Institutional Biosafety Committee
Icahn School of Medicine Mount Sinai

MEETING MINUTES

MEETING TIME RECORDS	
Meeting date:	11/20/2025 2:30 PM
Meeting time	2:30-3:30 PM
Meeting type	Hybrid / Videoconference
Call to order	2:38PM
Adjournment	3:09PM
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)	YES
R. ALBRECHT (Biological Safety Officer)	NO
T. BANIA (IBC member; Human Gene Therapy)	YES
R. BRODY (IBC member; Scientist)	NO
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
H. FRIEDMAN (Local Non-affiliated)	YES
C. NAPIER (IBC member; Employee Health)	YES
J. OCHANDO (IBC member; Scientist)	NO
C. SHOR (Local Non-affiliated)	YES
S. STRAUSS (Legal Counsel)	NO
N. TZAVARAS (IBC member; Scientist)	YES
S. ROSA (Administrative)	YES

QUORUM
The IBC has 12 voting members. 8 members are required to conduct business. Quorum was met.

OTHER INDIVIDUALS IN ATTENDANCE	
Name	**Affiliation / Title**
C. Aston, PhD	Columbia University IBC, Biosafety Director
K. Crowley, DrPH, MPH, PA-C	Columbia University IBC, Vice President, Environmental Health & Safety
C. Cameron	Columbia University IBC, BSO
S. Joussef-Pina, MSc, PhD	Columbia University IBC, BSO

REVIEW OF PRIOR MEETING MINUTES	
Date of meeting minutes	November 5, 2025
Motion	To approve the minutes as written
Votes	(6) For (0) Against (2) Abstain
Result	Approved

COMMITTEE REVIEW SUBMISSIONS

1. Review of SPROTO202500000121

Title:	Phase 3 siRNA Study for Hereditary Angioedema (STOP-HAE ADX-324)
Investigator:	PAULA BUSSE
Submission ID:	SPROTO202500000121
Submission Type:	Initial Protocol
Project Overview:	Hereditary angioedema (HAE) is a rare genetic disorder that affects approximately 1 in 50,000 people worldwide. The underlying cause of HAE is an abnormality in the kinin cascade resulting in increased bradykinin, a potent vasodilator that increases vascular permeability, leading to the characteristic swellings associated with the disease. This Phase 3 study will evaluate the efficacy of 2 dose levels and regimens of ADX-324 in preventing HAE attacks compared with placebo in participants with Type I and Type II HAE. ADX-324 is an investigational siRNA duplex oligonucleotide designed to specifically cleave PKK mRNA.
Highest Risk Group:	RG-2
Highest Biosafety Containment Level:	BSL-1
Highest Animal Containment Safety Level:	Not applicable
NIH Guidelines Section:	III-C
Biosafety Level Assignment	BL-1
Risk Assessment discussion	Potential exposure to drug by staff to be addressed
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Post-modification review by BSO. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

2. Review of SPROTO202500000127

Title:	Phase II CAR-T Therapy for SLE and LN (AUTI1-SL2/Obe-cel)
Investigator:	MON-WEI YU
Submission ID:	SPROTO202500000127
Submission Type:	Initial Protocol
Project Overview:	This is a single-arm, open-label, Phase II Study to determine the efficacy and safety of obe-cel in participants with severe, refractory systemic lupus erythematosus (SLE) with active lupus nephritis (LN). Obe-cel, consists of autologous peripheral blood T cells transduced ex vivo with a lentiviral vector which encodes a novel CD19 CAR, CD19 (CAT) CAR, with a lower affinity and faster disengagement from CD19.
Highest Risk Group:	RG-2
Highest Biosafety Containment Level:	BSL-2
Highest Animal Containment Safety Level:	Not applicable
NIH Guidelines Section:	III-C
Biosafety Level Assignment	BL-1
Risk Assessment discussion	No biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Approved. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

