Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING DETAILS	
Meeting Date	September 18, 2025
Meeting Time	2:30 PM - 3:30 PM
Meeting Type	Videoconference
Call to Order	2:31PM
Adjournment	3:30PM
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 (Chair; Scientist)	Yes
B. LEE (Vice-Chair; Scientist)	Yes
R. ALBRECHT (Biological Safety Officer)	Yes
T. BANIA (Human Gene Therapy)	No
R. BRODY (Scientist)	Yes
L. CHAUHAN (Biological Safety Officer)	Yes
J. COHEN (Veterinarian)	Yes
H. DONG (Human Gene Therapy)	No
D. D'SOUZA (Employee Health)	No
C. NAPIER (Employee Health)	Yes
J. OCHANDO (Scientist)	No
C. SHOR (Local Non-affiliated)	Yes
N. TZAVARAS (Scientist)	Yes
S. PATIL (Administrative)	No
S. ROSA (Administrative)	Yes
S. STRAUSS (Legal Counsel)	No

QUORUM
The IBC has 12 voting members. 7 members are required to conduct business. members were present. Quorum was met.

OTHER INDIVIDUALS IN ATTENDANCE
NYU Langone Health | NYU Grossman School of Medicine IBC 1. Ludovic Desvignes, PhD, IBC Chair 2. Natalie L. Mays 3. Sanoma Morrison 4. Shamsul Arfin Qasmi

REVIEW OF PRIOR MEETING MINUTES	
Date of meeting minutes	August 21, 2025
Motion	To approve the minutes as written
Votes	(7) For (0) Against (1) Abstain
Result	Approved for posting

REVIEW OF PRIOR BUSINESS	
Clinical Staff Training	
Description	**For confirmation:** only basic science researchers associated with a clinical trial are required to complete IBC / Biosafety specific CITI training
Resolution	Clinical trial teams to upload PEAK certificates in Supporting Documents Basic Researchers – all to be completed in CITI

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202500000105

Investigator Name(s):	GURBAKHASH KAUR
Registration Title:	Phase 3 Multiple Myeloma CAR-T Study (Kite Pharma, Anitocabtagene autoleucel)
Submission ID:	SPROTO202500000105
Submission Type:	Initial Protocol
Project Overview	Anitocabtagene autoleucel comprises of autologous T cells that have been genetically modified ex vivo to express a CAR that targets B-cell maturation antigen (BCMA). The active substance of anitocabtagene autoleucel is CD3+ T cells that have undergone ex vivo T-cell activation, gene transfer by replication-deficient 3rd generation lentiviral vector, and expansion. PRIMARY OBJECTIVE: To compare the efficacy of anitocabtagene autoleucel versus standard of care therapy in participants with relapsed/refractory multiple myeloma.
NIH Guidelines Section	III-C
Risk Assessment and Discussion	Study includes periodic monitoring for any evidence of replication competent lentivirus. The registration required modification to 1) include additional information of autologous T cells, 2) select the recombinant category for capturing and assigning NIH guidelines. Additional guidance specific to clinical research activities was provided to research team for PPE and waste management.
Training	Clinical trial staff complete clinical staff-required PEAK trainings.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL-2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	NA
IBC Vote	Motion: Clinical expertise members not available to provide review; to be sent to Designated member to clinical expertise members for final approval. Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

