Institutional Biosafety Committee – November 25, 2025 Minutes

Members Present	Members Absent
Rumela Chakrabarti, PhD**	Sophia George, Ph.D.
Pantelis Tsoulfas, M.D.*	Kevin Folta, Ph.D (ad hoc member)
Ellen Kapsalis, Ph.D.	Minh Tran, Ph.D
Micheline McCarthy, M.D., Ph.D	Dan Rothen, D.V.M
Shane Gillooly	Kevin Mullen[1]
Susanne Doblecki-Lewis, MD	
Kevin Sanders, D.V.M.	
Julia Zaias, D.V.M, Ph.D	
Mercina Drake[1]	
Jennifer Laine, PhD***	
Ela Koncza	
Lizzeth Meza ***	

* Denotes Chair
** Denotes Vice-Chair
*** Denotes BSO Alternate
[1] Denotes Community Representatives

1. **Call to Order and Announcements:**
   The IBC meeting was held on November 25th via Zoom. Dr. Chakrabarti chaired the meeting. After determining that there was a quorum, Dr. Chakrabarti called the meeting to order at 3:00 p.m.
   - Minutes from October 28th meeting – approved by vote 7-0
     - Minutes will be uploaded to the website

2. **Discussion:**
   I. Recap of needlestick incidents in Lasorella lab.
      - BSO provided update on meeting with PI and lab staff
        - Working on setting up an in-person meeting and re-training

Dr. Tsoulfas joined the meeting

New Business

Protocol Number: 25-094

Principal Investigator: Dr. Ahn Pham

Project Title: Mitochondrial model for glaucoma

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentivirus and AAV vectors for Cre delivery; pantropic host range
- Non-replicating vectors; low environmental stability

Types of Manipulations:

- Intraocular injection of Cre via lentivirus/AAV
- Lentiviral transduction of trabecular meshwork cells

Source(s) of Nucleic Sequences: Mouse mitochondrial reporter genes; human cell lines

Nature of Nucleic Acid Sequences: Fluorescent reporter genes (mitoPhLux); Cre recombinase

Host(s) and Vector(s): Mouse models; lentiviral and AAV vectors

Transgene Expression: Yes; fluorescent proteins for mitochondrial visualization

Discussion Points:

- Clarify strain development responsibility
- Update risk assessment
- Provide plasmid maps
- Update viral vector form regarding host range and tropism

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-115

Principal Investigator: Dr. Lynn Feun

Project Title: IFx Hu2.0 as adjunctive therapy to pembrolizumab in Merkel Cell Carcinoma

Training Verification: Confirmed

NIH Guidelines Section: III-C

Containment Conditions: BSL-1

Agent Characteristics:

- Plasmid DNA (pAc/emm55) encoding Emm55 protein; non-replicating
- Low pathogenicity; stable under standard conditions

Types of Manipulations:

- Intratumoral injection of plasmid DNA complex

Source(s) of Nucleic Sequences: Streptococcus pyogenes (emm55 gene)

Nature of Nucleic Acid Sequences: Structural gene encoding immunogenic protein

Host(s) and Vector(s): Mammalian expression plasmid; no viral vectors used

Transgene Expression: Yes; Emm55 protein to stimulate immune response

Discussion Points:

- Clarify biosafety SOP details
- Add safety precautions for necrosis and immune-mediated events
- Complete training documentation

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-116

Principal Investigator: Dr. Alessia Fornoni

Project Title: Gene therapy PS-002 for IgA nephropathy

Training Verification: Confirmed

NIH Guidelines Section: III-C

Containment Conditions: BSL-1

Agent Characteristics:

- AAV vector (serotype LK03); replication-deficient
- ssDNA genome; stable under standard conditions

Types of Manipulations:

- Renal artery infusion of AAV vector

Source(s) of Nucleic Sequences: Human complement factor I gene

Nature of Nucleic Acid Sequences: Codon-optimized structural gene with nephrin promoter

Host(s) and Vector(s): Human patients; AAV vector

Transgene Expression: Yes; complement factor I protein for immune regulation

Discussion Points:

- Update SOP for household precautions and staff handling
- Include PI training record

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-117

Principal Investigator: Dr. Daphne Avgousti

Project Title: Investigating chromatin mechanisms using viral systems

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Adenovirus, herpesvirus, vaccinia virus; lentiviral vectors for cell line generation

Types of Manipulations:

- Viral infection of human cell lines
- CRISPR-mediated knockouts
- Protein purification

