The University of Texas Health Science Center at Houston (UTHealth Houston) Institutional Biosafety Committee June 12, 2025 Minutes

Meeting Attendance:

Voting Members

Dr. Catherine Denicourt (Chair)

Dr. Eric Brown Dr. Nancy Crider

Dr. Nicholas Justice Dr. Yang Liu

Dr. Yahuan Lou Dr. Emma Napoli

Dr. Duc Nguyen

Dr. Scott Patlovich Dr. Brett Perkison

Mr. Jesus Duran Ramirez (SM)

Mr. Petko Ivanov (CM)

Non-Voting Members

Dr. Joy Harrison

Dr. Kristin King

Dr. Mary Robinson

Mr. Zack Becker

Mr. Alan Lucas

Ms. Rebecca Kairis

Ms. Allison Lino

Ms. Meredith Mills

1. Call to Order

The meeting was called to order by Dr. Denicourt at 3:01 PM.

2. Conflicts of Interest

The Chairperson reminded the committee about the conflict of interest procedure. She also reminded the committee members that all protocols that are discussed at the meeting are to be considered confidential and are not to be discussed outside of the meeting with non-IBC members.

3. Review Previous Meeting Minutes (May 8, 2025)

Approved = 12

Opposed = 0

Abstained = 0

4. IBC Administrative Items

Notification to the committee of the NIH Office of Science Policy (OSP) has posted the rosters of all active and registered IBCs via the <u>IBC-Registration Management System</u>. Action item: Correct Dr. Justice's name on roster

Recombinant or Synthetic Nucleic Acid Molecules Research Applications Review

During the review the committee assessed the containment levels as well as the facilities, procedures, practices and training and expertise of the personnel involved in recombinant or synthetic nucleic acid molecules research. The committee also reviewed agent

characteristics, types of manipulations planned, sources of the inserted nucleic acid sequences, the nature of the inserted nucleic acid sequences and whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced. Furthermore, the PI must determine the applicable section(s) of the *NIH Guidelines*.

5. Clinical Protocol Reviews (HGT)

None

6. Protocol Reviews

IBC-25-059 – Dr. Xinzhu Yu – "Analysis of astrocyte-neuron interaction in mouse nervous system"

Containment Level: BSL-1, ABSL-1; Tetrodotoxin (ex vivo use on tissue) was reviewed by the CSC and set additional precautions (use in certified BSC or chemical fume hood, PPE includes double nitrile gloves with standard BSL-2 PPE, decontamination with 20% bleach, and inventory and usage log for annual review by EHS).

NIH Section: III-D-4-a, III-F-8

Training status: all personnel listed on the protocol are current on safety training requirements

Approved = 12

Opposed = 0

Abstained = 0

The protocol was presented and approved with no additional recommendations.

 $IBC-25-060-Dr.\ Changqing\ Ju-"Role\ of\ Eosinophils\ in\ Hepatic\ Ischemia\ Reperfusion$ Injury; Role of chitinase-3-like-1 (Chi311) in acetaminophen-induced liver injury"

Containment Level: BSL-2, ABSL-1

NIH Section: Not applicable

Training status: all personnel listed on the protocol are current on safety training

requirements Approved = 12 Opposed = 0 Abstained = 0

The protocol was presented and approved with no additional recommendations.

IBC-25-065 – Dr. Ziyin Li – "Mechanisms of the Unusual Cytokinesis in Trypanosomes" AND "Regulation of cell cycle transition by a cyclin-dependent kinase in trypanosomes"

Containment Level: BSL-2

NIH Section: III-D-1-a, III-D-2-a

Training status: Pending completion of Annual Lab and BBP Training for one personnel listed on the protocol

Approved = 12

Opposed = 0

Abstained = 0

The protocol was presented and approved pending clarification of the procedure for culturing or proliferating the parasite.

