

**Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai**

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	4/16/2026 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:33pm
Adjournment	3:30pm
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 (joined 2:50pm)
T. BANIA (IBC member; Human Gene Therapy)	YES
C. BERMUDEZ (Institutional Observer)	YES
R. BRODY (IBC member; Scientist)	YES
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)	NO
C. NAPIER (IBC member; Employee Health)	YES
C. SHOR (Local Non-affiliated)	NO
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	3-19-2026
Motion	To approve the minutes
Votes	(8) For (0) Against (1) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202600000013

Title	Phase 3b AAV5-IFN in NMIBC (ABLE-32)
Investigator	JOHN SFAKIANOS
Submission ID	SPROTO202600000013
Submission Type	Initial Protocol
Project Overview	<p>This is a multi-center, open-label, randomized phase 3b trial to evaluate the safety and efficacy of nadofaragene firadenovec versus observation in subjects with Intermediate Risk (IR) Non-Muscle Invasive Bladder Cancer (NMIBC).</p> <p>Urothelial carcinoma is the predominant type of urinary tract cancer, comprising approximately 90% of all bladder cancers in the United States (US). 70-80% of subjects with newly diagnosed bladder cancer have NMIBC. Low-grade Ta tumors are the most frequently occurring non-muscle invasive tumors (70%). Tumors with invasion into the lamina propria of the bladder (T1) and carcinoma in situ (CIS) are defined as high-grade. These have a higher rate of recurrence (80%) and can progress to invasive and metastatic disease.</p> <p>The investigational medicinal product (IMP) nadofaragene firadenovec is a replication-deficient recombinant type 5 adenovirus vector containing the human interferon-a2b (IFN-a2b) gene and the excipient Syn3NODA. Syn3NODA enhances gene transfer across the urothelium.</p>
NIH Guidelines Section	III-C; III-C-1
Risk Assessment discussion	Researchers provided appropriate handling, waste management and accidental exposure procedures.
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Not applicable
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	Not applicable
IBC Vote	<p>A motion was made to approve the registration.</p> <p>Votes: (8) For (0) Against (1) Abstain</p> <p>Conflict(s) of Interest: None</p>

2. Review of SPROTO202600000036

Title	Phase 1/2 mRNA-3927 Dose Optimization Study
Investigator	MARGO BREILYN
Submission ID	SPROTO202600000036
Submission Type	De Novo Review
Project Overview	<p>Propionic acidemia (PA) is an ultra-rare, inherited organic acidemia with no approved therapies and significant morbidity and mortality. The disorder mainly affects the pediatric population and typically presents during infancy.</p> <p>PA is an “intoxication-type” metabolic disorder characterized by the accumulation of toxic compounds due to dysfunction in the metabolic enzyme, PCC. Approximately half of all patients with PA have mutations in PCCA genes, and the other half have mutations in PCCB genes.</p> <p>As there remains an unmet medical need for treatment of patients with PA, the Sponsor is developing mRNA-3927, a novel, intravenously (IV)-administered, lipid-encapsulated mRNA-based therapeutic that contains 2 mRNAs encoding both hPCCA and hPCCB subunits.</p>
NIH Guidelines Section	III-C; III-C-1
Risk Assessment discussion	<p>The mRNA drug product is a lipid nanoparticle (LNP) based delivery system that is non-viral and non-infectious. The occupational hazards of working with this material do not include the possibility of DNA integration.</p> <p>The renewal amendments pertain to the conduct of the study and do not affect the biosafety of the product. The amendments include changes such as the maximum number of cohorts, additional dose expansion stage, and increasing the maximum dose.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Not applicable
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-2
Highest ABSL Practices	Not applicable
IBC Vote	<p>A motion was made to approve the registration.</p> <p>Votes: (8) For (0) Against (1) Abstain</p> <p>Conflict(s) of Interest: None.</p>

3. Review of SAMEND202600000009

Title	Amendment for SPROTO202500000098
Investigator	ALISON GOATE
Submission ID	SAMEND202600000009
Submission Type	Amendment
Project Overview	<p>Adding the use of siRNA is used to knock down expression in THP1 cells. Using lipid nanoparticles to deliver mRNA or siRNA into mouse brain.</p> <p>Research focuses on dementia (Alzheimer's disease & frontotemporal dementia) and addiction (alcohol use disorder (AUD)). The goal is to understand the molecular basis of disease to identify novel targets for therapeutic development. Lab uses both in vitro and in vivo studies to investigate these goals.</p>
NIH Guidelines Section	III-D
Risk Assessment discussion	<p>Information regarding accidental exposure to lentivirus not included.</p> <p>No vivarium concerns.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Not applicable
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	<p>A motion was made to approve the registration pending minor modifications.</p> <p>Votes: (8) For (0) Against (1) Abstain</p> <p>Conflict(s) of Interest: None.</p>

4. Review of SPROTO202500000119

Title	Immunopotentiating analogs in oncolytic treatments
Investigator	ADOLFO GARCIA-SASTRE
Submission ID	SPROTO202500000119
Submission Type	De Novo Review
Project Overview	This study tests novel immunopotentiating analog compounds to treat solid tumors using a combination of oncolytic vector and radiation treatment intratumorally. Several analogs of the natural agonist of the STimulator of INterferon Genes (STING) pathway: cyclic guanosine monophosphate–adenosine monophosphate, also known as cGAMP, will be used.
NIH Guidelines Section	III-D; III-D-4
Risk Assessment discussion	Requires clarifications regarding the Newcastle disease virus (NDV) strain used.
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Multiple members require updating annual OHSQ.
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	<p>A motion was made to require pending minor modification and re-review by BSO.</p> <p>Votes: (9) For (0) Against (0) Abstain</p> <p>Conflict(s) of Interest: None.</p>

