Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	6/18/2026 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:32pm
Adjournment	3:35pm
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
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
A. DOSUNMU (Biological Safety Officer)	YES
D. D'SOUZA (IBC member; Employee Health; Alternative)	YES
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 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	(8) For (0) Against (1) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202600000038

Title:	Phase 1/2 CAR-T Study (MS-IMPACT)
Investigator:	FRED LUBLIN
Submission ID:	SPROTO202600000038
Submission Type:	Initial Protocol
Project Overview	This is a Phase 1/2a, first in human (FIH), open label study evaluating the safety and tolerability of TRX319 in subjects with primary or secondary progressive multiple sclerosis (PPMS or SPMS). TRX319 is a cryopreserved, ex vivo expanded, single donor, allogeneic, off-the-shelf cellular therapy product designed for targeted depletion of CD19+ B cells, halting of pathogenic immune responses, and (re)-establishment of immune tolerance.
NIH Guidelines Section	III-C-1
Risk Assessment discussion	No concerns noted.
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	Not applicable
IBC Vote	A motion was made to approve the registration Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

2. Review of SPROTO202600000005

Title:	JNJ-6828452 Out-of-Specification (OOS) CAR-T Study
Investigator:	ADRIANA ROSSI
Submission ID:	SPROTO202600000005
Submission Type:	De Novo Review
Project Overview	Cilta-cel Out-of-Specification (OOS) is to be use as part of an expanded access program (EAP). The JNJ OOS expanded access program is a treatment program (not research) considered for patients with a serious/life-threatening disease or condition, where there is no alternative treatment or where other alternative treatments have been exhausted.
NIH Guidelines Section	III-C-1
Risk Assessment discussion	No concerns noted.
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	Not Applicable
IBC Vote	A motion was made to approve the registration Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

3. Review of SPROTO202600000040

Title:	Phase 1 Gene Therapy Study (PBGENE-HBV-01-LNP)
Investigator:	DOUGLAS DIETERICH
Submission ID:	SPROTO202600000040
Submission Type:	Initial Protocol
Project Overview	This is a phase 1, open-label, first-in-human, dose escalation (Part 1) and expansion (Part 2) study to evaluate the safety of PBGENE-HBV in participants with Chronic Hepatitis B (CHB). PBGENE-HBV is a lipid nanoparticle (LNP)-delivered mRNA encoding an ARCUS nuclease that is designed to be delivered and expressed preferentially in the liver to specifically target hepatitis B virus (HBV) DNA present in hepatocytes and covalently closed circular DNA (cccDNA). PBGENE-HBV is a novel, first-in-class, gene therapy investigational drug product (DP) being developed as a finite treatment.
NIH Guidelines Section	III-C
Risk Assessment discussion	No concerns noted
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
Biosafety Level Assignment	BL-1
Highest BSL Practices	BSL-1
Highest ABSL Practices	Not Applicable
IBC Vote	A motion was made to require post-modification BSO review before approval Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

4. Review of SPROTO202600000060

Title:	Phase 2 Study of DNA-Based Vaccine (GNOS-PV02; INO-9012)
Investigator:	DAN FENG
Submission ID:	SPROTO202600000060
Submission Type:	Initial Protocol
Project Overview	This is a randomized, open-label, multi-site Phase II study of a personalized neoantigen DNA vaccine (GNOS-PV02) and plasmid encoded IL-12 (INO-9012) in subjects with histologically or cytologically confirmed diagnosis of hepatocellular carcinoma (HCC).
NIH Guidelines Section	III-C-1
Risk Assessment discussion	No concerns noted.
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	Not Applicable
IBC Vote	A motion was made to approve the registration Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

5. Review of SPROTO202600000061

Title:	Phase 3 CAR-T Study (DURGA-5)
Investigator:	SHAMBAVI RICHARD
Submission ID:	SPROTO202600000061
Submission Type:	Initial Protocol
Project Overview	This is a randomised, multicentre, controlled, open-label, Phase III global study comparing the efficacy and safety of AZD0120 versus standard regimens (IsaVRd and DRd) in participants with newly diagnosed multiple myeloma (NDMM) who are ineligible to receive American Society for Transplantation and Cellular Therapy (ASCT) as initial therapy. CAR T-cell therapy targeting BCMA alone is highly effective in treating MM. The combined CD19 and BCMA-targeting of AZD0120 is anticipated to affect a wider range of malignant plasma cells as well as MM progenitor cells which express CD19 and to prevent antigen-negative escape.
NIH Guidelines Section	III-C-1
Risk Assessment discussion	No concerns noted.
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	Not Applicable
IBC Vote	A motion was made to approve the registration Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

