

**Minutes**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**August 26, 2025**  
**3:00 PM**  
**Remote Meeting via Zoom**

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Members Present

Pantelis Tsoulfas, M.D.\*  
Ellen Kapsalis, Ph.D.  
Micheline McCarthy, M.D., Ph.D.  
Rumela Chakrabarti, Ph.D.\*\*  
Susanne Doblecki-Lewis, M.D.  
Shane Gillooly  
Mercina Drake<sup>1</sup>  
Kevin Mullen<sup>1</sup>  
Julia Zaias, D.V.M, Ph.D.  
Ela Koncza  
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 Sanders, D.V.M.  
Jennifer Laine, Ph.D.\*\*\*

\* Denotes Chair

\*\* Denotes Vice-Chair

\*\*\* Denotes BSO Alternate

<sup>1</sup> Denotes Community Representatives

**1. Call to Order and Announcements:**

The IBC meeting was held on August 26<sup>th</sup> via Zoom. The Vice-Chair led the meeting until Project 25-084 was discussed. The Chair presided at that point. After determining that there was a quorum, the Vice-Chair called the meeting to order at 3:00 p.m.

- Minutes from July 22<sup>nd</sup> meeting – approved by vote 8-0
- Minutes will be uploaded to the website

**2. Discussion:**

- Needlestick incident involving EcoHIV will be reported to the NIH Office of Science Policy.
- Biosafety Officer to investigate potential increase in needlestick injuries.
- Proposal to merge Biosafety Hygiene Plan Form with Biohazardous Exposure Response Form submitted to Associate Vice Provost of Research Regulation, Integrity, Security and Evaluation.
- Retraining with EHS for all staff and PI along with animal handling training with DVR is recommended by Committee

**3. New Business:**

**Project 25-080: Investigating the role of integrin  $\alpha\beta 5$  in irisin induced neuroprotection**

- **PI Name:** Dr. Ami Raval
- **Project Title:** Investigating the role of integrin  $\alpha\beta 5$  in irisin induced neuroprotection
- **Agent Characteristics:** AAV2/PHP.eB vector; low pathogenicity; stable in vivo
- **Manipulations Planned:** Astrocyte-specific knockdown of integrin  $\alpha\beta 5$  using shRNA
- **Source of Nucleic Sequences:** Rat integrin gene (*Itgb5*)
- **Nature of Sequences:** Structural gene (*Itgb5*), shRNA targeting
- **Host/Vector:** Rats; AAV2/PHP.eB vector

- **Transgene Expression:** Yes; EGFP reporter and FLAG tag for tracking knockdown
- **Training Verification:** Implied via committee approval
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-1

**RECOMMENDATION:**

The reviewer recommends approval of the study. The Committee unanimously approved (8-0).

**Project 25-081: Neural Circuits - SCI**

- **PI Name:** Dr. Kajana Satkunendrarajah
- **Project Title:** Neural Circuits - SCI
- **Agent Characteristics:** AAV9 vector; low virulence; stable in CNS
- **Manipulations Planned:** Stereotaxic injection of AAV9-CaMKII $\alpha$ -GFP into mouse brain
- **Source of Nucleic Sequences:** Mouse CaMKII $\alpha$  promoter, GFP gene
- **Nature of Sequences:** Reporter gene (GFP)
- **Host/Vector:** C57BL/6J and Vglut2-Cre::Ai14 tdTomato mice; AAV9 vector
- **Transgene Expression:** Yes; GFP for tracing neural circuits
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-1

**RECOMMENDATION:**

The reviewer recommends conditional approval of the study. The Committee unanimously approved (8-0).

