Icahn School of Medicine at Mount Sinai

Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	5/21/2026 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:49PM
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 (IBC Chair; Scientist)	NO
B. LEE (IBC vice-Chair; Scientist)	YES
T. BANIA (IBC member; Human Gene Therapy)	YES
R. BRODY (IBC member; Scientist)	YES
C. BERMUDEZ (Institutional Observer)	YES
L. CHAUHAN (Biological Safety Officer)	YES
J. COHEN (IBC member, Attending Veterinarian)	YES
H. DONG (IBC member; Human Gene Therapy)	NO
A. DOSUNMU (Biological Safety Officer)	YES
D. D'SOUZA (Alternate IBC member; Employee Health)	NO
C. NAPIER (IBC member; Employee Health)	YES
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 10 voting members. 6 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	Yes
Motion	To approve the minutes as written
Votes	(6) For (0) Against (1) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SAMEND202600000025

Title	Amendment for SPROTO202500000122
Investigator	BRIAN KIM
Submission ID	SAMEND202600000025
Submission Type	Amendment
Project Overview	Research team focuses on understanding which specific immune cells and nerves mediate such processes will reveal new treatment strategies. Team uses various mouse models of chronic inflammatory diseases and stress/anxiety to model these interactions to demonstrate new mechanisms that govern such interactions, then we can find new treatments for patients with eczema, asthma, and food allergy. Amendment for: 1) Adding two new projects: a) Regulation of GBS-induced preterm labor by mast cell-sensory neuron circuit b) The Neuro-Immune Axis in Cutaneous Lyme Borreliosis 2) Adding Group B Streptococcus (GBS) and Borrelia burgdorferi
NIH Guidelines Section	III-D-1-A III-D-3, III-D-3-A III-D-4-C, III-D-4-C-2
Risk Assessment discussion	No biosafety or CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	7 members require completion of OHSQ for 2026.
Biosafety Level Assignment	BL-2 BL2-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	Approve after completion of minor modifications. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

2. Review of SAMENDCR202600000026

Title	Amendment/CR for SPROTO202500000024
Investigator	JUN WANG
Submission ID	SAMENDCR202600000026
Submission Type	Amendment/CR
Project Overview	Research team conducts research on drug discovery for neurological and psychiatric disorders, including Alzheimer's disease and depression, with the final goal of translating preclinical findings into clinical applications. Annual review was updated for more recombinant AAV work description. No cloning is involved. All virus are purchased from Addgene. 1. rAAV2/hSyn-DIO-hM3D(Gq)-mcherry: Syn-driven, Cre-dependent, hM3D(Gq) receptor with an mCherry reporter. 2. AAV9.CamKII-GCaMP6f: CamKII-driven ultra-sensitive format of GCaMP calcium sensor 3. pLKO.1 Lentivirus: replication-incompetent lentiviral vector used to express scrambled shRNA or shRNA specific for mouse CCR5
NIH Guidelines Section	III-D-1, III-D-1-a III-E-1
Risk Assessment discussion	No Biosafety or CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	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

3. Review of SPROTO202600000035

Title	Immune responses during chronic infections and cancer
Investigator	ALICE SILVA
Submission ID	SPROTO202600000035
Submission Type	De Novo Review
Project Overview	Research team utilizes animal model to gain mechanistic insights on T cell function. Activities include: 1) lenti and retroviruses to manipulate immune cells in vitro which will later be transferred to mice in vivo. 2) DNA plasmids to induce local expression of genes in the liver of mice via hydrodynamic injection.
NIH Guidelines Section	III-D-1-a
Risk Assessment discussion	Insufficient information regarding the lymphocytic choriomeningitis virus LCMV-LM
Training	No deficiencies were noted in staff training records.
Occupational Health	Advise all team members receive up to date vaccination against Diphtheria. Employees who are pregnant or actively planning to become pregnant should consult with their providers regarding Tamoxifen exposure, LCMV exposure and follow up with EHS.
Biosafety Level Assignment	BL-2 BL2-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made for post-mod review to BSO and potential committee re-review Votes: (6) For (0) Against (1) Abstain Conflict(s) of Interest: Chauhan associated with a patent for Norway Rat Hepacivirus

