

Institutional Biosafety Committee Icahn School of Medicine at Mount Sinai

MEETING MINUTES

MEETING DETAILS	
Meeting Date	July 17, 2025
Meeting Time	2:30 PM - 3:30 PM
Meeting Type	Videoconference
Call to Order	2:32 PM
Adjournment	3:48 PM
Conflicts of Interest	<p>The IBC Chair reminded all members present to identify any conflicts of interest as each registration is reviewed.</p> <p>Chair and Biosafety Director are involved in 2 submissions, either as PI or research team member respectively. The Chair and Biosafety Director recused from review and vote for respective submissions.</p>

ATTENDANCE	
Name	Present
V. SIMON (Chair; Scientist)	Yes
B. LEE (Vice-Chair; Scientist)	No
R. ALBRECHT (Biological Safety Officer)	Yes
T. BANIA (Human Gene Therapy)	Yes
R. BRODY (Scientist)	No
L. CHAUHAN (Biological Safety Officer)	Yes
J. COHEN (Veterinarian)	Yes
H. DONG (Human Gene Therapy)	Yes
D. D'SOUZA (Employee Health)	Yes
C. NAPIER (Employee Health)	Yes
J. OCHANDO (Scientist)	No
C. SHOR (Local Non-affiliated)	No
S. STRAUSS (Legal Counsel)	No
N. TZAVARAS (Scientist)	Yes
S. PATIL (Administrative)	No
S. ROSA (Administrative)	Yes

QUORUM
The IBC has 12 voting members. 7 members are required to conduct business. 9 voting members were present. Quorum was met.

OTHER INDIVIDUALS IN ATTENDANCE
None

REVIEW OF PRIOR MEETING MINUTES	
Date of meeting minutes	May 15, 2025
Motion	To approve the minutes as written: Approved
Votes	(9) For (0) Against (0) Abstain
Result	Meeting minutes approved

REVIEW OF PRIOR BUSINESS
No activities to report.

COMMITTEE REVIEW SUBMISSIONS

1. Review of SAMENDCR202500000065

Investigator Name(s):	OREN BECHER
Registration Title:	Amendment/CR for SPROTO202300000041
Submission ID:	SAMENDCR202500000065
Submission Type:	Amendment/CR
Project Overview	Annual review of research utilizing RCAS vector system for tissue-specific expression of oncogenes in mice.
<i>NIH Guidelines</i> Section	III-E-3
Risk Assessment and Discussion	Research activities includes handling of experimental mice, and sharps. No avian species are housed in the mouse facility, eliminating RCAS exposure risk to local avian population. The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL2; BL2N
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	Motion: BSO approved Votes: <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

2. Review of SPROTO202500000041

Investigator Name(s):	FLORIAN KRAMMER
Registration Title:	Group 2 Universal Influenza Virus Vaccine New
Submission ID:	SPROTO202500000041
Submission Type:	De Novo Review
Project Overview	Triennial review of previously approved registration. Research characterizes influenza vaccine candidates.
NIH Guidelines Section	III-D-a III-D-b
Risk Assessment and Discussion	Research activities includes handling of experimental mice, sharps and chimeric, inactivated influenza vaccine candidates and BSL-3 agents. The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.
Training	Some members have expired trainings
Occupational Health Representative review	Some members require completion / updating of Occupational Health Questionnaire.
Biosafety Level Assignment	BL3; BL3N
Highest BSL Practices:	BSL-3
Highest ABSL Practices:	ABSL-3
IBC Vote	Motion: Approval after completion of administrative modifications and trainings. Votes: <ul style="list-style-type: none"> • (8) For • (0) Against • (0) Abstain • Conflict(s) of Interest: Biosafety Director provides BSL-3 assistance to research team.