**Project 25-082: BMS-986393 CAR-T Therapy for Multiple Myeloma**

- **PI Name:** Dr. Damian Green
- **Project Title:** Phase 3 Study of BMS-986393 CAR-T Therapy
- **Agent Characteristics:** Lentiviral vector; replication-defective; pseudotyped with VSV-G
- **Manipulations Planned:** Ex vivo transduction of autologous T cells with CAR construct
- **Source of Nucleic Sequences:** Human GPRC5D gene
- **Nature of Sequences:** Chimeric antigen receptor (CAR) transgene
- **Host/Vector:** Human T cells; lentiviral vector
- **Transgene Expression:** Yes; CAR protein targeting GPRC5D
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-C
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of the study. The Committee unanimously approved (8-0).

*Dr. Tsoulfas joined the meeting*

**Project 25-083: CC-97540 CAR-T Therapy for SLE**

- **PI Name:** Dr. Lazaros Lekakis
- **Project Title:** Phase 2 Study of CC-97540 CAR-T for SLE
- **Agent Characteristics:** Lentiviral vector; replication-defective

- **Manipulations Planned:** Transduction of T cells with CD19-specific CAR
- **Source of Nucleic Sequences:** Human CD19 gene
- **Nature of Sequences:** CAR transgene
- **Host/Vector:** Human T cells; lentiviral vector
- **Transgene Expression:** Yes; CD19-targeting CAR protein
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-C
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of the study. The Committee unanimously approved (9-0).

**Project 25-084: Integrin Activation in Swine AVF Model**

- **PI Name:** Dr. Vazquez-Padron, Roberto
- **Project Title:** Integrin Activation to Prevent AVF Failure
- **Agent Characteristics:** Adenovirus vector; high transduction efficiency; transient expression
- **Manipulations Planned:** Infusion of Ad vectors carrying  $\beta$ -gal or GFP into swine veins
- **Source of Nucleic Sequences:** Reporter genes ( $\beta$ -galactosidase, GFP)
- **Nature of Sequences:** Reporter genes
- **Host/Vector:** Swine; adenovirus vector
- **Transgene Expression:** Yes; for transduction efficiency assessment
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of this study. The Committee unanimously approved (9-0).

**Project 25-085: 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**

- **PI Name:** Dr. Lutzky, Jose
- **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
- **Agent Characteristics:** Vesicular Stomatitis Virus (VSV); modified to target and kill cancer cells
- **Manipulations Planned:** Administration of VSV alone and in combination with ezabenlimab or pembrolizumab
- **Source of Nucleic Sequences:** VSV genome
- **Nature of Sequences:** Oncolytic viral genome
- **Host/Vector:** Human patients; VSV vector
- **Transgene Expression:** Yes; to assess tumor targeting and immune response
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-C
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends tabling this study due to lack of details. The Committee unanimously approved (9-0).

**Project 25-086: A Phase 2 Open-label Study to Evaluate the Safety of Laruparetigene Zovaparvovec Administered Bilaterally in Male Participants with X-Linked Retinitis Pigmentosa**

- **PI Name:** Dr. Lam, Byron
- **Project Title:** A Phase 2 Open-label Study to Evaluate the Safety of Laruparetigene Zovaparvovec Administered Bilaterally in Male Participants with X-Linked Retinitis Pigmentosa
- **Agent Characteristics:** Recombinant AAV vector; non-replicating; modified capsid for retinal delivery
- **Manipulations Planned:** Subretinal injection of laruparetigene zovaparvovec in both eyes
- **Source of Nucleic Sequences:** Human RPGR gene
- **Nature of Sequences:** Therapeutic gene
- **Host/Vector:** Human; AAV2tYF vector
- **Transgene Expression:** Yes; to restore RPGR function
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-C
- **Containment Conditions:** BSL-1

**RECOMMENDATION:**

The reviewer recommends conditional approval of this study. The Committee unanimously approved (9-0).

