

Institutional Biosafety Committee – April 28, 2026 Meeting Minutes

Members Present

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

Members Absent

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

* Denotes Chair

** Denotes Vice-Chair

*** Denotes BSO Alternate

¹ Denotes Community Representatives

1. Call to Order and Announcements:

The IBC meeting was held on April 28th via Zoom. Dr. Chakrabarti chaired the meeting. After determining that there was a quorum, Dr. Chakarabrti called the meeting to order at 2:30 p.m.

- Minutes from March 24th meeting – approved by vote 6-0
 - Minutes will be uploaded to the website

2. Discussion:

- Grad student working on a study under Dr. Satkunendrarjah sustained a laceration on right index finger from a surgical procedure on a transgenic mouse. Mouse in question had not been exposed to any viral agents or vectors.
 - Report to NIH is not needed/warranted
 - The committee acknowledged that while mouse bites are common in laboratory settings, proper training and safety protocols remain important. Tetanus shots are recommended for anyone with skin breaks.

Dr. Doblecki-Lewis joined the meeting

Shane Gillooly joined the meeting

New Business

26-025 – Phase 1/2 Multicenter, Open-Label, Dose-Escalation and Dose-Expansion Trial to Assess the Safety, Tolerability, Pharmacodynamics, and Preliminary Efficacy of AFTX-201 Administered to Adult Participants with BCL2-Associated Athanogene 3 (BAG3) Mutation-Associated Dilated Cardiomyopathy: UPBEAT Trial

PI: Joshua Hare, MD

Training: Verified.

NIH Guidelines: Section IIC

Containment: BSL-2 (due to complex construct).

Summary: Phase 1/2 clinical trial (UPBEAT trial) assessing safety and efficacy of AFTX201 gene therapy for patients with BAG3 mutation-associated dilated cardiomyopathy. Up to 22 participants, monitoring for vector shedding and genome presence in heart tissue.

Recommendation: Approval; unanimously approved (7-0).

26-026 – Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc)

PI: Lazaros Lekakis, MD

Training: Verified.

NIH Guidelines: Section IIC

Containment: BSL-2

Summary: Phase 3 randomized, open-label multicenter study comparing BMS 986353 (CD19-targeted CAR T cells) versus standard of care in patients with active systemic sclerosis. Same study agent as protocol 25-083 reviewed in August in 2025.

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

Dr. Doblecki-Lewis left the meeting

26-027 – Role of transcription factors driving gliomagenesis in the mouse

PI: Anna Lasorella, PhD

Training: Verified.

NIH Guidelines: Section III-D-4.

Containment: BSL-2.

Summary: Study on role of transcription factors driving gliomagenesis in mice.

Recommendation: Conditional approval; unanimously approved (6-0).

26-028 – Treatments for Acute Respiratory Distress Syndrome (ARDS)

PI: Lina Shehadeh, PhD

Training: Verified.

NIH Guidelines: Section III-D-4.

Containment: BSL-2.

Summary: Treatments for acute respiratory distress syndrome using chimeric VSV virus with SARS-CoV-2 spike protein in mice, plus three drugs and AAV virus for tracking.

Recommendation: Conditional approval; unanimously approved (6-0).

26-029 – Novel Mechanisms of ROS/RNS Signaling Underlying Castration-Resistant Prostate Cancer Emergence and Progression

PI: Priyamvada Rai, PhD

Training: Verified.

NIH Guidelines: Section III-D-4.

Containment: BSL-2.

Summary: Novel mechanism of ROS RNA signaling underlying castration-resistant prostate cancer emergence and progression.

Recommendation: Conditional approval; unanimously approved (6-0).

26-030 - Role of Metabolites and proteins in pseudoexfoliation glaucoma

PI: Sanjoy Bhattacharya, PhD

Training: Verified.

NIH Guidelines: Section III-D-4.

Containment: BSL-1.

Summary: Role of metabolites and proteins in pseudo-exfoliation glaucoma, focusing on vitamin D receptor. PI must clarify vector types, provide missing maps, explain mCherry purpose, clarify LRP2 relevance, and reduce technical jargon

Recommendation: Conditional approval; unanimously approved (6-0).

26-031 - Myeloid cell regulation by neurotransmitters in glioblastoma

PI: Defne Bayik Watson, PhD

Training: Verified.

NIH Guidelines: Section III-D-4.

Containment: BSL-1.

