Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	3/5/2026 12:00 PM
Meeting time	2:30-3:30 PM
Meeting type	Videoconference
Call to order	12:02 PM
Adjournment	12:35 PM
Conflicts of interest	The IBC Administrator 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)	YES
L. CHAUHAN (Biological Safety Officer)	YES
J. COHEN (IBC member, Attending Veterinarian)	YES (joined mid-meeting)
H. DONG (IBC member; Human Gene Therapy)	YES
D. D'SOUZA (Alternate IBC member; Employee Health)	NO
C. NAPIER (IBC member; Employee Health)	NO
C. SHOR (Local Non-affiliated)	YES
S. STRAUSS (Legal Counsel)	NO
N. TZAVARAS (IBC member; Scientist)	NO
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	1-11-2026
Motion	To approve the minutes as written
Votes	(5) For (0) Against (2) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202500000123

Title:	Phase 1b CRISPR-LNP Treatment - VERVE-201 (VT-20101)
Investigator:	ROBERT ROSENSON
Submission ID:	SPROTO202500000123
Submission Type:	Initial Protocol
Project Overview:	his is a first-in-human, open-label, single ascending dose (SAD), Phase 1b study to evaluate the safety of VERVE-201 in adult participants with refractory hyperlipidemia syndromes, including hypercholesterolemia and hypertriglyceridemia. VERVE-201 is designed to use base-editing technology—delivered by LNPs to introduce a precise A • T to G • C nucleotide base pair change in the ANGPTL3 gene. Recombinant work is performed by external entity as designated by Sponsor. Only clinical administration and related activities are performed within Mount Sinai.
NIH Guidelines Section:	III-C-1
Risk Assessment discussion	No safety concerns from clinical trial experts and BSO.
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 pending minor administrative modifications. Votes: (6) For (0) Against (1) Abstain Conflict(s) of Interest: none.

2. Review of SPROTO202500000126

Title:	Phase 1 CRISPR CAR-T Cell Study
Investigator:	ADRIANA ROSSI
Submission ID:	SPROTO202500000126
Submission Type:	De Novo Review
Project Overview:	CB11A is a Phase I, first-in-human, non-randomized, open-label study sponsored by Caribou Biosciences, Inc. and designed to assess the safety, tolerability, and preliminary efficacy of CB-011, an allogeneic (donor-derived) T cell product engineered using CRISPR/Cas12a and recombinant adeno-associated viral vectors to express a chimeric antigen receptor (CAR) targeting the tumor antigen B cell maturation antigen (BCMA) along with an HLA-E fusion protein to reduce graft rejection in participants with relapsed/refractory multiple myeloma (r/r MM).
NIH Guidelines Section:	Section III-C-1
Risk Assessment discussion	No safety concerns from clinical trial experts and BSO for this pre-existing study.
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 pending minor administrative modifications. Votes: (6) For (0) Against (1) Abstain Conflict(s) of Interest: none.

3. Review of SPROTO202600000010

Title:	A Phase III, Open-label, Randomised, Multicentre Study to Evaluate AZD0120 in Participants with Relapsed Refractory Multiple Myeloma
Investigator:	SHAMBAVI RICHARD
Submission ID:	SPROTO202600000010
Submission Type:	De Novo Renewal
Project Overview:	This is a randomized, multicenter, controlled, open-label, Phase III global study comparing the efficacy and safety of AZD0120 versus standard regimens in participants with RRMM. AZD0120 is a BCMA/CD19 dual-targeting autologous CAR-T therapy under investigation for the treatment of patients with MM as well as in other indications. Preliminary results from ongoing studies in participants with RRMM indicate that AZD0120 has significant anti-myeloma activity and a safety profile consistent with the known mechanism of action of CAR-T therapies.
NIH Guidelines Section:	Section III-C-1
Risk Assessment discussion	Research agent derived from replication competent lentivirus. BSO requested approval letter include statement for clinical team to report needlestick injuries to the IBC in addition to standard Mount Sinai needlestick injury reporting procedure.
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 (1) Abstain Conflict(s) of Interest: none.

4. Review of SPROTO202600000004

Title:	delta VP30
Investigator:	CHRISTOPHER BASLER
Submission ID:	SPROTO202600000004
Submission Type:	De Novo Review
Project Overview:	Lab team previously obtained the Ebola ΔVP30 replication incompetent virus system. Team will test compounds for antiviral effects toward this virus in the VP30 expressing cell lines. Team will introduce mutations into the Ebola ΔVP30-GFP genome. These mutations would be designed to disrupt interactions with viral or host factors. Team will not mutate the predicted stem-loop at the EBOV NP gene transcription start site that renders NP gene transcription in a minigenome assay VP30-dependent This is a recombinant Ebola virus and the corresponding cloned genome lacks the capacity to express the essential EBOV VP30 protein. In this virus and in the recombinant genome, VP30 has been replaced by GFP. VP30 deletion viruses can only replicate in VP30-expressing, complementing cells. This virus has been proven to be stably attenuated in cell culture and in animal studies and is designated as a Select Agent and Toxins excluded strain.
NIH Guidelines Section:	Section III-D-1; Section III-D-1-A Section III-D-2 Section III-D-3; Section III-D-3-A Section III-D-7-D
Risk Assessment discussion	No biosafety concerns for this pre-existing study.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
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 pending minor administrative modifications. Votes: (6) For (0) Against (1) Abstain Conflict(s) of Interest: none.