**Project 25-087: Mechanisms of vesicle fusion and neurotransmitter release**

- **PI Name:** Dr. Lindau, Manfred
- **Project Title:** Mechanisms of vesicle fusion and neurotransmitter release
- **Agent Characteristics:** Semliki Forest Virus (SFV); high expression efficiency; transient RNA expression
- **Manipulations Planned:** Transfection of chromaffin cells with SFV carrying SCORE2 construct
- **Source of Nucleic Sequences:** Rat SCORE2 gene
- **Nature of Sequences:** Reporter gene for SNARE complex monitoring
- **Host/Vector:** Mouse chromaffin cells; SFV vector
- **Transgene Expression:** Yes; for live-cell FRET imaging
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of this study. The Committee unanimously approved (9-0).

**Project 25-088: Reversing the effects of methamphetamine and cocaine in rodents model with nanoparticle platform**

- **PI Name:** Dr. Shar, Shanta
- **Project Title:** Reversing the effects of methamphetamine and cocaine in rodents model with nanoparticle platform
- **Agent Characteristics:** EcoHIV; modified HIV-1 virus with murine tropism
- **Manipulations Planned:** Injection of EcoHIV into mice to study neurodegenerative effects
- **Source of Nucleic Sequences:** EcoHIV genome
- **Nature of Sequences:** Modified viral genome
- **Host/Vector:** Mouse; EcoHIV
- **Transgene Expression:** Yes; to emulate HIV infection in rodents
- **Training Verification:** Will confirm in IBC office

- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of this study. The Committee unanimously approved (9-0).

**Project 25-089: Affordable and rapid AAV gene therapy for highly prevalent vascular disease**

- **PI Name:** Dr. Liu, Zhao-Jun
- **Project Title:** Affordable and rapid AAV gene therapy for highly prevalent vascular disease
- **Agent Characteristics:** AAV vectors; scalable production; therapeutic gene delivery
- **Manipulations Planned:** Injection of E-selectin/AAV vectors into mice and pigs
- **Source of Nucleic Sequences:** Mouse, human, and swine E-selectin genes
- **Nature of Sequences:** Therapeutic gene
- **Host/Vector:** Mouse and swine; AAV2/9 and AAV2/8 vectors
- **Transgene Expression:** Yes; to promote angiogenesis and wound healing
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-1

**RECOMMENDATION:**

The reviewer recommends tabling this study due to inconsistency in study details. The Committee unanimously approved (9-0).

#### **4. Old Business**

**Project 25-061: Allogenic MiHa/MHC induced marrow allograft transplants**

- **PI Name:** Dr. Levy, Robert
- **Project Title:** Allogenic MiHa/MHC induced marrow allograft transplants
- **Agent Characteristics:** CAR-T cells; bone marrow transplant; post-transplant cyclophosphamide
- **Manipulations Planned:** Transplantation of hematopoietic stem cells and CAR-T cells into mice
- **Source of Nucleic Sequences:** Donor mouse splenocytes and bone marrow
- **Nature of Sequences:** Chimeric antigen receptor and hematopoietic stem cell genes
- **Host/Vector:** Mouse; CAR-T and bone marrow transplant
- **Transgene Expression:** Yes; for immune modulation and anti-tumor efficacy
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends conditional approval of this study. The Committee unanimously approved (9-0).

**Project 25-065: Targeting the longevity regulator PAPP-A with small molecule inhibitors**

- **PI Name:** Dr. Lombard, David
- **Project Title:** Targeting the longevity regulator PAPP-A with small molecule inhibitors

- **Agent Characteristics:** Small molecule inhibitors; Tet-pLKO-puro knockdown system
- **Manipulations Planned:** Knockdown of PAPP-A and PAPP-A2 in cell lines; treatment with inhibitors
- **Source of Nucleic Sequences:** PAPP-A and PAPP-A2 genes
- **Nature of Sequences:** Longevity and IGF signaling regulators
- **Host/Vector:** Human cell lines; Tet-pLKO-puro vector
- **Transgene Expression:** Yes; for target validation and phenotypic analysis
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends tabling this study due to lack of clarity in proposed project. The Committee unanimously approved (9-0).

