Institutional Biosafety Committee – February 24, 2026 Meeting Minutes

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

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

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1. **Call to Order and Announcements:**
   The IBC meeting was held on February 24th via Zoom. Dr. Tsoulfas chaired the meeting. After determining that there was a quorum, Dr. Tsoulfas called the meeting to order at 2:30 p.m.
   - Minutes from January 27th meeting – approved by vote 8-0
     - Minutes will be uploaded to the website

2. **Discussion:**
   I. NIH townhall regarding biosafety oversight direction
   II. BioRaft update within the next coming months

NEW BUSINESS

26-013 – Epigenetics of Liver Cancer

PI: Dr. Lluis Morey
Project Title: *Epigenetics of Liver Cancer*
Training Verification: PI and all staff have completed required biosafety and recombinant DNA training per standard IBC requirements (implied by submission approval).
Applicable NIH Guidelines: Section **III-D** (recombinant DNA in whole animals; CRISPR-mediated gene editing; lentiviral manipulation ex vivo).
Containment Conditions: BSL-2 for in vitro and ex vivo work; ABSL-2 for murine

procedures.

Agent Characteristics:

- Mouse hepatocellular carcinoma models; genetically modified murine hepatocytes.
- Non-replicating recombinant plasmids (Sleeping Beauty transposon donors, CRISPR/Cas9 plasmids).
- Lentiviral CRISPR knockout libraries (non-replicating).
- Not pathogenic to humans; standard laboratory strains.

Types of Manipulations:

- Generation of conditional knockout mouse lines (Ring1B deletion).
- CRISPR-mediated screens in mouse and human HCC organoids.
- Hydrodynamic tail-vein plasmid delivery of oncogene constructs (e.g., cMyc, β-catenin, sgPTEN, sgTP53).
- Diet- and chemical-induced liver fibrosis/tumorigenesis.
- Orthotopic and intrasplenic organoid transplantation.
- Longitudinal blood sampling for biomarker analyses.

Sources of Nucleic Acid Sequences:

- Human and mouse HCC cell lines (Huh1, Huh7, HLE, Myc/p53, Myc/PTEN/β-Cat, Myc/Keap1).
- Mouse transgenic models.
- Plasmid constructs encoding oncogenes or CRISPR targets derived from murine or human sequences.

Nature of Nucleic Acid Sequences:

- Structural and regulatory genes associated with hepatocarcinogenesis (oncogenes and tumor suppressors).
- CRISPR guide RNA libraries targeting PRC1/PRC2 epigenetic regulators.

Hosts and Vectors:

- **Hosts:** Mouse (C57BL/6), NSG, RAG1-/- mice; human/mouse HCC cell lines and organoids.
- **Vectors:** Lentiviral CRISPR libraries; non-viral plasmids; Sleeping Beauty transposon system.

Transgene Expression:

- Yes. Expression of oncogenic or tumor-suppressor targets for liver cancer modeling.

- Functional proteins include transcription regulators, signaling molecules, and epigenetic modifiers.

Discussion Summary:

Committee discussed the need for clarified plasmid origins, CRISPR library component lists, clarification of in vitro vs. in vivo steps, and updates to lab biosafety summaries and vector registration documents.

Recommendation:

Conditional approval; unanimously approved 8-0.
Revised materials were later approved March 19.

26-014 – Toxicity and Efficacy of Schwann Cells and Combined Therapies in Spinal Cord Injury

PI: Dr. Damian Pearse
Project Title: *Toxicity and Efficacy of Schwann Cells and Other Combined Therapies for Spinal Cord Injury Therapeutics*
Training Verification: Required biosafety and rDNA training verified.
Applicable NIH Guidelines: Section III-D (recombinant DNA-modified cells for transplantation into animals).
Containment Conditions: BSL-1 (for non-viral manipulations) and BSL-2 for genetically modified cells.
Agent Characteristics:

- Genetically modified Schwann cells expressing GFP.
- Potential use of AAV (non-replicating viral vector).
- Not associated with human pathogenicity.

Types of Manipulations:

- Schwann cell genetic modification (GFP expression).
- Cell transplantation into spinal cord injury sites.
- Potential AAV transduction steps (details pending revision).

Nucleic Acid Sequence Sources:

- GFP reporter sequences (jellyfish origin).
- Mammalian Schwann cell genes modulated for therapeutic characterization.

Nature of Nucleic Acids:

- Reporter genes and regulatory sequences enhancing survival/tracking.

Hosts and Vectors:

- **Hosts:** Rodent spinal cord injury models.
- **Vectors:** GFP expression vectors; AAV vector use anticipated but requiring clarification.

Transgene Expression:

- Yes; GFP protein expression for tracking transplanted cells.

Discussion Summary:

Committee requested clarification of **how AAV will be used**, including route of administration and serotype, and methodology for toxicity and efficacy assessments.

Recommendation:

Conditional approval; unanimously approved 8-0.
Revised submission **pending** as of March 19.