6. Review of SPROTO202600000065

Title:	Electrical Activity and Calcium Signaling in Brain Development
Investigator:	GEORGIA PANAGIOTAKOS
Submission ID:	SPROTO202600000065
Submission Type:	De Novo Review
Project Overview	Use of genetic expression constructs to perform a series of molecular manipulations in neural stem/progenitor cells in vitro and in vivo. Targeting of genes whose protein products are known to be ion channels, transcription factors, related signaling molecules or other proteins regulated by or participating in calcium signaling. These expression vectors will initially be constructed and propagated in E. coli, but no protein products will be expressed in bacteria. There will be no extension of host range or alteration of bacterial strains beyond standard practices used in molecular biology.
NIH Guidelines Section	III-D-1-a III-D-4-a; III-D-4-b; III-D-4-c-(2) III-E-1
Risk Assessment discussion	Requires additional information: a) selection of rDNA NIH Section categories; b) LV generation; c) AAV and LV source / supplier
Training	No deficiencies were noted in staff training records.
Occupational Health	Not applicable
Biosafety Level Assignment	BL2 BL2-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-2
IBC Vote	A motion was made to approve the registration pending modifications and EnvHS SOPs. Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

7. Review of SPROTO202500000051

Title:	Bi-segmented paramyxoviruses
Investigator:	BENHUR LEE
Submission ID:	SPROTO202500000051
Submission Type:	Initial Protocol
Project Overview	Reverse genetics systems will be used to make recombinant (GFP or mCherry reporter) paramyxovirus reverse genetics systems which are biologically contained on their own. However, when rescued in combination (N-P-L replicon with M-F-RBP minigenome), a replication-competent, bi-segmented virus may be produced. The tropism of this virus is reliant upon the M-F-RBP gene segment, whereas the replication is reliant upon the N-P-L segment.
NIH Guidelines Section	III-D
Risk Assessment discussion	No concerns noted.
Training	No deficiencies were noted in staff training records. OR Corrective actions were identified to address minor deficiencies.
Occupational Health	Three staff require completion of annual OHSQ
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. Team informed to complete OHSQ. Votes: (8) For (0) Against (1) Abstain Conflict(s) of Interest: LEE

8. Review of SPROTO202600000029

Title:	Breast cancer ecosystem and metastasis
Investigator:	IGOR BADO
Submission ID:	SPROTO202600000029
Submission Type:	Initial Protocol
Project Overview	The proposed approach is to dissect the mechanisms of non-genomic intra-tumor heterogeneity in breast cancer. Methodology involves utilizing viral or plasmid vectors to achieve either stable or transient expression of target genes within cancer cell lines. Once the genetic modification is confirmed, these engineered cells are transplanted into murine models to evaluate how the specific gene expression alters the kinetics of tumor initiation and progression.
NIH Guidelines Section	III-D-1, III-D-1-a, III-D-4
Risk Assessment discussion	Biocontainment levels, NIH Guideline designation, risk to staff from animal handling exposures and diphtheria toxin waste management description require updating.
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health	Not applicable
Biosafety Level Assignment	BL-2, BL2-N
Highest BSL Practices	BSL-2
Highest ABSL Practices	ABSL-1
IBC Vote	A motion was made for post-modification by BSO and CCMS Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