**Project 25-066: Targeting autophagy via the Menin protein to inhibit melanoma metastasis**

- **PI Name:** Dr. Lombard, David
- **Project Title:** Targeting autophagy via the Menin protein to inhibit melanoma metastasis
- **Agent Characteristics:** Menin inhibitors; CRISPR Knock-in transgenic mice
- **Manipulations Planned:** Treatment of melanoma models with Menin inhibitors; gene expression analysis
- **Source of Nucleic Sequences:** Menin gene and autophagy-related genes
- **Nature of Sequences:** Autophagy regulators
- **Host/Vector:** Mouse melanoma models; Menin inhibitors
- **Transgene Expression:** Yes; for autophagy pathway analysis
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends tabling this study due to lack of clarity in proposed project. The Committee unanimously approved (9-0).

**Project 25-090: SIRT5 as novel therapeutic target in MPNST**

- **PI Name:** Dr. Lombard, David
- **Project Title:** SIRT5 as novel therapeutic target in MPNST
- **Agent Characteristics:** SIRT5 inhibitors; lentiviral knockdown vectors
- **Manipulations Planned:** Knockdown and pharmacological inhibition of SIRT5 in cell lines and mice
- **Source of Nucleic Sequences:** SIRT5 gene
- **Nature of Sequences:** Tumorigenic regulator
- **Host/Vector:** Human cancer cell lines and NPcis mice; lentivirus
- **Transgene Expression:** Yes; for tumorigenesis studies
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

**RECOMMENDATION:**

The reviewer recommends tabling this study due to lack of clarity in proposed project. The Committee unanimously approved (9-0).

**Project 25-091: HDACi as treatment for solitary fibrous tumor**

- **PI Name:** Dr. Lombard, David
- **Project Title:** HDACi as treatment for solitary fibrous tumor
- **Agent Characteristics:** HDAC inhibitors; lentiviral vectors; CRISPR Knock-in transgenic mice
- **Manipulations Planned:** Expression of NAB2-STAT6 fusion gene; treatment with HDAC inhibitors
- **Source of Nucleic Sequences:** NAB2-STAT6 fusion gene
- **Nature of Sequences:** Oncogenic fusion gene
- **Host/Vector:** Human and mouse cell lines; transgenic mice; lentivirus
- **Transgene Expression:** Yes; for tumor modeling and drug efficacy testing
- **Training Verification:** Will confirm in IBC office
- **NIH Guidelines Section:** III-D
- **Containment Conditions:** BSL-2

#### RECOMMENDATION:

The reviewer recommends tabling this study due to lack of clarity in proposed project. The Committee unanimously approved (9-0).

#### 5. Addenda:

**Number:** 22-131 IIIC ad04  
**Title:** Phase 1/2 study evaluating genetically modified autologous T cells expressing a T-cell receptor recognizing a cancer/germline antigen as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors (ACTengine® IMA203-101)  
**Principal Investigator:** Hernandez Aya, Leonel  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 23-108 IIIC ad  
**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:** Spiegel, Jay  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 23-120 IIIC ad06  
**Title:** A Phase 1 Basket Study Evaluating the Safety and Feasibility of T-Plex, Autologous Customized T Cell Receptor-Engineered T Cells Targeting Multiple Peptide/HLA Antigens in Participants with Antigen-positive Locally Advanced (Unresectable) or Metastatic Solid Tumors  
**Principal Investigator:** Lutzky, Jose  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 23-137 IIIC ad04  
**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:** Beitinjane, Amer  
**Primary Reviewer:** Tsoulfas, Pantelis

<b>Number:</b>	<b>24-030 IIIC ad</b>
<b>Title:</b>	Randomized, Open-Label Study Of The BRIA-IMT Regimen And Check Point Inhibitor Vs Physician's Choice In Advanced Metastatic Breast Cancer (BRIA-ABC)
<b>Principal Investigator:</b>	Negret, Lawrence
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

  

