixed when used in shared microscopy locations.
- **Animal Model:** In vitro only
- **Transgenic animals:** Yes **Generated at UTSW:** No **GDMO:** No
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:

- BSL1 – Standard molecular biology procedures
- BSL2 – Biosafety cabinet use during manipulation of infectious pathogen stocks and cultures and 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:** 4 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: Qian Zhang

Co-PI Jean-Laurent Casanova

- **Title:** Human genetic and immunological defects underline severe viral pneumonia
- **Note:** New. New PI, Safety met with on 7/6.
- **NIH Guideline Section(s):** III-D-3, III-E, III-E-1 and III-F-8
- **Project Summary:**
 - Use of viruses to infect cell lines.
 - Expression or modification of genes of interest in cell line hosts.
- **Pathogen not genetically modified: Risk Group 2**
 - Influenza A virus H1N1, strain A/California/04/2009
 - SARS-CoV-2, strain USA-WA1/2020
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: The use of a 2nd-generation packaging system is scientifically necessary for this protocol due to the architecture of our transfer vector.
 - Mammalian expression plasmids
 - CRISPR/*cas9* system: Ribonucleoprotein complex
- **Transgenes:** function (source)
 - interferon receptor component (human)
 - IFNB1, type I interferons (human)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (established human, human SV40-fibroblast, human EBV immortalized, non-human primate, and dog cell lines; primary cell lines: fibroblast, PBMCs – human); bacteria (*E. coli* K12)
- **Zoonotic Potential:** The PI is using Influenza A, 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 Influenza A.
- **Notes:**
 - Production of influenza A, SARS-CoV-2, and lentivirus.

- Use of A549-ACE2 cells provided by collaborator for infection with SARS-CoV-2.
- **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, viral vectors, and human and non-human primate materials 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:

- SARS-CoV-2:
 - Source for SARS-CoV-2 is a BSL2 laboratory.
 - Use of enhanced PPE including surgical mask during manipulations of SARS-CoV-2 will be needed for all individuals present during these manipulations.
- Discussion of 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 use of enhanced PPE during SARS-CoV-2 work.

Recombinant DNA Registration for IBC review and authorization.

PI: Shen-Ying Zhang

Co-PI: Jean-Laurent Casanova

- **Title:** Human Genetic and Immunological determinants of viral encephalitis
- **Note:** New PI, Safety met with on 7/6/2026
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
 - Investigates genetic and immune factors that increase susceptibility to viral encephalitis, especially herpes simplex encephalitis.
 - Uses genomic sequencing and stem cell-based models to identify causes of severe viral brain infections.
 - Studies antiviral immune responses within brain cells and their role in protection against viral infection.
 - Evaluates patient-derived cell models to validate genetic risk factors and disease mechanisms using Lentivirus vector and CRISPR/Cas9.
- **Pathogen not genetically modified: Risk Group 2**
 - Herpes Simplex Virus type 1, strain KOS
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification: A second-generation lentiviral system ensures higher viral titers and simpler three-plasmid transfection workflow, which makes it much easier

to package virus efficiently for hard-to-transfect or primary cells. It is also more cost-effective, less complex to optimize, and highly reproducible in the lab. Additionally, because the essential viral components remain split across separate plasmids to prevent replication, second-generation vectors provide an excellent standard of safety for routine in vitro research under BSL-2 guidelines.

- Mammalian expression plasmid
- CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Autophagy regulation (human)
 - snRNA modification and repair (human)
 - RNA lariat debranching enzyme (human)
 - Large T antigen (SV40)
 - Endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** SV40gp6 immortalization disables tumor suppressors pRB and p53.
- **Toxic Genes:** None
- **Host:** Mammalian (human and non-human primate packaging cell lines; established human cell lines; primary human cell lines); bacteria (*E. coli* K12)
- **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, viral vectors, and human cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** New PI

Summary:

- Safety procedures and SOPs are adequately described, but additional safety information has been requested for inclusion in SOPs.
- A simpler explanation of how HSV-1 virus will be used was requested.
- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Safety information updates to SOPs, and simpler explanation for work with HSV-1 virus

Recombinant DNA Registration for IBC review and authorization.