IBC-25-066 – Dr. Harry Karmouty-Quintana – "Hypoxic Vasoconstriction in COVID-19-induced Acute Respiratory Distress Syndrome (ARDS); Alterations in the Pulmonary Vasculature of COVID-19-induced Acute Respiratory Distress Syndrome (ARDS)" AND "3'UTR shortening in Pulmonary Vascular Disease", AND "Respiratory Viral infection and acute lung injury: uncovering the role of hyaluronan", AND "NUDT21 depletion in viral infection and ventilator induced lung injury"

Containment Level: BSL-2 NIH Section: Not applicable

Training status: all personnel listed on the protocol are current on safety training

requirements
Approved = 12
Opposed = 0
Abstained = 0

The protocol was presented and approved with no additional recommendations.

IBC-25-070 – Dr. Carmen Dessauer – "Regulation Of Adenylyl Cyclase Signaling Pathways" AND "Mechanisms of cAMP Signaling that Drive Spontaneous Activity in Nociceptors" AND "Mechanisms of Opioid Resistance after Spinal Cord Injury" AND "Regulation of nociceptor excitability by macrophage migration inhibitory factor (MIF) as a therapeutic strategy for chronic pain treatment after spinal cord injury"

Containment Level: BSL-2; ABSL-2 (ABSL-2 requested by PI) NIH Section: III-D-1-a, III-D-2-a, III-D-4-a, III-F-1, III-F-6

Training status: pending completion of Annual Lab and BBP Training for several personnel listed on the protocol

Approved = 12

Opposed = 0

Abstained = 0

The protocol was presented and approved with no additional recommendations.

7. Conditionally Exempt Protocol Reviews

IBC-25-058 – Dr. Carolyn Pickering – "Mechanisms Linking Chronic Stress to Cognitive Aging in Women"

IBC-25-064 – Dr. J Marc Rhoads – "Gut-brain interaction in babies with colic as determined by MEG scanning"

IBC-25-071 – Dr. Gabriel Fries – "Neuromodulation + Prolonged Exposure Therapy: Evaluation of a Technology-Enhanced, Entirely Remote 2-week Integrated Treatment for Pain and PTSD"

IBC-25-072 – Dr. Anneliese Gonzalez – "Tumor Tissue and Laboratory in Breast Cancer (Protocol #T-09-105)"

8. Protocol Updates

a. Significant updates:

IBC-23-056: Dr. Jianguo Wen – "Optimizing mRNA sequences with deep neural networks" AND "Developing mRNA designer tool package for optimization of mRNA sequences" AND "Systematic optimization of mRNA sequences for mRNA therapies"

- Addition of bolded title
- Addition of work: Experiment 2 (mRNA vaccine with sequence optimized by dendritic cell-specific model) and Experiment 3 (Claudin18.2 mRNA vaccine)
- Addition of rDNA: Pseudotyped lentivirus for chimeric antigen receptor for claudin 18.2 (Creative Biolabs Kit) to be used in neutralization assay
- Addition of bioagents: Human CLDN18.2 and T cells
- Addition of mouse strain: NSG

Containment Level: BSL-2, ABSL-1 (no change from previous approval) NIH Section: III-D-1-a, III-D-2-a, III-D-4-b (no change from previous approval) Training status: all personnel listed on the protocol are current on safety training requirements

Approved = 12

Opposed = 0

Abstained = 0

The protocol was presented and approved with no additional recommendations. The IBC committee requested that the PI be notified that if lentiviral vectors are added in an amendment, this will change the precautions.