3. Review of SPROTO202500000044

Investigator Name(s):	MARGRIT WIESENDANGER
Registration Title:	Phase 1 - First-in-Human CAR-T Study (RESOLUTION)
Submission ID:	SPROTO202500000044
Submission Type:	Initial Protocol
Project Overview	The purpose of this study is to evaluate the safety and tolerability of CAR-T product ALLO-329 in adults with autoimmune disease, determine the recommended Phase 2 regimen, and provide initial evidence of biological activity and clinical response to the treatment.
NIH Guidelines Section	III-C-1
Risk Assessment and Discussion	<p>Research activities includes handling of blood/body fluid/tissue and sharps.</p> <p>The registration and lab SOPs include required PPE and handling guidelines.</p> <p>Waste Management and Spill Response information requires updating to current institutional guidelines.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review	No occupational health concerns were noted.
Biosafety Level Assignment	BL-1
Highest BSL Practices:	BSL-1
Highest ABSL Practices:	NA
IBC Vote	<p>Motion: Approval after completion of administrative modifications</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

4. Review of SPROTO202500000057

Investigator Name(s):	JEFFREY JOHNSON
Registration Title:	In vitro SARS-CoV-2 and HIV-1 infections in human cells
Submission ID:	SPROTO202500000057
Submission Type:	Initial Protocol
Project Overview	<p>The PI proposes in vitro experiments using vector particles, generated by a second generation system, to stably express transgenes of interest. These systems are derived from HIV, and retain the ability to integrate into the genome of infected cells.</p> <p>Transgenes delivered include fluorescent proteins used as reporters of various cellular activities (GFP, RFP, mCherry), human proteins and protein mutants of interest (RPS20, USP7, ACE2), and individual viral proteins derived from SARS-CoV-2 or HIV-1.</p>
NIH Guidelines Section	III-D-1
Risk Assessment and Discussion	<p>Research activities includes handling of infectious agents with integration ability.</p> <p>The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.</p>
Training	Some members have expired trainings
Occupational Health Representative review	No occupational health concerns were noted.
Biosafety Level Assignment	BL2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	NA
IBC Vote	<p>Motion: Modifications required, including storage of replication competent HIV-2 and SARS-CoV-2 isolates and completion of trainings.</p> <p>Post modification review by BSO for approval confirmation.</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

5. Review of SPROTO202500000060

Investigator Name(s):	PETER PALESE
Registration Title:	In-Ovo and Poultry Vaccination
Submission ID:	SPROTO202500000060
Submission Type:	Initial Protocol
Project Overview	<p>The research aims to develop innovative vaccine strategies using avian paramyxoviruses (APMV) to protect poultry from highly pathogenic avian influenza (HPAI). The study focuses on antigen design optimization, thermostable formulations, early-life immunity through in-ovo delivery and multivalent coverage.</p> <p>The sequence of the antigen of interest was inserted into pNDV rescue plasmid.</p>
NIH Guidelines Section	III-D-1-a III-D-7
Risk Assessment and Discussion	<p>Research activities includes handling of experimental chickens, sharps and infectious agents.</p> <p>The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.</p>
Training	Some members have expired trainings
Occupational Health Representative review	Some members require completion / updating of Occupational Health Questionnaire.
Biosafety Level Assignment	BL2; BL2N
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	<p>Motion: Approval after completion of administrative modifications and trainings.</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

6. Review of SPROTO202500000052

Investigator Name(s):	YOUNGWOOK AHN
Registration Title:	MGGT CoRE
Submission ID:	SPROTO202500000052
Submission Type:	Initial Protocol
Project Overview	<p>This submission is an umbrella registration to capture overall activities and biohazards of the institutional Mouse Transgenic Core. Research labs who utilize core services are to reference this registration and include location and staff of the core.</p> <p>The core provides various services: the isolation, microinjection and reimplantation of mouse eggs for the production of transgenic mice, for the microinjection of embryonic stem cells into mouse blastocysts for the production of knockout mice, for in vivo gene editing with CRISPR/Cas9 reagents and for IVF rederivation of mouse lines into animal colonies. For the genome editing in mouse eggs, the facilities utilize recombinant DNA molecules as a repair template or transgene and rAAV as a vehicle for delivery of repair templates into mouse eggs ex vivo.</p>
NIH Guidelines Section	<p>III-D-1</p> <p>III-E-1</p>
Risk Assessment and Discussion	<p>Research activities includes handling of experimental mice and sharps.</p> <p>The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review	NA
Biosafety Level Assignment	BL1; BL1N
Highest BSL Practices:	BSL-1
Highest ABSL Practices:	ABSL-1
IBC Vote	<p>Motion: Approve.</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