PI: Olaf Stuve

- **Title:** Antigen specificity of T lymphocytes in autoimmune disorders of the central nervous system
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-E and III-F

- **Project Summary:**
 - Use viral vector-mediated gene delivery, CRISPR/Cas9, and virus-like particles in mouse models to investigate antigen-specific T-cell responses and mechanisms underlying autoimmune disorders of the central nervous system.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus (Addgene)
 - Justification: pending
 - Replication incompetent, VSV-G pseudotyped, 3rd generation lentivirus (IDT)
 - Replication Incompetent Retrovirus (collaborator)
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - library for membrane-associated proteins expressed by myeloid cells (mouse)
 - fluorescent marker (*Discosoma sp.*)
 - endonuclease (*S. pyogenes*)
 - antigenic component of prion protein (human)
 - myelin oligodendrocyte glycoprotein (mouse)
 - core antigen (Hepatitis B)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines – human; primary cell lines – mouse); bacteria (*E. coli* K12)
- **Notes:** PI will be producing, purifying and concentrating virus in the laboratory.
- **Animal Model:** Mouse
- **Route(s) of Administration:** Intravenous – allograft of rDNA 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:
 1. IV – Inoculation of agent in a BSC followed by ABSL1 housing
 2. PPE – Disposable jumpsuit, hair bonnet, face mask, nitrile gloves, shoe covers, and eye protection
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 3 deficiencies found, all corrected

Summary:

- The reviewers expressed concern regarding the limited experience of laboratory personnel and requested a work continuation meeting with Biosafety to discuss appropriate procedures and safety practices.
- No other safety concerns.

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Resolution of minor pending comments, justification for use of 2nd generation lentivirus use, and work continuation meeting with Safety.

Recombinant DNA Registration for IBC review and authorization.

PI: Nicholas Conrad

- **Title:** Posttranscriptional gene regulation by regulation of RNA processing.
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-2, III-D-3, and III-F
- **Project Summary:**
 - Study the function of host and viral genes involved in gene expression and viral replication using cultured cell models.
 - Use of lentiviral-mediated gene knockout and inducible gene knockdown approaches to evaluate gene function during Kaposi's sarcoma-associated herpesvirus infection.
- **Pathogen to be genetically modified: Risk Group 2**
 - HHV8, bacmid (BAC16, BAC16deltaORF57)
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus (Addgene)
 - Justification: We have been using this system for some time and the effort/cost to regenerate these vectors in a third gen would be significant. As such, we continue to use this system. Notably, no high-risk activities (oncogenes) are expressed with these vectors.
 - Mammalian expression plasmids (Addgene)
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - methyltransferase (human)
 - nuclear binding protein (human)
 - transferase (human)
 - RNA splicing and export factor (human)
 - 3'-end processing factor (human)
 - synthetase (human)
 - sgRNA library (human)
 - mRNP assembly and export (human)
 - RNA-binding protein (KSHV)
 - splicing factor (human)
 - elongation factor (human)
 - endonuclease (*S. pyogenes*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines – human) bacteria (*E. coli* K12)
- **Notes:** PI will be producing, purifying, and concentrating virus in the laboratory.
- **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:** 5 individuals require NIH training

- **2024-25 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:** Completion of training

Recombinant DNA Registration for IBC review and authorization.