IBC-24-084 – Dr. Minghua Wu— "Interferon Regulatory Factor7 Links Interferon Pathway Activation to the Exaggerates Fibrotic Response in Systemic Sclerosis"

- Addition of rDNA: Lentivirus vector to overexpress IRF7 in cell line
- Addition of bioagent: Lentivirus vector

Containment Level: BSL-2 (increase with amendment)

NIH Section: III-D-1-a (added with amendment)

Training status: all personnel listed on the protocol are current on safety training

requirements Approved = 12 Opposed = 0 Abstained = 0

The protocol was presented and approved with no additional recommendations.

b. Administrative updates:

IBC-20-070 – Dr. Qingyun Liu – "Discovery of novel therapeutic agents for the treatment of human diseases" AND "Function and Mechanism of LGR4 and LGR5 in Modulation of Wnt Signaling" AND "Investigation of drug conjugates of LGR4 antibodies and RSPO antagonists" AND "LGR4 in Breast Cancer Progression and Therapy" AND "Discovery of antibody-drug conjugates targeting a receptor broadly expressed in solid tumors" AND "Investigation of antibody-drug conjugaes of a novel target" AND "Discovery and development of a novel peptibody-drug conjugate for treating cancers of the digestive system" AND "LGR5 antibody drug conjugate for the treatment of neuroblastoma" AND "A preclinical development core for large molecule therapeutics" AND "Simultaneous targeting of LGR4/5/6 for the treatment of gastrointestinal cancer" AND "Development of drug conjugates of R-spondin peptibodies for the treatment of colorectal cancer" AND "Integrating proteolysis-targeting capability into antibodies to augment therapeutic efficacy" AND "Drug conjugates of modified LGR4/5/6 ligands for cancer treatment"

- Addition of bioagent: mouse colon cancer cell line (CT26)

IBC-20-079 – Dr. Kyoji Tsuchikama – "Novel Antibody-Drug Conjugate Linker Technologies for Multidrug Loading" AND "Dual-Loading ADCs for Combating Cancer Drug Resistance and Heterogeneity" AND "Chemically Generated Bispecific Antibody-Drug Conjugates for Treating Triple-Negative Breast Cancer" AND "Chemical approaches for generating blood-brain barrier-permeable antibody conjugates" AND "Antibody-dual drug conjugates for eradicating triple-negative breast cancer with heterogeneity" AND "Optimization of antibody drug conjugate design to maximize the therapeutic window for glioblastoma therapy" AND "Targeting leukemia stem cells with the novel antibody drug conjugate"

- Addition of bolded titles
- Addition of personnel: Kiyotaka Kobayashi
- Addition of Bioagent: murine mammary tumor cell lines EO771 and EO771/Trop2

IBC-21-041 – Dr. Absalon Gutierrez – "Pharmacogenetics of the Response to GLP-1 in Mexican-Americans with Prediabetes"

- Addition of work: Microbial profile of stool and oral samples
- Addition of bioagent: Human feces, Human oropharyngeal swab

- Addition of location: MSB 1.020

IBC-21-076 – Dr. Ali Azhdarinia – "Molecular Imaging Probe Development"

- Addition of bioagents: Human pancreatic cancer cells (BON1-SSTR2-GFP); Human lung cancer cell line (Calu-6); Human small cell lung cancer cells (NCI-H524); Human pancreatic cancer cells (PDX)

IBC-21-080 – Dr. Michael Zhu – "Excitatory neurotransmission by PTX-sensitive G proteins" AND "Molecular mechanism of acidotoxicity to neurons" AND "Molecular mechanism of TRPC4 regulation in endothelium permeability" AND "Molecular Mechanism of Brain Regulation of Chronic Pain"

- Addition of work: Preliminary study of Long COVID-19 patients' serum on mice brain neurons, evaluated via electrophysiology techniques
- Addition of bioagent: Human blood
- Update of AWC: AWC-25-0029
- Removal of personnel: Jian Xiong and Jaepyo Jeon
- **Addition of location**: MSB 4.314 (Patch-Clamp Electrophysiology Equipment Room)

IBC-21-082 – Dr. Steven Norris – "Physiologic Characteristics of Treponema pallidum" & "Infection of Rabbits with Treponema pallidum" & "Factors Affecting Treponema pallidum in vitro multiplication and gene transcription" & "Factors affecting long-term in vitro culture of Treponema pallidum"

