

Minutes
INSTITUTIONAL BIOSAFETY COMMITTEE
July 22, 2025
3:00 PM
Remote Meeting via Zoom

Members Present

Pantelis Tsoulfas, M.D.*
Ellen Kapsalis, Ph.D.
Kevin Sanders, D.V.M.
Micheline McCarthy, M.D., Ph.D
Rumela Chakrabarti, PhD**
Susanne Doblecki-Lewis, MD
Shane Gillooly
Mercina Drake¹
Julia Zaias, D.V.M, Ph.D
Ela Koncza
Jennifer Laine, PhD***
Lizzeth Meza ***

Members Absent

Sophia George, Ph.D.
Kevin Folta, Ph.D (ad hoc member)
Minh Tran, Ph.D
Dan Rothen, D.V.M
Kevin Mullen¹

* Denotes Chair

** Denotes Vice-Chair

*** Denotes BSO Alternate

¹ Denotes Community Representatives

1. Call to Order and Announcements:

The IBC meeting was held on July 22nd via Zoom. Dr. Tsoulfas chaired the meeting. After determining that there was a quorum, Dr. Tsoulfas called the meeting to order at 3:00 p.m.

- Minutes from June 24th meeting – approved by vote 8-0
- Minutes will be uploaded to the website.

2. Old Business

Protocol 25-061 (*renewal of 22-066*)

Principal Investigator: Dr. Levy, Robert

Project Title: Allogenic MiHa/MHC induced marrow allograft transplants

Training Verified: Pending revision

NIH Guidelines Section: Section III-D-1

Containment Conditions: BSL-2/ABSL-2

Agent Characteristics: CAR-T cells, mouse splenocytes, bone marrow cells

Types of Manipulations: Transplantation, CAR-T therapy, cyclophosphamide treatment
Source of Nucleic Sequences: Mouse (B6, BALB/c, C3H.SW)
Nature of Nucleic Acid Sequences: Chimeric antigen receptor gene
Hosts and Vectors: Murine models, lentiviral vectors
Transgene Expression: Yes, CAR-T protein for anti-tumor efficacy
**** Revised entry pending as of July 18th -- not scheduled for discussion**

3. New Business:

Protocol 25-064
Principal Investigator: Dr. Lombard, David
Project Title: Epigenetic and metabolic mechanisms of cadmium cytotoxicity
Training Verified: Verified
NIH Guidelines Section: Section III-D-3
Containment Conditions: BSL-2/ ABSL-1
Agent Characteristics: Cadmium, BRD4, BET inhibitors
Types of Manipulations: ChIP-seq, RNA-seq, mutagenesis, proteomics
Source of Nucleic Sequences: Human renal epithelial cells
Nature of Nucleic Acid Sequences: Epigenetic regulators, transcription factors
Hosts and Vectors: PTC22, 293T cells, lentiviral vectors
Transgene Expression: Yes, BRD4 mutants to study Cd toxicity
Committee Decision: Conditional approval (8-0)

Protocol: 25-070
Principal Investigator: Dr. Kuddanaya, Shreta
Project Title: Intra-arterial cell therapy in mouse model of photothrombotic stroke
Training Verified: Verified
NIH Guidelines Section: Section III-D-4
Containment Conditions: BSL-2+/ ABSL-2
Agent Characteristics: GFP/mCherry tagged stem cells
Types of Manipulations: Lentiviral transduction, in vivo imaging
Source of Nucleic Sequences: Human and murine stem cells
Nature of Nucleic Acid Sequences: Fluorescent reporter genes
Hosts and Vectors: C57BL/6 mice, lentiviral vectors
Transgene Expression: Yes, GFP and mCherry for cell tracking
Committee Decision: Conditional approval (8-0)

Protocol: 25-071 (*renewal of 22-027*)
Principal Investigator: Dr. Stelekati, Erietta
Project Title: Improving anti-tumor immunity with microRNAs
Training Verified: Verified
NIH Guidelines Section: Section III-D-5
Containment Conditions: BSL-2/ABSL-2
Agent Characteristics: miR-29, PD-1 antibody
Types of Manipulations: Transduction, adoptive transfer, antibody treatment

Source of Nucleic Sequences: Transgenic mice
Nature of Nucleic Acid Sequences: microRNA sequences
Hosts and Vectors: C57BL/6 mice, viral vectors
Transgene Expression: Yes, miR-29 to improve T cell function
Committee Decision: Conditional approval (8-0)

Protocol: 25-072
Principal Investigator: Dr. Moraes, Carlos
Project Title: Eliminating Mutant mtDNA to Increase Endurance
Training Verified: Verified
NIH Guidelines Section: Section III-D-3
Containment Conditions: BSL-1/ABSL-1
Agent Characteristics: AAV-CAP-B10, LNP/mitoARCUS
Types of Manipulations: Gene editing, retro-orbital and intramuscular injection
Source of Nucleic Sequences: Mouse
Nature of Nucleic Acid Sequences: Gene editing enzyme
Hosts and Vectors: Mouse, AAV and LNP vectors
Transgene Expression: Yes, enzyme to eliminate mutant mtDNA
Committee Decision: Conditional approval (8-0)

Protocol: 25-073
Principal Investigator: Dr. Shah, Ashish
Project Title: Use of Recombinant Retroviruses Encoding VPX for Gene Delivery in Glioblastoma Models
Training Verified: Verified
NIH Guidelines Section: Section III-D-3
Containment Conditions: BSL-2
Agent Characteristics: VPX protein, retroviral vectors
Types of Manipulations: Retroviral packaging, transduction, western blot, qRT-PCR
Source of Nucleic Sequences: SIVmac239, Moloney MLV
Nature of Nucleic Acid Sequences: VPX accessory protein, yCD2
Hosts and Vectors: GBM cell lines, MLV-based retroviral vectors
Transgene Expression: Yes, VPX and yCD2 for gene delivery and safety
Committee Decision: Conditional approval (8-0)

4. Addenda:

Number:	25-002 IIC ad01
Title:	Sonoma SBT77701-02 HS
Principal Investigator:	Lev-Tov, Hader
Primary Reviewer:	Tsoufas, Pantelis

Number: 25-003 IIIC ad01
Title: SCI Cell Therapeutics
Principal Investigator: Pearse, Damien
Primary Reviewer: Tsoulfas, Pantelis

5. Exemptions:

Number: 25-067 IIIF
Title: Fibroblasts and Fistula Failure - the mouse model
Principal Investigator: Martinez, Laisel
Primary Reviewer: Tsoulfas, Pantelis

Number: 25-068 IIIF
Title: Fibroblasts and Fistula Failure - the pig model
Principal Investigator: Martinez, Laisel
Primary Reviewer: Tsoulfas, Pantelis

Number: 25-069 IIIF
Title: Breeding protocol
Principal Investigator: Satkunendrarajah, Kajana
Primary Reviewer: Tsoulfas, Pantelis

6. Renewals-Closures

Number: 22-007 IIIC – RENEWAL
Title: Expanded access protocol (EAP) for subjects receiving idecabtagene vicleucel that is nonconforming for commercial release
Principal Investigator: Pereira, Denise
Primary Reviewer: Tsoulfas, Pantelis