Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	3/19/2026 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:33PM
Adjournment	3:02PM
Conflicts of interest	The IBC Admin reminded all members present to identify any conflicts of interest as each registration is reviewed.

ATTENDANCE	
Name	**Present**
V. SIMON (IBC Chair; Scientist)	YES
B. LEE (IBC vice-Chair; Scientist)	YES
T. BANIA (IBC member; Human Gene Therapy)	YES
R. BRODY (IBC member; Scientist)	NO
L. CHAUHAN (Biological Safety Officer)	YES
J. COHEN (IBC member, Attending Veterinarian)	YES
H. DONG (IBC member; Human Gene Therapy)	YES
D. D'SOUZA (IBC member; Employee Health- Alternate)	NO
C. NAPIER (IBC member; Employee Health)	YES
C. SHOR (Local Non-affiliated)	YES
M. C. BERMUDEZ (Institutional Observer)	YES
S. STRAUSS (Legal Counsel)	NO
N. TZAVARAS (IBC member; Scientist)	YES
S. ROSA (Administrative)	YES

QUORUM
The IBC has 9 voting members. 5 members are required to conduct business. Quorum was met.

OTHER INDIVIDUALS IN ATTENDANCE	
Name	**Affiliation / Title**

REVIEW OF PRIOR MEETING MINUTES	
Date of meeting minutes	3-5-2026
Motion	To approve the minutes
Votes	(6) For (0) Against (2) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202600000015

Title:	Phase 1b/II CAR-T Human Multiple Myeloma AZD0120 (GC012F)
Investigator:	SHAMBAVI RICHARD
Submission ID:	SPROTO202600000015
Submission Type:	De Novo Review
Project Overview:	This is a Phase Ib/II clinical trial sponsored by AstraZeneca and designed to evaluate the safety, tolerability, and efficacy of the study agent, AZD0120 (GC012F), which is composed of autologous T cells genetically engineered using a self-inactivating, replication-deficient recombinant lentiviral vector to express Chimeric Antigen Receptors (CARs) targeting CD19 and B-cell maturation antigen (BCMA) in adult subjects with relapsed / refractory multiple myeloma after receiving at least three prior treatment lines of therapy. Multiple Myeloma (MM) is the third most common type of blood cancer and accounts for approximately 10% of all hematological malignancies in the United States (US). MM is characterized by several features because of the malignant transformation of plasma cells, and accumulation of myeloma cells within the bone marrow. Myeloma cells produce high levels of single antibodies, resulting in dysfunction of the immune system and kidneys and other organs. The underlying cause of the disease is still unknown.
NIH Guidelines Section:	III-C-1
Risk Assessment discussion	No biosafety or human research subject concerns. On campus activities are minimal: recombinant product is produced by Sponsor, including residual lentiviral removal and provided to participating clinical trial teams.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	Not applicable
IBC Vote	A motion was made to approve the registration as is Votes: (6) For (0) Against (2) Abstain Conflict(s) of Interest: none

2. Review of SPROTO202600000012

Title:	Metabolic Physiology
Investigator:	TIMOTHY KENNY
Submission ID:	SPROTO202600000012
Submission Type:	Initial Protocol
Project Overview:	The lab uses systems biology approaches to understand the influence of nutrient transporters and cellular metabolism on mammalian physiology and disease. This work uses lentiviral and retroviral vectors to manipulate in vitro cell lines and perform CRISPR-based genetic screens. They use AAV vectors in mice to modulate gene expression and query the physiological relevance of our discoveries.
NIH Guidelines Section:	III-D-1; III-D-1-a
Risk Assessment discussion	No Biosafety or CCMS concerns. Administrative corrections needed regarding NIH section selections.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
Biosafety Level Assignment	BL-2 BL-2N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending minor modifications Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

3. Review of SPROTO202600000025

Title:	Molecular mechanisms of neuroplasticity
Investigator:	IAN MAZE
Submission ID:	SPROTO202600000025
Submission Type:	De Novo Review
Project Overview:	Lab's research focuses on the neuroepigenetic processes that play critical roles in neural development and plasticity-related modifications of the adult brain. They investigate the neuroepigenetic phenomena in the context of neurodevelopmental and psychiatric disorders such as Alzheimer's, Parkinson's diseases, Down Syndrome, substance use disorders and major depressive disorders. Research uses viral vectors for exogenous gene expression or gene knock-down both in vivo and in vitro. For in vivo studies, high titer AAV and lentiviral vectors are purchased from commercial sources and injected into mouse brains. In addition, we are using insect cells and baculoviruses to recombinantly express mammalian proteins for in vitro biochemical characterization.
NIH Guidelines Section:	III-D-1; III-D-1-a III-D-3-a III-E-1 III-F-1
Risk Assessment discussion	Recombinant research activities are standard. Tetrodotoxin is only used in cell culture, not animals. However, team must provide clarification and justification regarding the use of: insect cells, baculovirus and Sindbis Virus.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
Biosafety Level Assignment	BL-2 BL2-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending minor modifications Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

4. Review of SPROTO202600000026

Title:	Studies of Bourbon virus
Investigator:	CHRISTOPHER BASLER
Submission ID:	SPROTO202600000026
Submission Type:	Initial Protocol
Project Overview:	Bourbon virus is a tick-borne Orthomyxovirus belonging to the Thogotovirus genus. This six-segmented, enveloped, negative-sense RNA virus was first discovered in 2014 in Bourbon County, Kansas and has been isolated from lone star ticks (Amblyomma americanum). It has been associated with at least 5 human infections, including fatal infections. Much about its molecular virology and interactions with host factors remains to be determined. They will obtain the virus from BEI Resources, propagate the virus on Vero cells, perform a genome-wide CRISPR-Cas9 knockout screen to identify host factors critical for infection, identify host proteins that interact with viral proteins, generate cell lines with CRISPR-Cas9 knockouts and perform siRNA knockdowns and infect these to determine the impact of specific host factors on viral replication. We will also generate recombinant Bourbon virus using strategies that have been successful for generating recombinant influenza viruses.
NIH Guidelines Section:	III-D-1; III-D-1-b; III-D-2-a III-D-3; III-D-3-b; III-D-4-a
Risk Assessment discussion	Reverse genetics performed in BSL-3 and cell culture only; no ticks involved in the research reducing transmission concerns. Research team to include pathogen information sheet to registration. BSO will discuss with team the assigned BSL-3 space for performing experiments.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Some staff require OHSQ completion.
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-3
Highest ABSL Practices	Not applicable
IBC Vote	A motion was made to approve the registration pending minor modifications Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

OTHER AGENDA ITEMS

5. IBC Membership

Description:	Introduction of new institutional observer,
Discussion:	M. C. Bermudez joining committee as non-voting, institutional observer

Review of Incidents
Nothing to report

Inspections / Ongoing Oversight
Nothing to report

IBC Training
Nothing to report

Public Comments
There were no public comments