9. Review of SAMENDCR202600000048

Title:	Amendment/CR for SPROTO202500000050
Investigator:	JEAN LIM
Submission ID:	SAMENDCR202600000048
Submission Type:	Amendment/CR
Project Overview	Addition of Tioman virus, Pseudotyped VSV and vaccina virus (VACV). Tioman will be used to infect animals (mice) for research involving pathogenesis. We will make TioV-GFP and TioV-Cre-GFP. VACV to infect wild type mice. VSV pseudotyped viruses to infect mice to generate antibody responses against surface proteins.
NIH Guidelines Section	III-D-1; III-D-1-a, III-D-1-b, III-D-4
Risk Assessment discussion	NIH Guideline designation, biocontainment level
Training	No deficiencies were noted in staff training records.
Occupational Health	Two staff require completion of annual OHSQ. Recommendations for vaccination and pregnant staff provided to research team.
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. Research team will be informed to separate BSL-2 vs BSL-3 protocols. Votes: (9) For (0) Against (0) Abstain Conflict(s) of Interest: None

10. Review of SPROTO202600000047

Title:	HIV Env Immune Complex Vaccines
Investigator:	CATARINA HIOE
Submission ID:	SPROTO202600000047
Submission Type:	De Novo Review
Project Overview	This proposal will test the concept that induction of Abs against HIV Env is influenced by the presence of anti-Env Abs that form immune complexes (ICs) and that consequently modify epitopes on Env. Immunization of animals will be conducted using DNA plasmid or mRNA-LNP vaccine expressing the HIV-1 envelope protein. DNA plasmids will also be used in vitro to express the HIV-1 envelope protein or monoclonal antibodies.
NIH Guidelines Section	III-D-2-a
Risk Assessment discussion	Correction of animal housing location to ensure facility meets safety requirements and experimental needs.
Training	No deficiencies were noted in staff training records.
Occupational Health	Not Applicable
Biosafety Level Assignment	BL-1 BL1-N
Highest BSL Practices	BSL-2+
Highest ABSL Practices	ABSL-1
IBC Vote	A motion was made to approve the registration pending modifications. Votes: (9) 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.
Notes:	Requires further review and discussion

12. Review of Incident: Animal; Mouse Adapted Zika:

Description:	Date: April 21st 2026, 4:30 PM Location: Research lab located in the Annenberg Building (Satellite Animal Housing facility). Incident: A researcher was handling a mouse experimentally infected with the mouse-adapted Zika virus in an ABSL-2 laboratory. During the procedure, a needle previously used to administer a ketamine and xylazine mixture inadvertently punctured the researcher's index finger following use. First Aid: Washing hands with antibacterial soap and water. Notification: BSO was notified immediately. Immediate Action: The researcher was referred to and evaluated at the Emergency Department that same day and subsequently followed up with Employee Health Services on the following day. Notification: The BSO informed the Institutional Biosafety Committee (IBC) Chair and Vice-Chair, as well as relevant institutional leadership. Follow-up: No additional concerns or secondary exposures have been identified. Root Cause: Mishandling of the sharp/ missing needle recapper.
Notes:	Report submitted to NIH as per guidelines

13. Review of Amending RedCap Survey:

Description:	Review and update as relevant the RedCap Survey categories completed by clinical trial teams when submitting a study protocol to the IRB
Notes:	Add clarification that mAb to not applicable or FDA approved

14. Review of Incident: Animal; MNV-GFP:

Description:	Date: April 25th 2026, 6:30 PM Incident: A researcher was handling a hamster experimentally infected with Menangle virus expressing GFP (MNV-GFP) in the ABSL-3 laboratory when the animal (Hamster) bit the researcher's hand. At the time of the incident, the researcher was wearing the required personal protective equipment, including double gloves. Although both gloves remained intact with no visible breach, the bite penetrated the skin, as identified during subsequent handwashing. Buddy was present at the time. First Aid: Washing hands with antibacterial soap and water. Notification: BSO was notified immediately. Immediate Action: The researcher was referred to and evaluated at the Emergency Department that same day and subsequently followed up with Employee Health Services on the following Monday. Notification: The BSO informed the Institutional Biosafety Committee (IBC) Chair and Vice-Chair, as well as relevant institutional leadership. Follow-up: No additional concerns or secondary exposures have been identified. Root Cause: Aggravated animal.
Notes:	Report submitted to NIH as per guidelines

Review of Incidents
Agenda Topics 12 and 14

Inspections / Ongoing Oversight
Nothing to report

IBC Training
Nothing to report

Public Comments
There were no public comments