PI: Laurent Calvier

- **Title:** Molecular Basis of Development, Health, and Disease
- **Note:** New
 - Other PI has previously been overseeing this in vitro and in vivo work. That PI continues to maintain his own permit, as the oversight of the in vitro work is now shared between himself and Dr. Calvier. Oversight of the in vivo work now falls under Dr. Calvier.
- **NIH Guideline Section(s):** III-D-3, III-D-4, III-E, III-E-1, III-F-1, and III-F-8
- **Project Summary:**
 - To explore the molecular and cellular mechanisms by which an ancient class of conserved and structurally closely related cell surface receptors, the LDL receptor gene family, controls fundamental signaling pathways that are essential for brain development, neurotransmission, and vessel wall integrity and that broadly impacts human diseases such as Alzheimer's and atherosclerosis.
 - Use of viral vectors and non-viral plasmids for expression of genes of interest.
- **Vectors:**
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus
 - Justification for 2nd generation system: Lab has meticulously optimized lentivirus production in our particular line of cells with the 2nd generation of lentivirus production, and have published using this system for multiple decades.
 - Replication incompetent Adenovirus
 - Replication incompetent Adeno-associated virus
 - Mammalian expression plasmids
 - Bacterial expression plasmids
- **Transgenes:** function (source)
 - extracellular matrix protein (human, mouse, synthetic)
 - sodium-hydrogen exchange proteins (mouse, synthetic, human)
 - biosynthesis protein (human)
 - lysosome proteins (human)
 - phospholipid scramblase (synthetic)
 - cell surface receptor (mouse)
 - microtubule assembly and stability (human, synthetic)
 - amyloid-beta precursor (mouse)
 - anti-Reelin antibody (human)
 - low density lipoprotein receptor (mouse)
 - histone deacetylase (synthetic)
 - various cellular functions (human)

- enzyme production protein (human)
- synaptic vesicle fusion protein (human, mouse)
- lipid droplet protein (human)
- calcium channel subunit (mouse)
- fluorescent markers (*Discosoma* sp., synthetic, *A. victoria*, *B. lanceolatum*, *Clavularia* sp.)
- recombinase (P1 bacteriophage)
- **Oncogenes/Tumor suppressor:** Alteration of genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Nanoparticles:** Yes **Type:** Lipid
- **Host:** Mammalian (established cell lines: human, non-human primate, hamster, mouse; primary cell lines: iPSC, hepatic stellate cells, brain microvascular endothelial cells – human; neurons, glia, bone marrow derived macrophages - murine); bacteria (*E. coli* K12, BL21)
- **Notes:**
 - Viral production:
 - Production, purification, and concentration of AAV, adenovirus, and lentivirus.
 - Use of ready-to-use AAV stocks.
 - Proteins utilized in vivo:
 - Proteins obtained from collaborators or vendors are used in vivo.
- **Animal Model:** Mouse
- **Transgenic animals:** Yes **Generated at UTSW:** Yes (core facility) **GDMO:** No
- **Route(s) of Administration:**
 - Intravenous (tail vein, jugular vein) – adenovirus
 - Intrathecal, intracisternal magna, intracranial, intraparietal, retro-orbital, tail vein – AAV
 - Intracranial, intraventricular, intravenous (tail vein, hydrodynamic tail vein) – Lentivirus
 - Subcutaneous, intraventricular, micropump and cannula, intracisternal magna, intrathecal – Anti-sense oligonucleotides
 - Intravenous, intramuscular, retro-orbital, intraperitoneal – mRNA in lipid nanoparticles
 - In utero – plasmid DNA
 - Intravenous (retro-orbital, tail vein) – Allograft of rDNA 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 and non-human primate cell lines when procedures involve the generation of aerosols and splashes
 - PPE – Laboratory coat, gloves, and eye protection are required
 - In-Vivo Procedures:
 - Non-stereotaxic route for viral vectors – Inoculation of agent in a BSC, mandatory 48h cage change followed by ABSL1 housing
 - Intrathecal route for viral vectors – Inoculation of agent in approved area, mandatory 48h cage change followed by ABSL1 housing
 - Stereotaxic routes for viral vectors, and all routes for non-viral nucleic acids and allograft – Inoculation of agent in approved area 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:** 11 deficiencies found, all corrected

