Institutional Biosafety Committee – January 27, 2026 Meeting Minutes

Members Present	Members Absent
Rumela Chakrabarti, PhD**	Sophia George, Ph.D.
Ellen Kapsalis, Ph.D.	Kevin Folta, Ph.D (ad hoc member)
Julia Zaias, D.V.M, Ph.D	Minh Tran, Ph.D
Susanne Doblecki-Lewis, MD	Dan Rothen, D.V.M
Micheline McCarthy, M.D., Ph.D	Ela Koncza
Kevin Mullen1	Shane Gillooly
Jennifer Laine, PhD***	Kevin Sanders, D.V.M.
Mercina Drake1	
Pantelis Tsoulfas, M.D.*	
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 January 27th via Zoom. Dr. Chakrabarti chaired the meeting. After determining that there was a quorum, Dr. Chakrabarti called the meeting to order at 2:30 p.m.

- Minutes from December 16th meeting – approved by vote 7-0
  - Minutes will be uploaded to the website

2. Discussion:

I. Transgenic mouse bite from 25-081 Satkunendrarajah study reported to IBC and EHS. Mouse was naïve. Report to NIH not required

II. On January 26th, a nurse working on 25-081 Negret IIIC was splashed in the face and eyes with agent (peginterferon alpha2a) due to malfunction of the syringe. Preliminary report sent to NIH January 27th.

Mercina Drake joined the meeting

OLD BUSINESS (Unfinished)

Protocol 25-101 — PI: Dr. Ashish Shah

Project Title: HERV-K Envelope as a Target for CAR T Immunotherapy in Glioblastoma

Training Verification: PI and laboratory staff are appropriately trained for BSL-2 operations, lentiviral vector work, and animal procedures.

NIH Guidelines Category: Section III-D (lentiviral vectors and recombinant T-cells)

Containment Conditions: BSL-2 for in vitro work; ABSL-2 recommended for in vivo mouse studies involving CAR T cells.

Agent Characteristics: Replication-deficient HIV-based lentiviral vector; engineered human donor T cells targeting HERV-K (HML-2) Env expressed in GBM; low environmental stability; potential for inflammatory responses if accidental exposure occurs.

Types of Manipulations: Validation assays (cytotoxicity, cytokine secretion); production and use of 4-plasmid lentiviral system; intracranial tumor implantation in mice; intracranial/intravenous CAR T-cell administration; monitoring of tumor progression.

Source(s) of Nucleic Sequences: Human donor T-cells; lentiviral plasmids; nanobody sequences specific to HERV-K Env.

Nature of Nucleic Acid Sequences: CAR transgene with costimulatory domains; VSV-G envelope for pseudotyping.

Hosts and Vectors: Hosts: human T cells, human GBM cell lines, NSG mice; Vectors: HIV-based 4-plasmid lentiviral system.

Transgene Expression: Yes. CAR transgene expressed in engineered T cells to target HERV-K Env.

Summary of Discussion Points: Risk severity for human harm increased from Very Low to Low due to potential inflammatory side effects. Committee requested corrections and additions in the rDNA survey and laboratory biological summary. ABSL classification recommended as ABSL-2.

Recommendation: Conditional approval; unanimously approved (8–0).

Dr. Tsoulfas joined the meeting

NEW BUSINESS

Protocol 26-009 — PI: Dr. Kevin Van der Jeught

Project Title: Targeting the Immune System to Improve Cancer Immunotherapy

Training Verification: All personnel completed applicable BSL-2, lentiviral vector, and rDNA training.

NIH Guidelines Category: Section III-D (lentiviral vectors and recombinant DNA)

Containment Conditions: BSL-2 for all recombinant and viral vector work.

Agent Characteristics: HIV-based, replication-incompetent lentiviral vectors; mRNA/plasmid constructs expressing immune-modulating genes; inactivated by standard disinfectants.

Types of Manipulations: Plasmid construction, transfection, lentiviral transduction; CRISPR knockouts, shRNA knockdowns; in vitro immunological assays; mRNA vaccine platform optimization.

Source(s) of Nucleic Sequences: Human and mouse immune-related genes (e.g., ST2, IL-33, OVA); commercial and core vectors.

Nature of Nucleic Acid Sequences: Structural/signaling genes; reporter genes (fluorescent, luciferase).

Hosts and Vectors: Hosts: human and mouse cell lines; Vectors: HIV-based, VSV-G pseudotyped lentiviral systems.

Transgene Expression: Yes. Expression of immune-modulating genes, reporters, and knockdown constructs.

Summary of Discussion Points: Risk ratings to be corrected from Moderate to Low; corrections to viral vector form (helper virus, host range, clinical-use question); transgenic arthropod entry to be corrected.