5. Review of SAMEND202600000004

Title:	Amendment for SPROTO202500000080
Investigator:	JOSEPH CASTELLANO
Submission ID:	SAMEND202600000004
Submission Type:	Amendment
Project Overview:	Lab team requesting the addition of AAV usage in mice (Risk group 1; no helper virus or any use in cell lines or human lines/tissue).
NIH Guidelines Section:	Section III-D-1; Section III-D-1-A Section III-D-4; III-D-4-A; III-D-4-B
Risk Assessment discussion	Research team has pre-existing approval for lentivirus-based experiments. No Biosafety or Veterinary concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration as is Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

6. Review of SPROTO202500000143

Title:	Mechanism of neurological disorders
Investigator:	ANNE SCHAEFER
Submission ID:	SPROTO202500000143
Submission Type:	De Novo Review
Project Overview:	Using pioneering technologies including cell type-specific analysis of mRNAs, miRNAs, and chromatin modifications in neurons in vivo, the researchers aim to understand the mechanism of neurological disorders and their potential treatment by targeting the neuronal epigenome.
NIH Guidelines Section:	III-D; Section III-D-1; III-D-1-A;III-D-4
Risk Assessment discussion	No Biosafety or Veterinary concerns for this pre-existing research.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
Biosafety Level Assignment	BL-1; BL1-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending minor administrative modification Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

7. Review of SPROTO202500000148

Title:	Transcriptional regulation of lung cancer
Investigator:	HIDEO WATANABE
Submission ID:	SPROTO202500000148
Submission Type:	De Novo Review
Project Overview:	Lung cancer remains the number one cause of cancer-related deaths despite recent advances in targeted therapeutics revolution.To improve precision and efficacy, it is critical to distinguish different subgroups of lung cancer by additional features represented in each subgroup. Our studies focus on: 1) factors that are essential during the formation of the lung at developmental stage and control the identity of lung cells in adult 2) provide new perspectives of anti-relapse therapeutic strategies for lung cancer, that target a newly identified “drug-tolerant persisters (DTPs)” through chromatin (packaged DNAs) enzymes that dictate cell states and developmental pathways essential for DTP survival and adaptability to change their states later. 3) molecular features that are essential for maintaining the cell fate/lineage transformation after immunotherapy.
NIH Guidelines Section:	Section III-D-1; Section III-D-1-A Section III-D-2; Section III-D-2-A Section III-D-3-A Section III-D-4; Section III-D-4-B
Risk Assessment discussion	No Biosafety or Veterinary concerns for this pre-existing research.
Training	No deficiencies were noted in staff training records
Occupational Health Representative review (if applicable)	Not assigned for review
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 administrative modification Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

8. Review of SPROTO202500000120

Title:	Applications with Human iPSCs Derivatives
Investigator:	MATHEUS VICTOR
Submission ID:	SPROTO202500000120
Submission Type:	Initial Protocol
Project Overview:	The team combines advanced stem cell engineering, functional genomics, and human postmortem brain profiling to decode how innate immune mechanisms contribute to neurodegeneration. The team utilizes third-generation, replication-incompetent lentiviral vectors to deliver defined transcription factors (TFs) into human induced pluripotent stem cells (iPSCs).
NIH Guidelines Section:	III-D; III-D-1; III-D-1-a; III-D-4
Risk Assessment discussion	No Biosafety or Veterinary concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2+
Highest ABSL Practices	ABSL-1
IBC Vote	A motion was made to approve the registration pending minor administrative modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

9. Review of SPROTO202500000135

Title:	Gene Therapy for Cardiac Disease in Animal Models
Investigator:	MICHAEL KATZ
Submission ID:	SPROTO202500000135
Submission Type:	De Novo Review
Project Overview:	The lab performs comprehensive studies in various animal models for the treatment of cardiac disease. Their main vision is to continue highly reproducible relevant infarction model and compare the biomarker, contractility, and gene therapy effects in a new, lesser-degree model of non-ischemic disease. Additionally, understanding the pathophysiology and developing effective strategies to protect vulnerable brain regions from hypoxic injury during circulatory support with extracorporeal membrane oxygenation (ECMO) are of fundamental importance for improving outcomes in children with congenital heart disease. The team seeks integrate various data sets to determine if their AAV gene therapies and investigate 4 established routes of administration to assess suitability for translation and to Phase I trials.
NIH Guidelines Section:	III-D; III-D-1; III-D-4
Risk Assessment discussion	No Biosafety or Veterinary concerns for this pre-existing research.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
Biosafety Level Assignment	BL-1; BL1-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending the following minor modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

10. Review of SPROTO202200000226

Title:	Kidney disease induction and intervention in mice
Investigator:	ILSE DAEHN
Submission ID:	SPROTO202200000226
Submission Type:	De Novo
Project Overview:	While podocytes have been studied extensively as primary targets in CKD, only recently endothelial dysfunction has been recognized to play a critical role in the development and progression of glomerular disease. In diabetic kidney disease, glomerular endothelial cell (GEC) dysfunction and glycocalyx damage represent initiating steps in diabetic albuminuria in human and in experimental models. Team will test synthetic antisense oligonucleotides (ASOs) targeting Bmper mRNA for degradation via RNAse H in mice.
NIH Guidelines Section:	Section III-F; Section III-F-1
Risk Assessment discussion	BSO and Veterinary expert require more information regarding the waste management of chemicals used in animal experiments.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Not assigned for review
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-1
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made for post-modification review by the BSO pending additional information and modifications. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

OTHER AGENDA ITEMS

Review of Incidents
Nothing to report

Inspections / Ongoing Oversight
Nothing to report

IBC Training
Nothing to report

Public Comments
There were no public comments