Summary:

- Genes of interest include those that may cause tumorigenic effects
- 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: Bertrand Boisson

Co-PI: Jean-Laurent Casanova

- **Title:** Human genetics of bacterial infection
- **Note:** New PI, Safety met with on 7/6/2026
- **NIH Guideline Section(s):** III-D-3, III-E-1, and III-F-8
- **Project Summary:**
 - Investigates genetic immune defects that may increase susceptibility to severe pneumococcal and staphylococcal infections in otherwise healthy individuals using an integrated human genetics approach that combines sequencing analyses, refined immunological stratification, and functional validation.
 - Uses genomic sequencing and immunological analyses to identify inherited and acquired causes of invasive bacterial disease.
 - Uses lentiviral vector transduction of patient-derived cells to restore gene function and confirm genotype-phenotype relationships.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus
 - Mammalian expression plasmids
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - NF-KB pathway immune response and inflammation (human)
 - Fluorescent markers (*Discosoma sp.*)
 - Endonuclease (*S. pyogenes*)
 - Reporter (*Renilla reniformis*)
 - Reporter (*Photinus pyralis*)
- **Oncogenes/Tumor suppressor:** None
- **Toxic Genes:** None
- **Host:** Mammalian (Human packaging cell lines, established human cell lines, primary human cell lines); bacteria (*E. coli* K12)
- **Notes:** Production, purification, and concentration of Lentivirus.
- **Animal Model:** In vitro only
- **Required Training, Procedures, and Containment:**
 - In-Vitro Procedures:
 - BSL1 – Standard molecular biology procedures

- BSL2 – Biosafety cabinet use during manipulation of viral vectors and human cell lines when procedures involve the generation of aerosols and splashes
- PPE – Laboratory coat, gloves, and eye protection are required
- **Training:** 1 individual requires NIH training
- **2025-26 Lab Survey Results:** New PI

Summary:

- Studies of human genetics and bacterial infection related to *S. pneumoniae* and *S. aureus*
- Committee members had questioned how these experiments are performed without the use of the actual *S. pneumoniae* and *S. aureus* pathogens and requested clarification from the lab
- No other safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved with stipulations. **These include:** Completion of training, clarification and confirmation that *S. pneumoniae* and *S. aureus* agents are not used in experiments.

Recombinant DNA Registration for IBC review and authorization.

PI: Alec Zhang

- **Title:** Function of ITIM Receptors
- **Note:** Renewal
- **NIH Guideline Section(s):** III-D-3, III-D-4, and III-F
- **Project Summary:**
 - Investigation of signaling pathways involved in immune regulation and cancer development.
 - Use of retroviral and lentiviral gene transfer in cell culture, mouse transplantation, and xenograft models to characterize gene function and disease progression.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 3rd generation Lentivirus (Aldevron, Takara, ATCC)
 - Replication incompetent Retrovirus (Addgene)
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - regulates blood stem cells (human, mouse)
 - fluorescent marker (*Zoanthus sp.*, *A. victoria*)
 - endonuclease (*S. pyogenes*)
 - tumor suppressor (human)
 - oncogene (human)
 - Chimeric antigen receptor (human, mouse)
- **Oncogenes/Tumor suppressor:** PI indicates that alteration of several genes of interest might result in tumorigenic effects.
- **Toxic Genes:** None
- **Host:** Mammalian (packaging cell lines; established cell lines – human, mouse; primary cell lines – mouse) bacteria (*E. coli* K12)
- **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:** IV, IP, RO, SC, Intramammary, or Interfemoral – xenografts and allografts
- **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, IP, RO, SC, Intramammary, or Interfemoral – Inoculation of agent in a BSC followed by ABSL1 housing
 - PPE – Hair bonnet; Disposable jumpsuit; Nitrile gloves; Shoe covers; Face masks
- **Training:** All individuals have required training
- **2025-26 Lab Survey Results:** 8 deficiencies found, all corrected

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Recombinant DNA Registration for IBC review and authorization.