Summary: Myeloid cell regulation by neurotransmitters in glioblastoma, involving cell transplantation from transgenic mice

Recommendation: Conditional approval; unanimously approved (6-0).

26-032 - Small molecule cosignaling inhibitors as immune and inflammatory modulators

PI: Peter Buchwald, PhD

Training: Verified.

NIH Guidelines: Section III F

Containment: BSL-1.

Summary: Small molecule co-signaling inhibitors as immune and inflammatory modulators for transplant recipients and autoimmune disease patients.

Recommendation: Conditional approval; unanimously approved (6-0). PI must provide specific information on recombinant DNA aspects,

26-033 - Immunomodulation via localized drug delivery

PI: Peter Buchwald, PhD

Training: Verified.

NIH Guidelines: Section III F

Containment: BSL-1.

Summary: Immunomodulation via localized drug delivery for type 1 diabetes using PEG polymers and nanoparticles.

Recommendation: Conditional approval; unanimously approved (6-0). PI must provide specific information on recombinant DNA aspects,

Addenda:

Number:

22-131 IIIC ad05

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:

Tsoufias, Pantelis

Number:

25-002 IIIC ad02

Title:

Sonoma SBT77701-02 HS

Principal Investigator:

Lev-Tov, Hadar

Primary Reviewer:

Tsoufias, Pantelis

Number:

25-041 IIIC ad03

Title: A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)

Principal Investigator: Hernandez Aya, Leonel
Primary Reviewer: Tsoulfas, Pantelis

Number: 25-041 IIIC ad04
Title: A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)

Principal Investigator: Hernandez Aya, Leonel
Primary Reviewer: Tsoulfas, Pantelis

Number: 25-045 IIIC ad01
Title: A Phase 1/2 Study of EG-70 as an Intravesical Administration to Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) and High-Risk NMIBC Patients who are BCG Naïve or Received Incomplete BCG Treatment

Principal Investigator: Gonzalgo, Mark
Primary Reviewer: Tsoulfas, Pantelis

Number: 26-001 IIIF ad01
Title: Breeding of transgenic and knockout mice

Principal Investigator: Liebl, Daniel
Primary Reviewer: Tsoulfas, Pantelis

Number: 26-003 IIIF ad01
Title: Stabilizing the tripartite synapse – 2026

Principal Investigator: Liebl, Daniel
Primary Reviewer: Tsoulfas, Pantelis

Exemptions:

Number: 26-022 IIIF
Title: Novel TDP-43 mouse models
Principal Investigator: Petrucelli, Leonard
Primary Reviewer: Tsoulfas, Pantelis

Number: 26-023 IIIF
Title: The role of the TET-dependent DNA demethylation pathway in photoreceptor development and pathology
Principal Investigator: Ivanov, Dmitry
Primary Reviewer: Tsoulfas, Pantelis

Number: 26-024 IIIF
Title: The Role of Inflammasomes in Neonatal Lung, Brain, and Eye Injury
Principal Investigator: Wu, Shu
Primary Reviewer: Tsoulfas, Pantelis

Renewals-Closures

Number: 22-067 IIIC – Renewal
Title: A Phase 3 Randomized Study Comparing Bortezomib, enalidomide and Dexamethasone (VRd) followed by Ciltacabtagene Autoleucel, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA versus Bortezomib, Lenalidomide, and Dexamethasone (VRd) followed by Lenalidomide and Dexamethasone (Rd) Therapy in Participants with Newly Diagnosed Multiple Myeloma for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy
Principal Investigator: Kazandjian, Dickran

Primary Reviewer: **Tsoulfas, Pantelis**

Number: **22-131 IIIC – Renewal**
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: **23-084 IIIC – Renewal**
Title: A Phase 1, Multicenter, Open-Label Study of CB-011, a CRISPR-Edited Allogeneic Anti-BCMA CAR-T Cell Therapy in Patients with Relapsed/Refractory Multiple Myeloma (CaMMouflage Trial)
Principal Investigator: Spiegel, Jay
Primary Reviewer: **Tsoulfas, Pantelis**

Number: **24-030 IIIC – Renewal**
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: **25-045 IIIC – Renewal**
Title: A Phase 1/2 Study of EG-70 as an Intravesical Administration to Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC) and High-Risk NMIBC Patients who are BCG Naïve or Received Incomplete BCG Treatment
Principal Investigator: Gonzalgo, Mark
Primary Reviewer: **Tsoulfas, Pantelis**