Recommendation: Conditional approval; unanimously approved (9–0).

Protocol 26-008 — PI: Dr. Defne Bayik Watson

Project Title: Investigation of New Therapeutic Targets for Glioblastoma

Training Verification: Personnel trained for BSL-2 tissue culture and lentiviral work.

NIH Guidelines Category: Section III-D (lentiviral vectors and genetic modification)

Containment Conditions: BSL-2 for cell/vector work; ABSL-2 for in vivo implantation of modified cells.

Agent Characteristics: Replication-deficient lentiviral vectors; genetically modified mouse GBM cell lines (RG2 agents).

Types of Manipulations: Lentiviral transduction; intracranial implantation; co-culture assays; perfusion and tissue harvesting.

Source(s) of Nucleic Sequences: Mouse tumor-associated genes (e.g., NRAS-G12V, shP53, shATRX); standard lentiviral backbones.

Nature of Nucleic Acid Sequences: Oncogenic drivers, shRNA constructs, fluorescent markers.

Hosts and Vectors: Hosts: multiple mouse GBM models; Vectors: lentiviral and transposon-based systems.

Transgene Expression: Yes. Knockdown and overexpression of target genes in tumor models.

Summary of Discussion Points: Clarify "injection" vs. "transfection"; risk severity set to Low; provide viral production details; update rDNA survey responses.

Recommendation: Conditional approval; unanimously approved (9–0).

Dr. Zaias left the meeting

Protocol 26-007 — PI: Dr. Defne Bayik Watson

Project Title: Drivers of Local and Systemic Immunosuppression in Glioblastoma

Training Verification: Personnel trained for BSL-2 and ABSL-2 work.

NIH Guidelines Category: Section III-D

Containment Conditions: BSL-2 for vector and culture work; ABSL-2 for implantation of modified tumor cells.

Agent Characteristics: Lentiviral vectors; genetically altered murine tumor cells expressing immunologic markers.

Types of Manipulations: Lentiviral transduction; intracranial implantation; flow cytometry; perfusion and tissue processing.

Source(s) of Nucleic Sequences: Mouse tumor antigens and knockdown constructs; fluorescent reporters.

Nature of Nucleic Acid Sequences: shRNA/overexpression vectors; antigen constructs (e.g., OVA).

Hosts and Vectors: Hosts: WT and knockout mice; tumor cell lines. Vectors: lentiviral.

Transgene Expression: Yes. Expression of OVA, GFP, and other markers as designed.

Summary of Discussion Points: Clarify plasmids used; increase risk levels to Low; correct helper virus and host-range responses in viral vector form.

Recommendation: Conditional approval; unanimously approved (8–0).

Protocol 26-010 — PI: Dr. Sundaram Ramakrishnan

Project Title: Immunotherapy of Cancer

Training Verification: Training in rDNA, lentiviral systems, animal handling, and BSL-2 confirmed.

NIH Guidelines Category: Section III-D

Containment Conditions: BSL-2 for recombinant work; ABSL-2 for tumor implantation and vaccine studies.

Agent Characteristics: Recombinant bacterial proteins (superantigen domains); lentiviral vectors expressing immune-stimulatory proteins; non-toxic DT-B domain.

Types of Manipulations: Protein coating of tumor cells; lentiviral transduction; murine vaccination and tumor challenge; chemo–immunotherapy combinations.

Source(s) of Nucleic Sequences: Bacterial superantigen domains and DT-B subunit sequences cloned into mammalian vectors.

Nature of Nucleic Acid Sequences: Immune-stimulatory domains designed to enhance tumor immunogenicity.

Hosts and Vectors: Hosts: multiple mouse tumor models; Vectors: mammalian expression vectors and lentiviral systems.

Transgene Expression: Yes. Expression of TSST-1 domains and DT-B in cancer cells.

Summary of Discussion Points: Remove outdated cross-reference; ensure OHP enrollment with DT vaccine access; submit biological hygiene plan.

Recommendation: Conditional approval; unanimously approved (8–0).

Protocol 25-011 — PI: Dr. Anna Lasorella

Project Title: Testing the Role of DNA Repair Inhibitors in Sensitizing Malignant Glioma to Gamma Irradiation

Training Verification: Personnel trained in rDNA, lentiviral use, and animal procedures.

NIH Guidelines Category: Section III-D

Containment Conditions: BSL-2 for lentiviral and tumor cell manipulation; ABSL-2 for xenograft studies.

Agent Characteristics: Lentiviral vectors expressing shRNA/CRISPR reagents; glioblastoma cell lines; DNA repair inhibitors.

Types of Manipulations: Lentiviral transduction; subcutaneous and intracranial xenografts; irradiation; histology.