2. Review of SPROTO202500000086

Investigator Name(s):	LUCAS FERRARI DE ANDRADE
Registration Title:	Antibody-based immunotherapies for cancers
Submission ID:	SPROTO202500000086
Submission Type:	De Novo Review
Project Overview	The research team uses lentiviral vectors and recombinant DNA to develop monoclonal antibodies that promote immunity against cancers. The research aims to improve cancer care, by promoting protective immunity. They utilize antibodies for in-vitro and in-vivo models of cancer. In vitro studies include genetic engineering of CHO and 293T cells that will produce recombinant antibodies, genetic engineering of tumor cell lines that will express the antigens that are recognized by the antibodies, and the work with primary cells from healthy donors and cancer patients to test the antibodies in in-vivo and in-vitro assays.
NIH Guidelines Section	III-D-1-a
Risk Assessment and Discussion	Main recombinant work is E. coli based. 2nd generation lentivirus used in vivo and in vitro animal models. Proper waste management is described in the registration. BSO requesting clarification for the use of 2nd generation lentivirus. No concerns from vivarium.
Training	Research team current on required basic science trainings.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL-2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	Motion: Approve after completion of minor, administrative modifications Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

3. Review of SPROTO202500000080

Investigator Name(s):	JOSEPH CASTELLANO
Registration Title:	Systemic Interactions with the CNS in Health & Disease
Submission ID:	SPROTO202500000080
Submission Type:	Initial Protocol
Project Overview	This project will investigate how a blood-borne protein tissue inhibitor of metalloproteinases 2 (TIMP2) improves hippocampal function and learning and memory. The work may inform therapies directed at restoring TIMP2 function as a treatment for aging or Alzheimer's disease, while also providing insights into how other blood-borne factors may influence the brain. In vivo work includes stereotaxic injection of commercial lentivirus for knockdown of genes or reporter expression.
NIH Guidelines Section	III-D-1, III-D-1-a III-D-4, III-D-4-a, III-D-4-b
Risk Assessment and Discussion	No Vivarium, waste management or PPE concerns.
Training	Research team current on required basic science trainings.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL-1
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	Motion: Approve after completion of minor, administrative modifications Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

4. Review of SPROTO202500000067

Investigator Name(s):	Modulating Iron Trafficking to Ameliorate Ineffective Erythropoiesis
Registration Title:	YELENA GINZBURG
Submission ID:	SPROTO202500000067
Submission Type:	Initial Protocol
Project Overview	The focus of the lab's research is to understand the nuances of regulation in the interface between erythropoiesis and iron metabolism. They use banked patient samples and mouse models of various disorders associated with expanded erythropoiesis and concurrent iron disorders. The work involves the use of lentiviral vectors used both in vivo (intra-hepatic injection) and ex vivo (transduction of Hematopoietic Stem Cells for bone marrow transplant).
NIH Guidelines Section	III-D, III-D-1, III-D-1-a III-D-3, III-D-3-a III-D-4, III-D-4-a
Risk Assessment and Discussion	No Vivarium, waste management or PPE concerns.
Training	Research team current on required basic science trainings.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL-2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	Motion: Approved Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

5. Review of SPROTO202500000091

Investigator Name(s):	Alphavirus
Registration Title:	GUSTAVO PALACIOS
Submission ID:	SPROTO202500000091
Submission Type:	Initial Protocol
Project Overview	These experiments will provide essential data on determinants of replication and tropism while supporting the development of translational models of virus–host interactions. In parallel, we will continue advancing the Eilat virus (EILV)-based vaccine platform, designed to generate multivalent candidates targeting WEEV, VEEV, Sindbis, and chikungunya viruses. Comparative studies will be performed against a benchmark alphavirus vaccine (e.g., TC-83), integrating single-cell omics and ex vivo tissue models to dissect the quality and durability of the immune response. There will be animal use component for viruses TC-83 and CHIKV.
NIH Guidelines Section	III-D, III-D-1-a III-D-2 III-D-3, III-D-3-a
Risk Assessment and Discussion	Current information is not clear: 1) full-length vs. construct of each virus that will be used for the studies 2) Inconsistent text regarding wildtype strain use 3) Clarification if ex vivo work will be included
Training	Research team current on required basic science trainings.
Occupational Health Representative review	Concerns, if any, to be assessed with updated submission.
Biosafety Level Assignment	BL-3
Highest BSL Practices:	BSL-3
Highest ABSL Practices:	ABSL-3
IBC Vote	Motion: Modifications required. Return for full committee review. Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