Source(s) of Nucleic Sequences: Human and viral genes

Nature of Nucleic Acid Sequences: Histone-related genes; viral chromatin regulators

Host(s) and Vector(s): Human cell lines; lentivirus; adenovirus; herpesvirus; vaccinia virus

Transgene Expression: Yes; viral and host proteins for chromatin studies

Discussion Points:

- Provide detailed breakdown of experiments per virus
- Clarify vaccinia use and update safety forms
- Update risk assessment and rDNA survey responses

Recommendation: Tabled; unanimously approved (8-0)

Protocol Number: 25-118

Principal Investigator: Dr. Ahn Pham

Project Title: Mitochondrial function in glaucoma

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentivirus and AAV vectors for transgene delivery

Types of Manipulations:

- Cell culture transduction
- Mitochondrial DNA sequencing

Source(s) of Nucleic Sequences: Human ocular tissues; viral vectors

Nature of Nucleic Acid Sequences: Reporter and functional genes

Host(s) and Vector(s): Human ocular cells; lentivirus; AAV

Transgene Expression: Yes; for functional studies

Discussion Points:

- Insufficient details; clarify experimental design and viral use

Recommendation: Tabled; unanimously approved (8-0)

Protocol Number: 25-119

Principal Investigator: Dr. Sabita Roy

Project Title: Engineered probiotic therapy for chemotherapy-induced neuropathy

Training Verification: Confirmed

NIH Guidelines Section: III-E-3

Containment Conditions: BSL-1

Agent Characteristics:

- Engineered E. coli Nissle 1917 strain; non-pathogenic
- Plasmid encoding GAD and BUT operons; stable under GI conditions

Types of Manipulations:

- Plasmid construction
- Oral gavage in mice

Source(s) of Nucleic Sequences: E. coli K-12; Clostridium butyricum

Nature of Nucleic Acid Sequences: Biosynthetic genes for GABA and butyrate production

Host(s) and Vector(s): Mouse models; engineered probiotic strain

Transgene Expression: Yes; metabolic enzymes for neuroprotection

Discussion Points:

- Clarify route of administration and proof-of-principle data
- Correct room assignments and biosafety practices

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-120

Principal Investigator: Dr. Vivek Kanumuri

Project Title: Synaptic tracing and neural activity using AAV

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-1

Agent Characteristics:

- AAV vectors; non-pathogenic; stable under standard conditions

Types of Manipulations:

- Stereotaxic injection of AAV into rodent tissues

Source(s) of Nucleic Sequences: Fluorescent proteins and light-sensitive ion channels

Nature of Nucleic Acid Sequences: Structural genes for GFP, tdTomato, Chronos, hCHR2

Host(s) and Vector(s): Rodent models; AAV vectors

Transgene Expression: Yes; for neural circuit imaging and optogenetics

Discussion Points:

- Update project summary and clarify animal species
- Amend disinfection protocols for AAV spills

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-121

Principal Investigator: Dr. Nagaraj Nagathihalli

Project Title: Impact of CREB-driven mechanism in shaping tumor-immune landscape

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentiviral vectors; CRISPR/Cas9 components

Types of Manipulations:

- Genetic knockout/overexpression
- Orthotopic tumor implantation

Source(s) of Nucleic Sequences: Mouse and human genes (CREB, LIF)

Nature of Nucleic Acid Sequences: Regulatory and signaling genes

Host(s) and Vector(s): Mouse models; lentiviral vectors

Transgene Expression: Yes; CREB and LIF for mechanistic studies

Discussion Points:

- Experimental details need refinement; clarify vector involvement

Recommendation: Tabled; unanimously approved (8-0)

Protocol Number: 25-122

Principal Investigator: Dr. Zhao-Jun Liu

Project Title: Stem cells for longevity and wound healing

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-1

Agent Characteristics:

- AAV vectors for MSC transduction

Types of Manipulations:

- MSC isolation and transduction
- Tail vein and intradermal injections

Source(s) of Nucleic Sequences: Mouse E-selectin gene

Nature of Nucleic Acid Sequences: Structural gene for adhesion molecule

Host(s) and Vector(s): Mouse models; AAV vectors

Transgene Expression: Yes; E-selectin for enhanced MSC function

Discussion Points:

- Provide project aims and context

Recommendation: Conditional approval; unanimously approved (8-0)

Protocol Number: 25-123

Principal Investigator: Dr. Kevin Collins

Project Title: Neuromodulator signaling in C. elegans egg-laying circuit

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-1

Agent Characteristics:

