Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	12/18/2025 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:35 PM
Adjournment	3:32 PM
Conflicts of interest	The IBC Chair 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)	NO
T. BANIA (IBC member; Human Gene Therapy)	NO
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
J. OCHANDO (IBC member; Scientist)	NO
C. SHOR (Local Non-affiliated)	YES
H. FRIEDMAN (Local Non-affiliated)	NO
S. STRAUSS (Legal Counsel)	NO
N. TZAVARAS (IBC member; Scientist)	YES
S. ROSA (Administrative)	YES

QUORUM
The IBC has 11 voting members. 6 members are required to conduct business. Quorum was met.

OTHER INDIVIDUALS IN ATTENDANCE	
Name	**Affiliation / Title**
None	

REVIEW OF PRIOR MEETING MINUTES	
Date of meeting minutes	November 20, 2025
Motion	To approve the minutes as written
Votes	(7) For (0) Against (0) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202500000140

Title:	Phase 1 CAR-T Study for Relapsed / Refractory Multiple Myeloma (P-BCMA-ALLO1)
Investigator	GURBAKHASH KAUR
Submission ID	SPROTO202500000140
Submission Type	Initial Protocol
Project Overview	P-BCMA-ALLO1 is being evaluated in subjects with relapsed/refractory multiple myeloma (MM). P-BCMA-ALLO1 is a chimeric antigen receptor (CAR) T cell product, designed to target antigen B-cell maturation antigen (BCMA) selectively expressed on the surface of MM cells.
NIH Guidelines Section	III-C
Risk Assessment and Discussion	Non-viral product, non-infective.
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	NA
IBC Vote	A motion was made to approve the registration Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none.

2. Review of SPROTO202500000139

Title	Hepatitis B Surface antigen (HBsAg) Test for POC Use
Investigator	JONATHAN SCHIMMEL
Submission ID	SPROTO202500000139
Submission Type	Initial Protocol
Project Overview	This multicenter, prospective, noninterventional clinical performance study will be conducted at ≥3 geographically diverse, non-laboratory-based CLIA-waived point-of-care (POC) sites in the U.S. The objective is to evaluate the statID Pro HBsAg Test for qualitative detection of hepatitis B surface antigen (HBsAg) in heparinized fingerstick whole blood (FWB) specimens by untrained users.
NIH Guidelines Section	Not applicable
Risk Assessment and Discussion	Collection and handling of Hepatitis B positive samples for kit testing. No Biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Advise team members to vaccinate against Hep B.
Biosafety Level Assignment	Not applicable
Highest BSL Practices	BSL-2
Highest ABSL Practices	Not applicable
IBC Vote	A motion was made to approve the registration Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

3. Review of SAMENDCR202500000156

Title	Amendment/CR for SPROTO202500000006
Investigator	ROLAND FRIEDEL
Submission ID	SAMENDCR202500000156
Submission Type	Amendment/CR
Project Overview	Laboratory uses plasmids and lentiviruses that carry recombinant DNA for transfection or transduction of cell lines, respectively. Among the recombinant DNA sequences are cDNA fragments for expression of Plexin proteins, green fluorescent protein (GFP) sequences, Cas9 sequences for expression of CRISPR/Cas9 gene editing endonuclease Cas9, and genes for puromycin resistance or neomycin resistance as selection markers. Laboratory also uses recombinant Rabies virus vectors that carry as recombinant DNA an expression cassette for GFP. The purpose of the Rabies virus is to transduce “starter cells” in culture, which will express GFP and Rabies virus.
NIH Guidelines Section	III-D-1-a
Risk Assessment and Discussion	Transgenic mice clarification for the selection of III-E-3. Request from vendor Safety / Packaging or Certificate of Rabies Virus product regarding replication-deficient status. No propagation concerns
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	No occupational health concerns were noted.
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 modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

4. Review of SPROTO202500000099

Title	Deciphering tissue microenvironment at single cell resolution in Cancer and Aging
Investigator	ALEXANDER TSANKOV
Submission ID	SPROTO202500000099
Submission Type	Initial Protocol
Project Overview	Induce gliomas in adult mice by stereotactically injecting DF-1 chicken fibroblast cells producing RCAS retroviruses encoding oncogenes and/or shRNAs targeting tumor suppressor genes into various brain regions.
NIH Guidelines Section	III-F-1
Risk Assessment and Discussion	No Biosafety concerns Animal housing verification required to ensure activities can be supported
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Research staff must complete OHSQ
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending modifications and OHSQ Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

5. Review of SAMENDCR202500000162

Title:	Amendment/CR for SPROTO202200000169
Investigator:	THOMAS O'LOUGHLIN
Submission ID:	SAMENDCR202500000162
Submission Type:	Amendment/CR
Project Overview	The goal of this research is to understand the metabolic networks underlying cancer development using functional genomics tools. Key aspects of this work involve the systematic characterization of gene function in metabolic networks and requires manipulation of these genes using reagents to perturb gene function by transcriptional repression or activation or overexpression of synthetic cDNAs. Lentivirus will be used to generate cancer cell lines stably expressing a construct of interest.
NIH Guidelines Section	III-D-1, III-D-1-a, III-D-2-a III-D-3, III-D-3-a III-F-1
Risk Assessment and Discussion	No biosafety concerns.
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 modifications. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