4. Review of SPROTO202600000019

Title	Cellular Therapy Laboratory
Investigator	CAMELIA IANCU RUBIN
Submission ID	SPROTO202600000019
Submission Type	De Novo Review
Project Overview	Cellular Therapy Laboratory (CTL) is a clinical laboratory performing clinical procedures related to handling and storage of cell-based therapeutics for standard of care treatment or used as investigational drugs/biologics in clinical studies. CTL, along with the Bone Marrow Transplant Program and Apheresis Services, are the only institutional services accredited by the Foundation for Accreditation of Cellular Therapies (FACT), licensed by The New York State Department of Health (NYDOH) and FDA registered to handle cellular therapies. Therefore, in addition to handling standard of care cell products, CTL also manages investigational cellular therapies which are part of clinical research at Mount Sinai Hospital. Of note, CTL does not perform procedures related to cells modifications but manages the final products from their arrival at Mount Sinai until they are ready for infusion into the patients, including storage, thawing preparation for infusion.
NIH Guidelines Section	Not applicable
Risk Assessment discussion	Registration used to capture CTL staff handling CAR-T agents. Clinical trial teams associate and reference the CTL within individual study protocols. No biosafety concerns
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
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

5. Review of SAMENDCR202600000001

Title	neurological disorder studies
Investigator	ZHENYU YUE
Submission ID	SAMENDCR202600000001
Submission Type	Amendment/CR
Project Overview	The laboratory focuses on investigating the molecular, cellular, network, circuitry, and behavioral mechanisms underlying various neurological disorders and psychiatric conditions, including Parkinson's disease, Alzheimer's disease, Huntington's disease, bipolar disorder, and schizophrenia. Annual continuing review of ongoing research with updates to staff and addition of AAV-nanoparticles. AAV-Nanobody, will be delivered into mouse brain by local stereo-injection and by IV injection. The AAV-nanobody will be amplified and packed into HEK293 cells.
NIH Guidelines Section	III-E-1
Risk Assessment discussion	No biosafety or CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
Biosafety Level Assignment	BL-1 BL1-N
Highest BSL Practices	BSL-1
Highest ABSL Practices	ABSL-1
IBC Vote	A motion was made to approve the registration pending minor modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

6. Review of SPROTO202600000014

Title	Avian virus surveillance
Investigator	FLORIAN KRAMMER
Submission ID	SPROTO202600000014
Submission Type	De Novo Review
Project Overview	Surveillance of wild birds for viruses of interest is key to understanding the circulation of those viruses and is conducted across the globe. New York City's parks, which are large undeveloped spaces surrounded by ubiquitous human construction, are widely recognized as a key stopover location for migrating birds. The research team conducts viral surveillance on migratory and resident wild birds in the New York City area and determine the prevalence and dynamics of AIV and avian paramyxovirus (APMV) in that population. Samples will be obtained in two streams: by collecting fecal samples from surfaces in New York City's parks, and testing cloacal, oropharyngeal, and fecal samples collected by the Wild Bird Fund and the Animal Care Centers of New York City, two non-profit organizations focused on animal welfare that regularly treat sick and injured birds.
NIH Guidelines Section	Not applicable
Risk Assessment discussion	Routine activities and potential exposure are RG-2. Committee agreed registration should be updated to RG-2 with escalation to RG3 if relevant agents are found during screenings.
Training	No deficiencies were noted in staff training records.
Occupational Health	2 members require completion of OHSQ for 2026.
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 pending modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

Icahn School of Medicine at Mount Sinai

7. Review of SPROTO202600000041

Title	Studying neuronal circuit remodeling induced by brain cancer cells
Investigator	RICHARD DREXLER
Submission ID	SPROTO202600000041
Submission Type	Initial Protocol
Project Overview	Research team investigates the bidirectional interactions between brain cancer cells and neuronal circuits, with the goal of understanding how tumors hijack and remodel neural activity - and how neuronal circuits, in turn, influence cancer cell phenotype and tumor progression. General experimental approach combines in vitro co-culture systems (cancer cells, neurons, and supporting cell types), mouse allograft and xenograft models, and viral vector injections. This research involves the use of recombinant viral vectors — specifically adeno-associated virus (AAV) and lentiviral vectors — containing recombinant or synthetic nucleic acid molecules for both in vitro and in vivo applications.
NIH Guidelines Section	III-D-3, III-D-3-a III-D-4-a, III-D-4-b
Risk Assessment discussion	No biosafety or CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
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 minor modifications Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