- Plasmid DNA for gene expression in C. elegans

Types of Manipulations:

- Microinjection of plasmids into germline

Source(s) of Nucleic Sequences: C. elegans genes; synthetic promoters

Nature of Nucleic Acid Sequences: Channels, receptors, signaling molecules

Host(s) and Vector(s): C. elegans; plasmid vectors

Transgene Expression: Yes; for functional studies of neural circuits

Discussion Points:

- None noted

Recommendation: Approved; unanimously approved (8-0)

4. Addenda:

Number:	**21-008 IIIC ad09**
Title:	AN OPEN-LABEL, MULTICENTER, PHASE 1B/2STUDY OF RP1 IN SOLIDORGAN AND HEMATOPOIETIC CELLTRANSPLANT RECIPIENTS WITH ADVANCED CUTANEOUSMALIGNANCIES
Principal Investigator:	Tang, Jennifer
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**23-130 IIID ad01**
Title:	Dynorphin/KOR axis in the regulation of glucose homeoastasis
Principal Investigator:	Blandino Rosano, Manuel
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**23-137 IIIC ad05**
Title:	A Phase I, Multicenter Study of CD4- directed chimeric antigen receptor engineered T-cells (CD4CAR) in patients with Relapsed or Refractory CD4+ Lymphoid Hematological Malignancies
Principal Investigator:	Beitinjaneh, Amer
Primary Reviewer:	**Meza, Lizzeth**

Number:	**24-065 IIIC ad03**
Title:	PIVOT-006: A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)
Principal Investigator:	Mousannar, Ali
Primary Reviewer:	**Meza, Lizzeth**

Number:	**25-079 IIIC ad02**
Title:	A Phase I/IIa Study to Evaluate the Efficacy of DB107-RRV (Formerly Toca 511), Administered to Subjects at Time of Resection and Intravenously Thereafter, in Combination with DB107-FC (Formerly Toca FC) and Radiation Therapy or DB107-FC, Temozolomide (TMZ) and Radiation Therapy in Patients with Newly Diagnosed High-Grade Glioma
Principal Investigator:	Hosein, Peter
Primary Reviewer:	**Meza, Lizzeth**

Number:	**25-036 IIIC ad01**
Title:	CTO-IUSCCC-0851: Chimeric Antigen Receptor T Cell Redirected to Target CD4 Positive

Relapsed Refractory Acute Myeloid Leukemia (AML) As a Bridge to Allogeneic Stem Cell

Principal Investigator: Beitinjaneh, Amer
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-041 IIIC ad02**
Title: SUPRAME - ACTengine® IMA203 vs. investigator's choice of treatment in previously treated, unresectable or metastatic cutaneous melanoma
Principal Investigator: Hernandez Aya, Leonel
Primary Reviewer: **Tsoulfas, Pantelis**

5. Exemptions:

Number: **25-113 IIIF**
Title: FA-DF in the study of retinopathy
Principal Investigator: Abdulreda, Midhat
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-114 IIIF**
Title: Targeting lipid clearance pathways to promote repair after SCI
Principal Investigator: Lee, Jae
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-124 IIIF**
Title: Role of localized hypothermia in neuro-protection in the inner ear
Principal Investigator: Rajguru, Suhrud
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-125 IIIF**
Title: The intersection of hypoxia and protein modification after SCI
Principal Investigator: Pearse, Damien
Primary Reviewer: **Tsoulfas, Pantelis**

6. Renewals-Closures

Number: **20-004 IIIC – CLOSURE**
Title: A Randomized, Controlled, Open-Label, Phase 2 Study of Cemiplimab as a Single Agent and in Combination With RP1 in Patients With Advanced Cutaneous Squamous Cell Carcinoma
Principal Investigator: Lutzky, Jose
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **23-007 IIIC – Renewal**
Title: A Phase 1/2, open-label study of PD-1 knockout tumor-infiltrating lymphocytes (IOV-4001) in participants with unresectable or metastatic melanoma or Stage III or IV non-small-cell lung cancer
Principal Investigator: Lutzky, Jose
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-058 IIIC– Renewal**
Title: Phase 2/3, Open-Label, Randomized, Controlled, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, Versus Ongoing Standard-Of-Care Immunosuppressive Therapy in Patients with Refractory Generalized Myasthenia Gravis (KYSA-6)
Principal Investigator: Perieira, Denise

Primary Reviewer: **Tsoulfas, Pantelis**