5. Review of SPROTO202600000020

Title	In vivo modeling of biliary tract cancers
Investigator	DANIELA SIA
Submission ID	SPROTO202600000020
Submission Type	De Novo Review
Project Overview	The research team's overall goal is to decipher the molecular forces shaping the immune microenvironment of biliary tract cancers and identify and test novel therapeutic strategies. The research team combines new techniques, such as single cell sequencing and mass cytometry with more traditional in silico approaches in animal models of the disease. Carbon tetrachloride is used in combination with injection of plasmid DNA (KRAS/TP53 plasmids) to induce cholangiocarcinoma models. In other models, injection of plasmid DNA is sufficient to induce cholangiocarcinoma with short latency.
NIH Guidelines Section	III-F; III-F-1
Risk Assessment discussion	No research activity changes since original submission. No CCMS or Biosafety concerns. Recommend CCL4 documentation review by Chemical Safety.
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Not applicable
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 after Chemical Safety review. Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None.

6. Review of SPROTO202600000024

Title:	neurobiological and molecular mechanisms in neuropsychiatric and metabolic disorders
Investigator	PAUL KENNY
Submission ID	SPROTO202600000024
Submission Type	Initial Protocol
Project Overview	<p>The laboratory conducts research aimed at understanding the neurobiological and molecular mechanisms underlying neuropsychiatric and metabolic disorders, including substance use disorders and obesity. This work focuses on identifying the neural circuits, receptor systems, and molecular pathways that regulate motivated behaviors and reward processing.</p> <p>A multidisciplinary approach is employed, integrating behavioral neuroscience, molecular biology, and physiological techniques in rodent models. Experimental strategies include the use of viral vector-mediated gene delivery to manipulate gene expression in discrete brain regions, as well as the administration of pharmacological agents to assess their effects on behavior and neural function.</p>
NIH Guidelines Section	III-D; III-D-1; III-D-1-A
Risk Assessment discussion	<p>Requires more detailed descriptions of AAV strains/constructs, promoters, and transgenes; specify concentrations and quantities of diphtheria toxin; update PPE for animal handlers; correct inconsistencies in gene expression and biosafety sections; add missing exposure information for diphtheria toxin; revise risk language in biohazard section; correct incomplete sentence in HSV section.</p> <p>BSO to perform in-lab review</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	One staff member requires annual OHSQ
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	<p>Post mod-review by BSO and Neuroscience expert for approval.</p> <p>Votes: (9) For (0) Against (0) Abstain</p> <p>Conflict(s) of Interest: None.</p>

7. Review of SPROTO20260000021

Title	Generation APMV and influenza-specific monoclonal antibodies
Investigator	IRENE GONZALEZ DOMINGUEZ
Submission ID	SPROTO20260000021
Submission Type	Initial Protocol
Project Overview	<p>Research team's goal is to identify viral residues critical for neutralizing monoclonal antibody (mAb) binding to the hemagglutinin (HA) or the hemagglutinin-neuraminidase (HN) and fusion (F) proteins of different influenza and avian paramyxoviruses (APMV).</p> <p>This will be achieved through the selection and characterization monoclonal antibodies in the mouse model using the hybridoma antibody production platform. The main objective is to define neutralizing epitopes on the HA, HN and F proteins.</p>
NIH Guidelines Section	III-D; III-D-1-a
Risk Assessment discussion	Strain information for all viruses is required, including clarification if human or mouse adapted; updating PPE requirements from Face Mask to N95 if viruses are human strains; clarifying statement regarding the NDV strain used.
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	PI informed of recommendation for annual flu vaccination for staff. One lab member requires completion of annual OHSQ.
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	<p>Post modification review required by BSO and CCMS</p> <p>Votes: (9) For (0) Against (0) Abstain</p> <p>Conflict(s) of Interest: None.</p>

8. Review of SPROTO202600000006

Title	Developing novel anti-prostate cancer therapies
Investigator	QIN YU
Submission ID	SPROTO202600000006
Submission Type	Initial Protocol
Project Overview	<p>The overall research goal is to identify the molecular determinants / therapeutic targets in tumor microenvironment that play essential roles in the cancer initiation and progression, therapeutic resistance of cancer cells, and maintenance of cancer stem cell niche; to understand the underlying mechanisms of their effects; and to develop therapeutic agents and combinations that can effectively inhibit the functions/activities of these therapeutic targets. The knowledge gained and therapeutic agents developed from these studies can be translated into the clinic to slow down, stop, and/or reverse a variety of malignant cancers.</p> <p>Lentiviral and Murine Leukemia Virus vectors are used for in vitro and in vivo experiments.</p>
NIH Guidelines Section	III-E; III-E-1
Risk Assessment discussion	Researchers provided appropriate handling, waste management and accidental exposure procedures. Requires minor administrative corrections.
Training	No deficiencies were noted in staff training records.
Occupational Health Review (if applicable)	Not applicable
Biosafety Level Assignment	BL-2; BL-2N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	<p>A motion was made to approve the registration pending minor modifications.</p> <p>Votes: (9) For (0) Against (0) Abstain</p> <p>Conflict(s) of Interest: None.</p>

OTHER AGENDA ITEMS

9. Review of IBC Membership:

Description	Discuss considering additional faculty based on the type of studies reviewed, e.g.: <ul style="list-style-type: none"> • Nanobiology • Cancer • Mouse Transgenics
Result	Specialist to contact candidates

10. Poliovirus Survey:

Description	Response plan for the US NAC Survey
Result	Update message to PIs and create internal survey for assessing next steps

Review of Incidents

Nothing to report

Inspections / Ongoing Oversight

Nothing to report

IBC Training

Nothing to report

Public Comments

There were no public comments