6. Review of SPROTO202500000078

Investigator Name(s):	orthohantaviruses and bunyaviruses host interactions
Registration Title:	GUSTAVO PALACIOS
Submission ID:	SPROTO202500000078
Submission Type:	Initial Protocol
Project Overview	The project aims to uncover the molecular mechanisms underlying these evolutionary constraints and leverage them for the development of broad-spectrum vaccines and antivirals. The study focuses on two viral families, Orthohantavirus and Bunyavirus, both of which represent zoonotic diseases that have crossed over to humans multiple times. The study will characterize the relevance of key protein interactions and specific viral mutations at different stages of the viral life cycle using pseudotyped viruses based on VSV or lentiviral platforms, minigenome systems, and viral protein expression, using an in vitro approach. No in vivo studies will be performed
NIH Guidelines Section	III-D, III-D-2, III-D-2-a III-D-3, III-D-3-b, III-D-3-e
Risk Assessment and Discussion	BSO provided research team with updated consequences of exposure hazards from recent publication on Oropouche orthobunyavirus to be included in the registration. No waste management or PPE concerns.
Training	Research team current on required basic science trainings.
Occupational Health Representative review	Current staff do not require additional review. However, PI must ensure staff list is kept up-to-date for Occupational Health review.
Biosafety Level Assignment	BL-3
Highest BSL Practices:	BSL-3
Highest ABSL Practices:	NA
IBC Vote	Motion: Approve after confirmation from Employee Health and minor modification request. Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

7. Review of SPROTO202500000061

Investigator Name(s):	Nitric Oxide in Hyperglycemia and Addiction
Registration Title:	JESSICA ABLES
Submission ID:	SPROTO202500000061
Submission Type:	Initial Protocol
Project Overview	The research team utilizes AAVs in the brains of mice to visualize calcium dynamics as a proxy for neuronal activity, to overexpress or knock-down genes of interest, or to express proteins that are light-responsive to modulate neuron activity or protein translation, or to express membrane tethered toxins that bind voltage-gated calcium channels. The research team only uses commercially-sourced, replication-incompetent adeno-associated viral vectors.
NIH Guidelines Section	III-D, III-D-4-a, III-D-4-c-(2) III-E, III-E-1-a, III-E-3-a
Risk Assessment and Discussion	Registration was well-written with clear information for review. No Vivarium, waste management or PPE concerns.
Training	PI is missing 2 CITI trainings.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL-2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	Motion: Approve after completion CITI training. Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

8. Review of SPROTO202500000074

Investigator Name(s):	Harnessing native glycosylation to improve immunogenicity of HIV-1 Env immunogens
Registration Title:	CHITRA UPADHYAY
Submission ID:	SPROTO202500000074
Submission Type:	Initial Protocol
Project Overview	Findings from this study will provide information that could lead to the development of new strategies and designs for the urgently needed HIV vaccines. The research team will perform immunization experiments in mouse and rabbit models to evaluate the immunogenicity of different vaccine candidates. Pseudoviruses will be generated by co-transfecting HEK293T cells with HIV-1 envelope, and pNL4-3Δenv plasmids using jetPEI.
NIH Guidelines Section	III-D
Risk Assessment and Discussion	Registration did not clarify if neutralization assays will be performed. No Vivarium, waste management or PPE concerns.
Training	Research team current on required basic science trainings.
Occupational Health Representative review	One lab team has not completed annual Occupational Health Survey.
Biosafety Level Assignment	BL-2 BL-2N
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-1
IBC Vote	Motion: Post-modification review by BSO for final approval. Votes: • (8) For • (0) Against • (0) Abstain Conflict(s) of Interest: None.

OTHER AGENDA ITEMS

9. Review of Annual NIH Registration:

Description:	The annual registration with NIH is due in November 2025. Please inform Admin of updated CVs.