PI: Chen Yao

- **Title:** T cell differentiation and function during viral infection and cancer
- **Note:** Amendment for addition of in vivo use of Lentivirus vector and SB transposon system.
- **NIH Guideline Section(s):** III-D-4
- **Project Summary:**
 - In vivo use of Lentiviral vector to modify gene expression in immune cells.
 - In vivo use of transposon-based systems to generate disease models and evaluate gene function.
- **Vectors:** (source)
 - Replication incompetent, VSV-G pseudotyped, 2nd generation Lentivirus:
 - Justification pending
 - SB Transposon system plasmids
 - CRISPR/*cas9* system
- **Transgenes:** function (source)
 - Oncogene (human)
 - Tumor suppressor (human)
 - Antigen (chicken)
 - Endonuclease (*S. pyogenes*)
 - Reporter (*Photinus pyralis*)
- **Oncogenes/Tumor suppressor:** Alteration of genes might result in tumorigenic effects.
- **Toxic Genes:** None
- **Animal Model:** Mouse
- **Route(s) of Administration:**

- Intravenous (IV), intraperitoneal (IP) – Lentivirus
- Intravenous (IV tail vein) – SB transposon plasmid system mixture
- **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:
 - Animals previously infected with RG2 pathogens:
 - Inoculation of materials listed in a BSC (Lentivirus) followed by ABSL2 housing
 - Animals not infected with RG2 pathogens:
 - Intravenous (IV tail vein) – Inoculation of SB transposon plasmid system mixture in approved area followed by ABSL1 housing
 - PPE – Double nitrile gloves, hair bonnet, shoe covers, face masks, disposable white tie-back gown, eye protection
- **Training:** 2 individuals require NIH training
- **2025-26 Lab Survey Results:** 6 deficiencies found, all corrected

Summary:

- Amendment for the addition of Lentivirus vectors and SB transposon system for in vivo experiments.
- Minor comments in the application need to be addressed.
- 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: Larry Anderson

- **Title:** A Phase III Open-label, Randomised, Multicentre Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma
- **Note:** New
- **NIH Guidelines:** III-C
- **Sponsor:** AstraZeneca, Inc.
- **Project Summary:**
 - A Phase 3 study for comparing the efficacy and safety of investigational product versus standard regimens in participants with RRMM.
- **Product(s):**
 - Autologous T-cells transduced with replication incompetent Lentivirus
- **Transgenes: (source)**
 - Chimeric antigen receptor (human, mouse)
- **Host:** Human subjects

- **PPE:** Chemo gown, gloves, and eye protection are required.
- **Health Warnings and Safety Statements:**
 - A health consultation with Occupational Health is advised.
 - 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 liquid suspensions, culture waste and unused/unneeded product stocks must be disposed as Medical/Sharps Waste or autoclaved prior to disposal.
- **Required Training, Procedures, and Containment:**
 - Minimum Training requirements:
 - Sponsor Training (if applicable)
 - Bloodborne Pathogen Training for individuals listed on the registration
 - IATA Training for individuals shipping infectious samples
 - NIH Guidelines Training for PI
 - PI mediated intra-laboratory training
 - Procedures:
 - Other: UTSW Approved SOP for gene transfer project must be followed
 - Refer to supplemental documents for more information

Summary:

- No safety concerns

In favor: All

Opposed: None

Abstained: None

Status: Approved

Human Material Registration for IBC Notification.

PI: Hanine El Haddad

- **Title:** The OPTIMUM Study - A prospective randomized basket trial evaluating the clinical utility of plasma-based microbial cell-free metagenomic sequencing for diagnosis and management of suspected infections in adult immunocompromised outpatients
- **Note:** New

Biosafety Program Monthly Activity Reports

Other Business

Adjourn Time: 12:20 pm