26-015 – Charcot–Marie–Tooth Disease (CMT)

PI: Dr. Stephen Züchner
Project Title: *CMT*
Training Verification: All laboratory personnel maintain current biosafety and rDNA training.
Applicable NIH Guidelines: Section III-D (AAV use in culture; plasmid transfection into mammalian cells).
Containment Conditions: BSL-2 for plasmid and AAV work.
Agent Characteristics:

- Mammalian expression plasmids expressing wild-type or mutant human CMT-associated genes.
- AAV vectors used to deliver experimental constructs to mammalian cells.
- Non-replicating; non-pathogenic.

Types of Manipulations:

- Plasmid transfection of CMT-related genes.
- AAV infection of cultured cell lines and patient-derived cells.
- Functional and expression assays.

Nucleic Acid Sequence Sources:

- Human genes associated with CMT (Homo sapiens).
- Synthetic constructs used for functional assays.

Nature of Nucleic Acids:

- Structural, regulatory, and splicing-related sequences relevant to neurodegenerative disease.

Hosts and Vectors:

- **Hosts:** HEK293, patient fibroblasts, iPSC-derived neural and Schwann-like cells.
- **Vectors:** Plasmid expression vectors; AAV viral vectors.

Transgene Expression:

- Yes. Expression of wild-type or mutant human proteins related to peripheral nerve biology.

Discussion Summary:

Committee requested clarity on AAV workflow, distinction between plasmids and viral vectors, and corrections to rDNA and source materials sections. Requested clear differentiation between CMT and unrelated conditions to avoid protocol ambiguity.

Recommendation:

Conditional approval; unanimously approved 8-0.
Revised entry **pending** as of March 19.

26-016 – Hereditary Spastic Paraplegia (HSP)

PI: Dr. Stephen Züchner
Project Title: *HSP*
Training Verification: Required biosafety and rDNA training completed.
Applicable NIH Guidelines: Section III-D (recombinant plasmids and AAV in cell culture).
Containment Conditions: BSL-2 for plasmid and AAV manipulations.
Agent Characteristics:

- Plasmid expression constructs encoding human genes associated with HSP or related neurological disorders.
- AAV vectors for cell transduction (non-replicating).
- No pathogens involved.

Types of Manipulations:

- Plasmid transfection.
- AAV transduction of mammalian cell lines and patient-derived cells.
- Assays of RNA splicing, protein function, or neuronal phenotypes.

Nucleic Acid Sequence Sources:

- Human genes implicated in HSP.
- Synthetic constructs for mutational analysis.

Nature of Nucleic Acids:

- Structural, regulatory, and splicing-relevant sequences.

Hosts and Vectors:

- **Hosts:** HEK293 cells, patient fibroblasts, iPSC-derived neural cells.
- **Vectors:** Mammalian expression plasmids; AAV vectors.

Transgene Expression:

- Yes. Proteins associated with HSP pathogenesis and neuronal function.

Discussion Summary:

Committee requested step-by-step explanation of AAV use, corrections to plasmid descriptions, updates to biosafety materials, and clarification between HSP and unrelated spinocerebellar ataxia content.

Recommendation:

Conditional approval; unanimously approved 8-0.
Revised entry **pending** as of March 19.

Addenda:

Number:	**24-043 IIIC ad01**
Title:	Phase 1/2, First-in-Human, Open-label, Assessor-Masked, Randomized, Controlled, Dose Escalation/Expansion Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of a Subretinal Injection of SB-007 in Subjects with Stargardt Disease (STGD1) Caused by Bi-Allelic Autosomal Recessive Mutations in the ATP Binding Cassette Subfamily A Member 4 (ABCA4) Gene (ASTRA)
Principal Investigator:	Lam, Byron
Primary Reviewer:	**Tsoulfas, Pantelis**

Number:	**25-083 IIIC ad01**

Title:	A Phase 2, Multicenter, Open-Label Study of CC-97540 (BMS-986353), CD19- Targeted NEX-T CAR T Cells, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)
Principal Investigator:	Lekakis, Lazaros
Primary Reviewer:	**Tsoulfas, Pantelis**

Exemptions:

Number:	**26-017 IIIF**
Title:	Akt/mTOR in the Regulation of Pancreatic Beta Cell Mass Function and Development
Principal Investigator:	Bernal Mizrachi, Ernesto
Primary Reviewer:	**Tsoulfas, Pantelis**

Renewals-Closures

Number:	**18-112 IIIC - CLOSURE**
Title:	An open-label, multicenter, phase 1/2 study of RP1 as a single agent and in combination with PD1 blockade in patients with solid tumors
Principal Investigator:	Hernandez Aya, Leonel
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:	**21-008 IIIC -- Renewal**
Title:	AN OPEN-LABEL, MULTICENTER, PHASE 1B/2 STUDY OF RP1 IN SOLID ORGAN

TRANSPLANT RECIPIENTS WITH ADVANCED CUTANEOUS MALIGNANCIES

Principal Investigator: Tang, Jennifer
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-011 IIIC -- Renewal**
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
Principal Investigator: Shah, Ashish
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **25-036 IIIC -- Renewal**
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**