Source(s) of Nucleic Sequences: shRNA/CRISPR guides targeting DNA-PK and related DDR components.

Nature of Nucleic Acid Sequences: Knockdown constructs targeting DNA repair pathways.

Hosts and Vectors: Hosts: Nude and NOD-SCID mice; Vectors: lentiviral CRISPR and shRNA.

Transgene Expression: Yes. Knockdown of DNA-PK and related DDR targets.

Summary of Discussion Points: No substantive corrections requested; protocol was clear and comprehensive.

Recommendation: Full approval; unanimously approved (8–0).

Protocol 26-012 — PI: Dr. Kajana Satkunendrarajah

Project Title: Spinal Interneurons

Training Verification: All personnel trained in BSL-1/2 as applicable, AAV handling, and rodent surgery.

NIH Guidelines Category: Section III-D (AAV delivery)

Containment Conditions: BSL-1/2 depending on AAV use; ABSL-1/2 for animal procedures as applicable.

Agent Characteristics: AAV vectors expressing GCaMP variants; non-replicating; low pathogenicity.

Types of Manipulations: AAV delivery to spinal cord; GRIN lens implantation; longitudinal in vivo imaging; behavioral testing.

Source(s) of Nucleic Sequences: GCaMP indicator genes; Cre recombinase in certain cohorts.

Nature of Nucleic Acid Sequences: Reporter genes enabling neuronal activity imaging.

Hosts and Vectors: Hosts: WT and transgenic mice; Vectors: AAV for targeted neuronal labeling.

Transgene Expression: Yes. Expression of GCaMP in projection-defined or genetically defined neurons.

Summary of Discussion Points: Committee requested clarification of AAV use, target genes, and rationale relative to aims.

Recommendation: Conditional approval; unanimously approved (7–0).

Addenda:

Number:	**23-137 IIIC ad06**
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:	**Tsoulfas, Pantelis**

Number:	**23-137 IIIC ad07**
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:	**Tsoulfas, Pantelis**

Number:	**24-056 IIIC ad01**
Title:	CA061-1001 : A Phase 1 Study of CD19-targeted NEX-T CAR T Cells in Participants with Severe, Refractory Autoimmune Diseases
Principal Investigator:	Lekakis, Lazaros
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**24-080 IIIC ad08**
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:	Feun, Lynn
Primary Reviewer:	**Tsoulfas, Pantelis**

Exemptions:

Number:	**26-001 IIIF**
Title:	Breeding Protocol 2026
Principal Investigator:	Liebl, Daniel
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**26-002 IIIF**
Title:	Repetitive closed-skull mild traumatic brain injury in mice
Principal Investigator:	Liebl, Daniel
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**26-003 IIIF**
Title:	Stabilizing the tripartite synapse - 2026
Principal Investigator:	Liebl, Daniel
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**26-004 IIIF**
Title:	Optogenetic Intrinsic Retinal Stimulation in a Mouse Model of Amblyopia
Principal Investigator:	Lee, Richard
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**26-005 IIIF**
Title:	Breeding protocol for molecular and epigenetic mechanism of lymphomas
Principal Investigator:	Rivas, Martin
Primary Reviewer:	**Tsoulfas, Pantelis**

Number: **26-006 IIIF**
Title: Motor neuron function in WT and fALS mice
Principal Investigator: Barrett, Ellen
Primary Reviewer: **Tsoulfas, Pantelis**

Renewals-Closures

Number: **21-109 IIIC -- Renewal**
Title: Expanded access protocol (EAP) for subjects receiving lisocabtagene maraleucel that is nonconforming for commercial release
Principal Investigator: Beitinjaneh, Amer
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **22-082 IIIC -- Renewal**
Title: A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33-hNIS), Administered Intratumorally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumors (MAST)
Principal Investigator: Merchan, Jaime
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **23-108 IIIC -- Closure**
Title: A Phase 1 Open-label, single arm, multicenter study evaluating the safety and efficacy of KITE-197 in subjects with relapsed or refractory Large B-cell Lymphoma
Principal Investigator: Speigel, Jay
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-065 IIIC -- Renewal**
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: Mouzannar, Ali
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-079 IIIC -- Renewal**
Title: SVV-001-003 : Phase 1 Trial of SVV-001 with Nivolumab and Ipilimumab in Patients with Poorly differentiated NEC or Well-Differentiated High-Grade NET
Principal Investigator: Hosein, Peter
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-001 IIIC -- Renewal**
Title: CTO-IUSCCC-0840 : Chimeric Antigen Receptor T Cell Therapy Redirected to CD4 (CD4CAR)as a Second Line Treatment for Chronic Myelomonocytic Leukemia, CMML
Principal Investigator: Beitinjaneh, Amer
Primary Reviewer: **Tsoulfas, Pantelis**