Institutional Biosafety Committee – October 28, 2025

3:00 PM

Remote Meeting via Zoom

Members Present	Members Absent
Pantelis Tsoulfas, M.D.*	Sophia George, Ph.D.
Ellen Kapsalis, Ph.D.	Kevin Folta, Ph.D (ad hoc member)
Micheline McCarthy, M.D., Ph.D	Minh Tran, Ph.D
Susanne Doblecki-Lewis, MD	Dan Rothen, D.V.M
Kevin Sanders, D.V.M.	Kevin Mullen[1]
Julia Zaias, D.V.M, Ph.D	
Rumela Chakrabarti, PhD**	
Mercina Drake[1]	
Jennifer Laine, PhD***	
Shane Gillooly	
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 October 28th via Zoom. Dr. Chakrabarti chaired the meeting. After determining that there was a quorum, Dr. Chakrabarti called the meeting to order at 3:10 p.m.

   - Minutes from September 23rd meeting – approved by vote 7-0
     - Minutes will be uploaded to the website

2. **Discussion:**

   I. Incident involving mouse bite from IBC 22-003 IIID
      - Non-infected mouse bit lab member during initial acclimatation period
        - No issues with reporting

   II. On October 24th (Friday) a needlestick incident occurred in for IBC 22-147

- Incident involved lentivirus
- Individual reported to PI immediately and went to the Emergency Room for treatment
    - Incident occurred after regular working hours
    - Individual reached out to Employee Health 3 days later on October 27th (Monday)
        - Preliminary report sent to NIH on October 28th

- This is the 2nd needlestick incident in this lab
- PI needs to submit an action plan addressing what steps will be taken as this is a repeated incident.
- A communication will be sent to PI and Chair requiring PI and entire lab meet with the Biosafety Officer.

III. Discussion on how to address exposures/incidents
- Ideas on new signage/updated signage
- A discussion if and how an IBC mandate(s) should be implemented

Old Business

Protocol Number: 25-085

Principal Investigator: Dr. Jose Lutzky

Project Title: Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with an anti-PD-1 mAb in patients with advanced or metastatic solid tumors

Training Verification: Confirmed

NIH Guidelines Section: III-C

Containment Conditions: BSL-2; Class II BSC; aerosol precautions

Agent Characteristics:

- VSV-GP, replication competent, modified to reduce neurotropism
- Targets interferon-deficient cancer cells; neurotoxicity mitigated
- RNA virus; low recombination risk

Types of Manipulations:

- Preparation and administration of investigational viral product

Source(s) of Nucleic Sequences: LCMV WE HPI strain glycoprotein; VSV backbone

Nature of Nucleic Acid Sequences: Structural glycoprotein gene replacement; codon optimized

Host(s) and Vector(s): HEK293F cells; VSV-GP viral vector

Transgene Expression: No foreign gene expression beyond glycoprotein replacement

Discussion Points:

- Clarification requested on mechanisms limiting infection to cancer cells
- Committee emphasized need for precise language regarding biosafety cabinet use

Recommendation: Conditional approval; unanimously approved (7-0)

****Study approved November 13th**

New Business

Protocol Number: 25-105

Principal Investigator: Dr. Joana Almaca

Project Title: Studying vascular function in pancreatic islets

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- AAV for chemogenetic manipulation
- Pseudo-viruses encoding SARS-CoV spike protein

Types of Manipulations:

- In vivo ductal injections
- Ex vivo pancreas slice infection

Source(s) of Nucleic Sequences: Mouse and hamster tissue; viral vectors from repositories

Nature of Nucleic Acid Sequences: Chemogenetic constructs; SARS-CoV spike protein gene

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

Transgene Expression: Yes; spike protein and chemogenetic elements

Discussion Points:

- Clarification on AAV serotype and baculovirus use
- Details on spike protein involvement

Recommendation: Conditional approval; unanimously approved (7-0)

**** Revised entry pending as of November 18th**

Protocol Number: 25-106

Principal Investigator: Dr. Brian Walker

Project Title: Functional genomics in multiple myeloma

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentiviral vectors (2nd/3rd generation)
- CRISPR/Cas9 components
- siRNA

Types of Manipulations:

- Gene knockout/overexpression
- Lentiviral transduction
- Xenograft development

Source(s) of Nucleic Sequences: Human myeloma cell lines; patient-derived xenografts

Nature of Nucleic Acid Sequences: Oncogenes, RNA processing genes (e.g., DIS3, TENT5C)

Host(s) and Vector(s): Human cell lines; SCID mice; lentiviral and non-lentiviral vectors

Transgene Expression: Yes; functional studies of oncogenic mutations and gene regulation

Discussion Points:

- Concern over use of 2nd generation lentivectors
- Recommendation to split protocol into smaller projects for clarity

Recommendation: Conditional approval; unanimously approved (7-0)

**** Revised entry pending as of November 17th**

Protocol Number: 25-107

Principal Investigator: Dr. Kiran Kurmi

Project Title: Metabolic adaptations in cancer and immunity

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentiviral and retroviral vectors; replication-deficient

Types of Manipulations:

- Gene knockout/overexpression
- Viral transduction
- Metabolic assays

Source(s) of Nucleic Sequences: Human and mouse genes (e.g., PRPS2, HPRT1)

Nature of Nucleic Acid Sequences: Structural and regulatory genes

Host(s) and Vector(s): HEK293T packaging cells; mammalian cell lines; lentiviral/retroviral vectors

Transgene Expression: Yes; metabolic gene function studies

Discussion Points:

- Committee requested clearer breakdown of experiments by viral system
- Updates to registration forms and PPE details

Recommendation: Conditional approval; unanimously approved (7-0)

****Revised entry received – the study was approved November 11th**

Protocol Number: 25-108

Principal Investigator: Dr. Kirill Martemyanov

Project Title: Regulation of retina synaptic signaling

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2; ABSL-2 for animal work

Agent Characteristics:

- Lentivirus, AAV, adenovirus, pseudorabies virus (attenuated), bacteriophages

Types of Manipulations:

- Gene transfer in cultured cells and live mice
- Viral injections
- Electroporation

Source(s) of Nucleic Sequences: Mouse and human genes encoding GPCR signaling components

Nature of Nucleic Acid Sequences: Structural and regulatory genes; reporter constructs

Host(s) and Vector(s): Mammalian cell lines; Mus musculus; multiple viral vectors

Transgene Expression: Yes; functional studies of signaling proteins

Discussion Points:

- Clarification needed on pseudorabies and adenovirus use
- Request for detailed experimental breakdown and vector maps

Recommendation: Conditional approval; unanimously approved (7-0)

**** Revised entry received – protocol was approved November 10th**

Protocol Number: 25-109

Principal Investigator: Dr. Damien Pearse

Project Title: Harnessing the benefits of stem cells for the treatment of spinal cord injury

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Lentiviral vectors encoding fluorescent proteins and therapeutic peptides

Types of Manipulations:

- Ex vivo transduction of Schwann cells and neural stem cells

- Implantation into rodent SCI models

Source(s) of Nucleic Sequences: Human and mouse genes; lentiviral constructs

Nature of Nucleic Acid Sequences: Reporter genes (EGFP/RFP); peptides (RVG29, CB1); cytokines (IL-4); neurotrophic factors (GDNF)

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

Transgene Expression: Yes; for tracking and therapeutic modulation

Discussion Points:

- Committee requested details on changes since last review (new vectors, genes)

Recommendation: Conditional approval; unanimously approved (7-0)

**** Revised entry received – study approved October 30th**

Protocol Number: 25-110

Principal Investigator: Dr. Gregory Holt

Project Title: Augmentation of tumor microenvironments using nanoparticles and pro-inflammatory adjuvants

Training Verification: Confirmed

NIH Guidelines Section: III-D

Containment Conditions: BSL-2

Agent Characteristics:

- Plasmid DNA and RNA encoding immune-stimulating adjuvants; nanoparticle complexes

Types of Manipulations:

- Recombinant DNA preparation
- Nanoparticle formulation
- In vivo injections in mice

Source(s) of Nucleic Sequences: Immune-stimulatory genes from plasmid libraries

Nature of Nucleic Acid Sequences: Cytokine/adjuvant genes

Host(s) and Vector(s): Mouse tumor models; plasmid vectors; nanoparticles

Transgene Expression: Yes; immune modulation within tumor microenvironment

Discussion Points:

- Committee requested details on nanoparticle composition

Recommendation: Conditional approval; unanimously approved (7-0)

**** Revised form pending as of November 17th**

Addenda:

Number:	**23-007 IIIC ad04**
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:	**24-030 IIIC ad05**
Title:	Randomized, open-label study of the BRIA-IMT regimen and check point inhibitor vs physician's choice in advanced metastatic breast cancer (BRIA-ABC)
Principal Investigator:	Negret, Lawrence
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**24-057 IIIC ad02**
Title:	A Phase 1/1b Study of VET3-TGI Administered Alone and in Combination with Atezolizumab in Patients with Advanced Solid Tumors
Principal Investigator:	Merchan, Jaime
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**24-064 IIIC ad02**

Title:	Phase 2, Open-label, Multi center Study Investigating RP2 Oncolytic Immunotherapy in Combination with Second-line Therapy in Patients with Locally Advanced Unresectable, Recurrent and/or Metastatic Hepatocellular Carcinoma
Principal Investigator:	Sharma, Janaki
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**25-011 IIIC ad01**
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:	Shah, Ashish
Primary Reviewer:	**Meza, Lizzeth**

Number:	**25-028 IIIC ad01**
Title:	A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma
Principal Investigator:	Hernandez Aya, Leonel
Primary Reviewer:	**Tsoulfas, Pantelis**

Exemptions:

Number:	**25-111 IIIF**
Title:	Breeding protocol to study the role of myeloid-derived suppressor cells in local and systemic immunosuppression in glioblastoma

Principal Investigator: Bayik Watson, Defne
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-112 IIIF**
Title: Slow-Wave Sleep as a Mediator of DNA Damage and Repair Mechanisms in Mice
Principal Investigator: Wahlestedt, Claes
Primary Reviewer: **Tsoulfas, Pantelis**

Renewals-Closures

Number: **24-005 IIIC – CLOSURE**
Title: A Phase 1/2 study investigating the safety and efficacy of autologous TAC T cells in subjects with unresectable, locally advanced or metastatic claudin 18.2+ solid tumors
Principal Investigator: Hosein, Peter
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-053 IIIC – Renewal**
Title: Randomized Phase 2 Study Assessing the Efficacy and Safety of Olvimulogene Nanivacirepvec Followed by Platinum-doublet Chemotherapy + Physician's Choice of Immune Checkpoint Inhibitor Compared with Docetaxel in Patients with Non-Small-Cell Lung Cancer after First Progression While on Front-line Immune Checkpoint Inhibitor-based Maintenance (VIRO-25 Study)
Principal Investigator: Dawar, Richa
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**