7. Review of SPROTO202500000059

Investigator Name(s):	CAROL LEVY
Registration Title:	Phase 1: First in Human Treg Cell Therapy in Adults with Recently Diagnosed Type 1 Diabetes (POLARIS-GENTIBIO)
Submission ID:	SPROTO202500000059
Submission Type:	Initial Protocol
Project Overview	<p>This clinical study aims to evaluate the safety, tolerability, and cytokinetics (CK) of GNTI-122, an autologous T-reg cell therapy product, in adult participants with recently diagnosed Type 1 diabetes mellitus.</p> <p>GNTI-122 is created from autologous CD4+ T cells obtained by leukapheresis from the participant. The participant's cells are then genetically modified via site-specific, clustered regularly interspaced short palindromic repeats/CRISPR associated protein 9 (CRISPR/Cas9) gene editing at 2 loci: FOXP3 and T cell receptor alpha constant (TRAC), using adeno-associated virus (AAV) to deliver donor templates for targeted insertion of transgenes via a homology-directed repair mechanism.</p>
NIH Guidelines Section	III-C-1
Risk Assessment and Discussion	<p>Research activities includes handling of sharps and human blood/body fluid. No recombinant work is performed on-site.</p> <p>The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review	NA
Biosafety Level Assignment	NA
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	NA
IBC Vote	<p>Motion: Approval after completion of administrative modifications.</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

8. Review of SPROTO202400000095

Investigator Name(s):	MIHAELA SKOBE
Registration Title:	Lymphatics in melanoma
Submission ID:	SPROTO202400000095
Submission Type:	Initial Protocol
Project Overview	<p>The research team investigates the process of lymphatic metastasis.</p> <p>Additionally, we have developed a therapy involving an oncolytic virus, NDV (Newcastle disease virus), an avian virus that does not cause disease in human but that is capable of lysate tumor cells.</p> <p>The proposing using NDV LaSota strain. LaSota strain represents a lentogenic, avirulent strain and is not genetically modified. They will use mRNA lipid nanoparticles (LNPs) encoding the VEGF-C gene. These LNPs will be injected intratumorally into mice.</p>
NIH Guidelines Section	III-D-1-a
Risk Assessment and Discussion	<p>Research activities includes handling of NDV (Newcastle disease virus), an oncolytic, avian virus. NDV does not cause disease in human but is capable of lysating tumor cells.</p> <p>The registration and lab SOPs include required PPE, handling guidelines, Waste Management and Spill Response.</p>
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review	Some members require completion / updating of Occupational Health Questionnaire.
Biosafety Level Assignment	BL2
Highest BSL Practices:	BSL-2
Highest ABSL Practices:	ABSL-2
IBC Vote	<p>Motion:</p> <p>Approval after completion of modifications and post-modification review.</p> <p>Post-modification review by veterinarian.</p> <p>Votes:</p> <ul style="list-style-type: none"> • (9) For • (0) Against • (0) Abstain • Conflict(s) of Interest: None.

OTHER AGENDA ITEMS

New Business/Additional Topics

Review of [REDACTED] Lab: Modifications Required for Standard 3-Year Approval

Description	The [REDACTED] Lab has not completed IBC or Biosafety Program modification requests to eSafety registration.
Related Projects	SPROTO202400000123, SPROTO202400000168
Result	IBC Member and Admin to meet with research team for finalizing required modifications.

Review of Incidents

Nothing to report

Inspections / Ongoing Oversight

Nothing to report

IBC Training

The Biosafety Director presented an overview of NIH Guidelines and application to research with influenza viruses

Public Comments

There were no public comments

IBC Training

The Biosafety Director presented an overview of NIH Guidelines and application to research with influenza viruses. Further review and discussion by Occupational Health.

Public Comments

There were no public comments