3. Review of SPROTO202500000129

Title:	Phase 1 CAR-T Study in Refractory Autoimmune Diseases (KITE-363).
Investigator:	CHRISANNA DOBROWOLSKI
Submission ID:	SPROTO202500000129
Submission Type:	Initial Protocol
Project Overview:	Development of KITE-363, a dual antigen-targeting, anti-CD19/CD20 chimeric antigen receptor (CAR) T-cell product for the treatment of patients with relapsed and/or refractory (r/r) B-cell malignancies and for the treatment of patients with autoimmune diseases.
Highest Risk Group:	RG-2
Highest Biosafety Containment Level:	BSL-1
Highest Animal Containment Safety Level:	Not applicable
NIH Guidelines Section:	III-C-1
Biosafety Level Assignment	BL-1
Risk Assessment discussion	No biosafety concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Approved Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

4. Review of SPROTO202400000070

Title:	MERS-CoV Antivirals
Investigator:	KRIS WHITE
Submission ID:	SPROTO202400000070
Submission Type:	Initial Protocol
Project Overview:	Antiviral hits identified against coronaviruses, mainly through the ASAP AViDD center, will be provided to our lab and screened in live virus assays in cell culture models. Hits that demonstrate activity against MERS-CoV in these in vitro assays may move on to screening in murine models of MERS-CoV infection.
Highest Risk Group:	RG-3
Highest Biosafety Containment Level:	BSL-3
Highest Animal Containment Safety Level:	ABSL-3
NIH Guidelines Section:	Not applicable
Biosafety Level Assignment	Not applicable
Risk Assessment discussion	No CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	No occupational health concerns were noted.
IBC Vote	Approve pending minor modifications. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

5. Review of SAMEND202500000075

Title:	Amendment for SPROTO202500000050
Investigator:	JEAN LIM
Submission ID:	SAMEND202500000075
Submission Type:	Amendment
Project Overview:	Adding a new virus, Oropouche virus
Highest Risk Group:	RG-3
Highest Biosafety Containment Level:	BSL-3
Highest Animal Containment Safety Level:	ABSL-3
NIH Guidelines Section:	Not applicable
Biosafety Level Assignment	Not applicable
Risk Assessment discussion	No biosafety concerns. No CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Research staff must complete OHSQ and review vaccination recommendations.
IBC Vote	Approve pending OHSQ completion and minor modifications. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

6. Review of SPROTO202500000110

Title:	KDM1A-IL18 axis in pediatric gliomas
Investigator:	OREN BECHER
Submission ID:	SPROTO202500000110
Submission Type:	Initial Protocol
Project Overview:	The research will examine the role of the KDM1A-IL18 axis in pediatric high-grade gliomas using both genetic mouse modeling and human models. Tumor induction- Purified viruses (cDNA of oncogene or cDNA for Cre recombinase to delete tumor suppressor) cloned into our RCAS vector system are used to transfect DF1 cells (obtained from ATCC) to create virus producing cells.
Highest Risk Group:	RG-1
Highest Biosafety Level:	BSL-2
Highest Animal Containment Safety Level:	ABSL-2
NIH Guidelines Section:	III-E-3
Biosafety Level Assignment	BL-2 BL2-N
Risk Assessment discussion	No CCMS concerns
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative review (if applicable):	Research staff must complete OHSQ.
IBC Vote	Approve pending the completion of OHSQ and CITI trainings. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

7. Review of SPROTO202500000122

Title:	Neuroimmune Regulation and Sensory Dysfunction
Investigator:	BRIAN KIM
Submission ID:	SPROTO202500000122
Submission Type:	De Novo Review
Project Overview:	Chronic inflammatory diseases of the skin, lung, and gut are major causes of morbidity in the United States. Previous studies from our lab show that there are unique interactions between immune cells and the nervous system that significantly contribute to pathology in eczema, asthma, and food allergy. Propose to use various mouse models of chronic inflammatory diseases and stress/anxiety to model these interactions. Specific Aim 1: To generate a mouse model of chronic HSV infection using Aden-virus vector system. Specific Aim 2: To characterize the role of the IFN activation in sensory neuron system against HSV infection mouse model. Specific Aim 3: To characterize the role of the STING activation in sensory neuron system against HSV infection mouse model.
Highest Risk Group:	RG-2
Highest Biosafety Level:	BSL-2
Highest Animal Containment Safety Level:	ABSL-2
NIH Guidelines Section:	III-E-3, III-E-3-a III-D-3-a , III-D-4-c, III-D-4-c-(2)
Biosafety Level Assignment	BL-2 BL2-N
Risk Assessment discussion	No CCMS concerns
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative review (if applicable):	Research staff must complete OHSQ
IBC Vote	Approve pending minor modifications and OHSQ Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