6. Review of SPROTO202500000137

Title:	Mutation-targeted genome editing
Investigator:	TINGTING JIANG
Submission ID:	SPROTO202500000137
Submission Type:	Initial Protocol
Project Overview	Research will use molecular biology methods to engineer advanced CRISPR-based genome editing tools to accurately correct the causative genetic mutations to their wild-type counterpart or reprogram the defective DNA sequences to restore the functional domains in mammalian cells. Further, utilizing clinically relevant in vivo delivery methods (e.g. AAV and nanoparticles), we will deliver the gene editors into the target organs of relevant animal models, developing CRISPR-based gene therapy strategies to treat different monogenic diseases, such as cystic fibrosis.
NIH Guidelines Section	III-D-1-a III-D-3-a III-D-4-a, III-D-4-b, III-D-4-c, III-D-4-c-(2)
Risk Assessment and Discussion	No biosafety concerns
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 Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

7. Review of SPROTO202500000138

Title:	Mechanisms of Diabetic Atherosclerosis
Investigator:	LEIGH GOEDEKE
Submission ID:	SPROTO202500000138
Submission Type:	De Novo Review
Project Overview	Using murine experimental models of obesity, insulin resistance, type 2 diabetes and/or atherosclerosis, lab will apply established in vivo techniques to examine whether a novel drug may be effective at attenuating atherosclerosis in mice by burning fat, reversing hyperinsulinemia/insulin resistance and reducing plasma lipids. In addition, we will explore how hyperinsulinemia and/or hyperglycemia can alter the normal activity of immune cells (macrophages) by affecting their metabolism. In certain experiments, we will use AAV vectors to overexpress Cre, murine Pcsk9-D377Y or empty vector controls.
NIH Guidelines Section	III-E-1 III-E-3 III-D-4-b, II-D-4-c-(2)
Risk Assessment and Discussion	No biosafety concerns No veterinary concerns
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 Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

8. Review of SPROTO202500000145

Title:	Design of influenza virus vaccines - Recombinant and Non Recombinant Agents
Investigator:	FLORIAN KRAMMER
Submission ID:	SPROTO202500000145
Submission Type:	Initial Protocol
Project Overview	Animal models will be used for influenza virus transmission experiments to assess the transmissibility pathogenicity, and immune response. Use of these models allows for comprehensive assessment of influenza virus behavior and vaccine efficacy in vivo. The proteins to be expressed are cloned into the baculovirus expression system and used to produce recombinant baculoviruses. These are then use to infect insect cells which produce the proteins of interest.
NIH Guidelines Section	III-D
Risk Assessment and Discussion	Renewal of previously approved research. No biosafety concerns. Research team must provide additional detail for the animal housing/procedure rooms used for specific research activities.
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative review (if applicable)	Research staff must complete OHSQ Recommendation for updated vaccination for staff
Biosafety Level Assignment	BL-1, BL1-N
Highest BSL Practices	ABSL-2+
Highest ABSL Practices	BSL-2+
IBC Vote	A motion was made to approve the registration pending modifications and OHSQ Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

9. Review of SAMENDCR202500000161

Title:	Amendment/CR for SPROTO202400000144
Investigator:	JEAN LIM
Submission ID:	SAMENDCR202500000161
Submission Type:	Amendment/CR
Project Overview	Research team to study how MPXV infection alters pregnancy outcomes in mice and will also be infecting human placental cells and tissues. To read out viral infection, reporter genes will be used: ZSGreen and Luciferase and tdTomato positivity, induced by Cre recombination.
NIH Guidelines Section	III-D-1-b
Risk Assessment and Discussion	Previously approved Mpox research. Lab team aims to include Clade I research. BSO worked with the research team to structure work in the relevant biocontainment facility.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable)	Research staff must complete OHSQ
Biosafety Level Assignment	BL-3, BL3-N
Highest BSL Practices	BSL-3
Highest ABSL Practices	ABSL-3
IBC Vote	A motion was made to approve the registration pending modifications and OHSQ Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

10. Review of SPROTO202500000098

Title:	Using animal and cell models of neurodegeneration
Investigator:	ALISON GOATE
Submission ID:	SPROTO202500000098
Submission Type:	Initial Protocol
Project Overview	Research focuses on dementia (Alzheimer's disease & frontotemporal dementia) and addiction (alcohol use disorder (AUD)). Research goal is to understand the molecular basis of disease in order to identify novel targets for therapeutic development. Lab uses both in vitro and in vivo studies to investigate these goals. Lentivirus vectors are used for our in vitro experiments only; siRNA is used to knock down expression in THP1 cells.
NIH Guidelines Section	III-D
Risk Assessment and Discussion	No veterinary concerns. No biosafety concerns
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative 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 require post-modification review by BSO Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: none

OTHER AGENDA ITEMS

11. Review of IBC Membership:

Description:	Discuss considering additional faculty based on the type of studies reviewed, e.g.: • Nanobiology • Cancer • Mouse Transgenics • Infection Prevention • SATP
Discussion:	Administrator to provide analysis of review quantity per research department. Members to consider potential members.

12. SARS-CoV-2:

Description:	Revise procedures and guidance for transfer of samples outside of BSL-3
Discussion:	BSO to update guidelines and communicate to facility users

Review of Incidents
None

Inspections / Ongoing Oversight
None

IBC Training
Nothing to report

Public Comments
There were no public comments