- Addition of work and bioagents: Tissue samples (lesions and placenta), lesion swabs, and lesion aspirates from human patients infected with syphilis will be used to isolate new patient-acquired strains from Peru (IPP 20250506-154A)

IBC-22-047 – Dr. Mary Farach-Carson – "Mechanosensing in the Bone-Lacunar-Canalicular System" AND "ISS/Collaborative Research: 3D Bone Marrow Analogs to Determine the Contribution of Mechanical Signals to Aging MSC Function in Microgravity" AND "Assessing the Impact of Resolvins on Osteolasts in a 3D Biomimetic Implant Culture System" AND "Mapping Cellular Interplay of the Osteocyte Connectome in Metastatic Renal Cell Carcinoma"

- Addition of personnel: Claudia Villalobos, Allan Hu, Katelyn Kennedy
- **Removal of personnel:** Hannah Lloyd, Helen Tan

IBC-22-048 – Dr. Mary Farach-Carson – "Prostate Cancer Bone Metastasis Biology and Targeting: Project 2" AND "Acquisition and Experimental Use of Normal and Cancerous Tissue for Tissue Engineering and Biomarker Discovery" AND "Bone Metastasis Cell Collection" AND "CAM Based Cancer Xenograft Model" AND "Genetic basis for juvenile calcium phosphate nephrolithiasis with osteopenia (IRB#: HSC-DB-17-0154)" AND "A 3D Perfusable Platform for HTS Across Diverse Racial/Ethnic Cancer Specimens" AND "Mapping and Predicting Therapy Resistance in SCLC Liquid Biopsies at a Personalized Level"

- Addition of personnel: Anamarcela Longoria
- Removal of personnel: Subin Kim

IBC-22-057 – Dr. Blanca Restrepo – "Diabetes and Tuberculosis Research Program in South Texas (Umbrella 2)" AND "Role of metabolic Me-macrophages in the pathogenesis of tuberculosis during diabetes" AND "Interdisciplinary NexGen TB Research Advancement Center (IN-TRAC)" AND "Identification of biomarkers of audiologic outcomes in congenital cytomegalovirus infection" AND "LAM ELISA for TB diagnosis: Proof-of-concept testing" AND "Clinical Concordance evaluation of the T-SPOT®.TB test performance to support raw material change (OI-8)" AND "Immune and metabolic dysfunction during aging in human cohorts" AND "Improving rapid phenotypic drug susceptibility testing for drug resistant tuberculosis in high-burden areas" AND "A retrospective follow-up study of the durability of antiviral therapy on long-term hearing and neurodevelopmental outcomes among patients treated for congenital cytomegalovirus infection as infants or toddlers"

- **Addition of personnel:** Aquiles Ocana-Guzman, Fernando Diosdado and Samuel Marshal
- **Removal of personnel:** Sean Monday, Genesis Aquillon, Maricarmen Marroquin and Lizette Garza

IBC-22-060 – Dr. Chun-Teh Lee – "Bioactive Hydrogel Matrix for Gingiva Regeneration"

- Addition of personnel: Sara Babban

IBC-22-077 – Dr. Anne-Marie Miller – "Investigation of bacterial colonization, infection, and inter-species competition in vivo" AND "Mechanoregulation of EHEC Virulence" AND "Unraveling how gut microbiota influence form and function in the developing enteric nervous system" AND "Role of mucin sulfation and sulfation-specific adhesins in AIEC colonization"