8. Review of SPROTO202500000094

Title:	Lung adenocarcinoma invasion
Investigator:	CHARLES POWELL
Submission ID:	SPROTO202500000094
Submission Type:	Initial Protocol
Project Overview:	The Powell lab focuses on understanding the mechanisms important in tumor invasiveness in early-stage lung adenocarcinoma. We study role of tumor microenvironment in tumor invasion, including signaling pathways and cell-to-cell interaction mechanisms involved in lung cancer development and progression. Lentivirus is generated in our lab for cloning purpose for CRISPR/Cas9 mediated knockout of desired gene in cancer cell lines. AAV stocks are not generated in house and only purchased commercially. We perform intranasal Adeni Cre administration in transgenic mouse model of lung adenocarcinoma to initiate tumor formation.
Highest Risk Group:	RG-2
Highest Biosafety Level:	BSL-2
Highest Animal Containment Safety Level:	ABSL-2
NIH Guidelines Section:	III-D-1 III-D-4
Biosafety Level Assignment	BL-2 BL2-N
Risk Assessment discussion	Diptheria Toxin must be added and use described. No CCMS concerns
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Post-mod review by BSO. Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

9. Review of SPROTO202500000128

Title:	Investigating the role of splicing factor mutations using iPSCs
Investigator:	EIRINI PAPAPETROU
Submission ID:	SPROTO202500000128
Submission Type:	De Novo Review
Project Overview:	Lab uses lentiviral plasmids to package recombinant lentiviral vectors, for overexpression, knockdown, and CRISPR knockout of hematopoietic disorder related genes in induced pluripotent stem cells (iPSCs) and hematopoietic stem and progenitor cells (HSPCs). Also use ribonucleoprotein (RNP) complexes consisting of Cas9 protein and crRNA/tracrRNA to CRISPR knockout those genes in iPSCs and HSPCs, or including recombination sequences at the same time to introduce mutations or new elements.
Highest Risk Group:	RG-2
Highest Biosafety Containment Level:	BSL-2
Highest Animal Containment Safety Level:	ABSL-2
NIH Guidelines Section:	III-D-1-a III-D-1
Biosafety Level Assignment	BL-2 BL2-N
Risk Assessment discussion	No Biosafety concerns. No CCMS concerns.
Training	No deficiencies were noted in staff training records.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Approve pending minor modification Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

10. Review of SAMENDCR202500000157

Title:	Amendment/CR for SPROTO202400000093
Investigator:	SHUANG WANG
Submission ID:	SAMENDCR202500000157
Submission Type:	Amendment/CR
Project Overview:	Lab will use commercial vendors to clone shRNA into plasmids and packaging them into AAV8 end-product. These AAV end products are engineered so they cannot replicate in the host on their own. We will receive from vendor 3 AAV end-products: AAV8-H1-shRNA against two genes, Rorc and Cux2, and AAV8-H1-shRNA control. This is now a routinely performed procedure to delivery shRNA to mice to knockdown genes in hepatocytes. We will receive AAV8 end-products from vendors and use them in mice (i.e. in vivo).
Highest Risk Group:	RG-1
Highest Biosafety Containment Level:	BSL-1
Highest Animal Containment Safety Level:	ABSL-1
NIH Guidelines Section:	III-E-1
Biosafety Level Assignment	BL-1 BL1-N
Risk Assessment discussion	No CCMS concerns. No Biosafety concerns.
Training	Corrective actions were identified to address minor deficiencies.
Occupational Health Representative review (if applicable):	Not applicable
IBC Vote	Approve pending minor modifications Votes: (8) For (0) Against (0) Abstain Conflict(s) of Interest: none

OTHER AGENDA ITEMS

IBC Training
Nothing to report

Public Comments
There were no public comments