8. Review of SAMEND202600000026

Title	Amendment for SPROTO202200000222
Investigator	MONICA KRAFT
Submission ID	SAMEND202600000026
Submission Type	Amendment
Project Overview	Research team investigates innate immune responses of airway epithelial cells to different viruses. Amendment for: 1) SARS-CoV-2 has been reclassified from BSL-3 to BSL-2+. 2) use several strains of influenza A virus (IAV) in future experiments.
NIH Guidelines Section	III-F-1
Risk Assessment discussion	BSO worked with lab team to designate a dedicated BSL-2+ room, PPE and SOPs. No biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	3 members require completion of OHSQ for 2026. Advise up to date vaccination against Influenza and SARS-CoV2 if not already done.
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 after completion of OHSQ. Potential future action: remove the Human Clinical Trial category from registration - dependent on review of other approved non-gene transfer human studies. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

9. Review of SPROTO202600000027

Title	Replication-competent VSV expressing the SARS-CoV-2 S protein
Investigator	WEINA SUN
Submission ID	SPROTO202600000027
Submission Type	De Novo Review
Project Overview	We will first generate the recombinant DNA plasmids encoding the genome of the Vesicular Stomatitis virus (VSV) of the attenuated Indiana serotype, in which an EGFP reporter gene is added and the VSV-G gene is replaced with the S gene of the SARS-CoV-2. VSV is a single-stranded negative-sense RNA virus (member of Rhabdoviridae) and is not considered a human pathogen Since the G protein is required for virus infectivity, to replace the G protein with the Spike protein of the SARS-CoV-2 will result in a recombinant virus that is replication-competent only on permissive cells expressing ACE2 and the cognate proteases. The virus will be rescued and amplified from permissive cell cultures. The rVSVs expressing the spike protein of SARS-CoV-2 will be used in high through-put micro-neutralization assays to measure neutralizing activity of monoclonal antibodies or polyclonal sera against the spike of interests.
NIH Guidelines Section	III-D-3-a III-E-1
Risk Assessment discussion	No Biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-2
Highest ABSL Practices	Information missing
IBC Vote	A motion was made to approve registration after minor modifications. Post-meeting admin noted that non-recombinant work activities with animals was not described. New modification request sent to research team. Post-mod review by CCMS. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

10. Review of SPROTO202600000039

Title	Ex vivo models of virus interactions
Investigator	ANA FERNANDEZ-SESMA
Submission ID	SPROTO202600000039
Submission Type	De Novo
Project Overview	Recombinant DNA is used to overexpress human and mouse proteins (cGAS, STING) or viral proteins (hemagglutinin (HA), neuraminidase (NA) of influenza A viruses (IAV), capsid protein of Chikungunya virus (CHIKV)) in immortalized human, dog, and mouse cell lines. Further, recombinant nucleic acid is used to generate virus like particles (VLPs) pseudotyped with IAV glycoproteins. Small interfering RNA (siRNA) molecules are used to lower expression levels of host proteins. Reseach Aims: *Analysis of immune response to vaccinations and or infections in human tonsils histocultures and human primary cells. *Measure the dynamic changes in human immune profiles following (SARSCoV2, Influenza virus and dengue virus (DENV) vaccination that correlate with vaccine immune signatures Using different types of vaccines (RNA/adenoviral) and the generation of immune responses in humans. *Analysis of immune response to vaccinations in human tonsils histocultures.
NIH Guidelines Section	III-E-1
Risk Assessment discussion	Triennial review of ongoing research activities. No Biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health	All team members require completion of OHSQ for 2026. Advise up to date vaccination against Influenza, Chikungunya, and Yellow fever virus if not already done.
Biosafety Level Assignment	BL-2
Highest BSL Practices	BSL-2
Highest ABSL Practices	Not Applicable
IBC Vote	A motion was made to approve pending OHSQ completion and minor administrative modifications. Votes: (7) For (0) Against (0) Abstain Conflict(s) of Interest: None

OTHER AGENDA ITEMS

11. Review of CITI Recombinant Course for Clinical PIs:

Description	Discuss requiring Recombinant training course for clinical PIs conducting human recombinant research studies.
Result	Not discussed due to time constraints. Discussion postponed to next meeting.

REVIEW OF INCIDENTS
Nothing to report

INSPECTIONS / ONGOING OVERSIGHT
Nothing to report

IBC TRAINING
Nothing to report

PUBLIC COMMENTS
There were no public comments