- Addition of personnel: Cecilia Fadhel Alvarez

IBC-23-009 – Dr. Jordan Lake – "Umbrella protocol for the study of clinical, virological and immunological outcomes in HIV/HCV infected individuals." AND "Understanding the Spectrum of Liver Health in HIV Infection" AND "Understanding the Contributions of HIV Infection and Hormone Therapy to Cardiovascular Disease Risk Among Transgender Women: A Deadly Crossroads?" AND "HIV Replicative Fitness in the setting of Anti-retroviral Drug Resistance" AND "Cardiometabolic Risk in Transgender Women and its Relationship to HIV Infection and Feminizing Hormone Use" AND "HIV Reservoir Characterization before and after Hormone Replacement Therapy" AND "Feminas Study Stored Sample Analysis" AND "A Phase 3b, Multicenter, Open-Label Study to Evaluate Switching From a Regimen of Two Nucleos(t)ide Reverse Transcriptase Inhibitors (NRTI) plus a Third Agent to a Fixed Dose Combination (FDC) of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF), in Virologically-Suppressed, HIV-1 Infected African American Participants." AND "The Prevalence of and Risk Factors for Fatty Liver in HIV Infected Individuals Attending Multiethnic Urban HIV Clinics" AND "The Impact of Cannabinoids on Inflammation, HIV Viral Load and Symptoms of Distress among Persons Living with HIV/AID." AND "Explorations into the mechanism for INSTI-associated weight gain: a focus on energy balance" AND "Hepatic effects of simultaneous supra physiologic Estradiol supplementation and androgen deprivation in transgender women initiating genderaffirming hormone therapy" AND "Sarcopenic Obesity and Relationships with

Immunometabolic Parameters in People with HIV" AND "A Pilot Trial of Semaglutide Microdosing for Weight Maintenance in People With HIV"

- Addition of bolded title
- Addition of IRB Study: HSC-MS-25-0376

IBC-23-015 – Dr. Mary Farach-Carson – "Acquisition and Experimental Use of Head and Neck Tissue for Tissue Engineering and Biomarker Discovery" AND "Salivary Tissues for Relief of Xerostemia" AND "Directing Collective Epithelial Morphology in Space and Time Using a Light-Based Carving Tool" AND "Salivary Avatars for Screening Stimulants and Sialagogues" AND "Cell-Based Therapy in Minipig Model of Radiation-Induced Xerostomia" AND "Development of Surgically Implantable Minor Salivary Gland-Based Constructs for Treatment of Xerostomia" AND "SARS-CoV-2 Latency in Oral and Salivary Tissues" AND "Functional Biointegration of Bioengineered Salivary Tissues in Irradiated Animal Models" AND "Epithelial Organization in Thin Bioprinted Hydrogel"

- Addition of personnel: Kamile Kukleryte
- Removal of personnel: Danny Perez Sierra, Lauren Gillespe, Yu Yin, Hannah Lloyd

IBC-24-041 – Dr. Qingchun Tong – "Central Mechanisms of Energy Balance" AND "Mechanisms Underlying Glucose-lowering effects of Leptin in Type 1 Diabetes" AND "Sim1 Neurons and Bodyweight Regulation" AND "Leptin and Central Control of Thermoregulation" AND "GABAergicRip-Cre Neurons in Glucose Homeostasis" AND "Role of GABAergic Input to POMCNeurons in Body Weight Regulation" AND "To Deconstruct a Hypothalamic Neurocircuit for Feeding and Grooming" AND "A Direct LH to PVH Projection for Antagonistic Regulation of Feeding" AND "To Study the Function of non-AgRP Neurons in Body Weight Regulation" AND "Genetically Dissecting Basal Forebrain Circuits Underlying Eating Disorders" AND "To explore the mechanism underlying developmental compensations in PVH neurons" AND "A novel MC4R neural pathway in feeding" AND "Neural pathways for obesity development by AgRP neurons" AND "Genetically dissecting neural circuits underlying anorexia nervosa" AND "Hypothalamic CRH neurons in diet-induced obesity" AND "Genetic Dissection of A Unique Population of Appetite Stimulatory Neurons in the Hypothalamus" AND "A neural basis underlying diet-induced obesity and leptin resistance"