<b>Number:</b>	<b>24-058 IIIC ad02</b>
<b>Title:</b>	Phase 2, Open-Label, Multicentre Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, in Subjects with Refractory Generalized Myasthenia Gravis (KYSA-6)
<b>Principal Investigator:</b>	Pereira, Denise
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

  

<b>Number:</b>	<b>24-079 IIIC ad01</b>
<b>Title:</b>	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
<b>Principal Investigator:</b>	Chauhan, Aman
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

  

<b>Number:</b>	<b>24-080 IIIC ad</b>
<b>Title:</b>	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
<b>Principal Investigator:</b>	Feun, Lynn
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

## 6. Exemptions:

<b>Number:</b>	<b>25-074 IIIF</b>
<b>Title:</b>	Biodegradable synthetic nanoparticles for atherosclerosis
<b>Principal Investigator:</b>	Dhar, Shanta
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

  

<b>Number:</b>	<b>25-075 IIIF</b>
<b>Title:</b>	Improving Arteriovenous Fistula Remodeling Through Immunomodulation
<b>Principal Investigator:</b>	Vazquez-Padron, Roberto
<b>Primary Reviewer:</b>	<b>Tsoufas, Pantelis</b>

  

<b>Number:</b>	<b>25-076 IIIF</b>
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**Title:** MPZL3 as a Therapeutically Targetable Mitochondrial Regulator of Sebaceous Gland Homeostasis and Sebum Production  
**Principal Investigator:** Cao, Tongyu  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-077 IIIF  
**Title:** SMPDL3b as a Regulator of Podocyte Integrity and Innate Immune Signaling  
**Principal Investigator:** Merscher, Sandra  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-078 IIIF  
**Title:** Membrane Cholesterol and Podocyte Function  
**Principal Investigator:** Merscher, Sandra  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-079 IIIF  
**Title:** Dual Role of Lysyl Oxidase in Arteriovenous Fistula Failure: The Mouse Model  
**Principal Investigator:** Vazquez-Padron, Roberto  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-092 IIIF  
**Title:** Notch Signaling in Cardiovascular Diseases  
**Principal Investigator:** Liu, Zhao-Jun  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-093 IIIF  
**Title:** IL-2R-dependent mechanisms in regulation of Treg homeostasis and autoimmunity  
**Principal Investigator:** Malek, Thomas  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 25-094 IIIF  
**Title:** Mitophagy reporter  
**Principal Investigator:** Pham, Anh  
**Primary Reviewer:** Tsoulfas, Pantelis

## 7. Renewals-Closures

**Number:** 19-092 – RENEWAL  
**Title:** A Phase 2 Study of combination therapy with an IL-15 Superagonist (N-803), off-the-shelf- CD16-targeted natural killer cells (HANK), and avelumab without cytotoxic chemotherapy in subjects with merkel cell carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor  
**Principal Investigator:** Feun, Lynn  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 20-065 – Closure  
**Title:** An open-label, multi-centre, Phase Ib/II study evaluating the safety and efficacy of AUTO01, a CAR T cell treatment targeting CD19, in adult patients with relapsed or refractory B cell acute lymphoblastic leukemia  
**Principal Investigator:** Beitinjaneh, Amer  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 20-065 – Renewal  
**Title:** A Phase 2 study of Talimogene Laherparepvec (T-VEC) and radiation in localized soft tissue sarcoma  
**Principal Investigator:** D’Amato, Gina  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 20-065 – Renewal  
**Title:** Open-label, randomized Phase II trial with BNT111 and cemiplimab in combination or as single agents in patients with anti-PD-1/PD-L1-refractory/relapsed, unresectable stage III or IV melanoma  
**Principal Investigator:** Feun, Lynn  
**Primary Reviewer:** Tsoulfas, Pantelis

**Number:** 23-108 – Renewal  
**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:** Spiegel, Jay  
**Primary Reviewer:** Tsoulfas, Pantelis

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