- Addition of bolded title
- Addition of rDNA: lentiviral vector (LV-Flp-Off/Cre-ON-LepR-p2a-tdTomato, LV-Flp-Off/Cre-ON-tdTomato); AAV strains (AAV-Flp-ON/Cre-Off-NachBac-GFP, AAV-Flp-ON/Cre-Off-GFP, AAV-Flp-Off/Cre-ON-CA-STAT3-p2a-tdTomato, AAV-Flp-Off/Cre-ON-tdTomato, AAV-Flp-Off/Cre-ON-Kir2.1-eGFP, AAV-Flp-Off/Cre-ON-eGFP, AAV-Flp-ON/Cre-Off-Kir2.1-p2a-mCherry, AAV-Flp-ON/Cre-Off-mCherry)
- Addition of bioagent: Added lentiviral vector (LV-Flp-Off/Cre-ON-LepR-p2a-tdTomato, LV-Flp-Off/Cre-ON-tdTomato); AAV strains (AAV-Flp-ON/Cre-Off-NachBac-GFP, AAV-Flp-ON/Cre-Off-GFP, AAV-Flp-Off/Cre-ON-CA-STAT3-p2a-tdTomato, AAV-Flp-Off/Cre-ON-tdTomato, AAV-Flp-Off/Cre-ON-Kir2.1-eGFP, AAV-Flp-Off/Cre-ON-eGFP, AAV-Flp-ON/Cre-Off-Kir2.1-p2a-mCherry, AAV-Flp-ON/Cre-Off-mCherry)
- Addition of personnel: Runzhou Yang

IBC-24-053 – Dr. Hongyuan Yang – "AGPAT2 in whole body metabolism and the interactions between AGPAT2 and GPAT3/4 in vivo"

- **Addition of bioagent:** plasmids, lentiviral vectors, and AAV vectors carrying the GRAM insert.
- Addition of CSC protocol: CSC-25-046 (tamoxifen)

IBC-24-069 – Dr. Brian Skaug – "Pathogenic effects of DNASE1L3 R206C polymorphism in systemic sclerosis pathogenesis"

- Addition of IRB Study: HSC-MS-02-004 (genotyping on the DNA samples)

IBC-25-014 – Dr. Argyrios Stampas – "First-In-Human Phase 1b/2a Dose Escalation Study of EG110A, a Non-replicative Herpes Simplex Virus 1-derived Gene Therapy Expressing a Transgene Encoding the Light Chain of Botulinum Toxin F, Administered by Intradetrusor Injections to Adult Participants with Neurogenic Detrusor Overactivity-related Incontinence Following Spinal Cord Injury Who Regularly Perform Clean Intermittent Catheterization"

 Clinical protocol update: regimen of prophylactic antibiotic administration will be standardized across all sites to 3 days, an additional urine sample will be collected predose on Day 1, and concentration of EG110A vial was corrected from 1.24x10⁸ pfu/mL to 1.25x10⁸ pfu/mL

IBC-25-016 – Dr. Andrew Pountain – "Transcriptional heterogeneity in microbial growth and pathogenesis"

- Addition of work: Work related to Pseudomonas aeroginosa
- Addition of rDNA: Pseudomonas aeruginosa (PA14, PA-1, and derived mutants), Plasmids (pEXG2, GFP, dsRed), E coli (reporter strain pSB536)
- Addition of bioagent: Pseudomonas aeruginosa (PA14, PA-1, and derived mutants)

IBC-25-048 – Dr. Souvik Bhattacharyya – "The Impact of Bacterial Behaviors on the Evolution of Antibiotic Resistance"

- Addition of personnel: Marta Cano Minarro

9. BSL-3 Update

No BSL-3 updates

10. Biological Safety Program Activity Report

The Biological Safety Program Activity Report was provided for the committee to review. There was 1 reported injury in May. Sharps injury in the laboratory with clean sharp.

11. Environmental Protection Program Activity Report

The Environmental Protection Program Activity Report was provided for the committee to review.

12. Other Items

None

13. Next Meeting

The meeting scheduled for July 10, 2025 was cancelled due to multiple voting members being unable to attend.

14. Adjournment

The meeting was adjourned by Dr. Denicourt at 4:00 PM.