



COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE



Minutes
Thursday, August 6th, 2026

Teleconference

Present	Present	Excused
C. Aston	J.J Miranda (Chair)	K. Crowley
L. Butaud-Rebbaa	S. Morse	L. Kam
H. Blumm	T. McConville	D. Ng
C. Cameron	P. Muranski	E. Riber (Coordinator)
K. Fritz	N. Ozten Kandas	M. Underwood
S. Hughes	E. Peterson	Y. Wojcicki
S. Joussef Pina	C. Pitoscia	
B. Karolewski	M. Quick	
J. Kaushal	V. Racaniello	
	A. Romanov	
	Q. Wang	

J.J Miranda convened the Institutional Biosafety Committee (the **Committee**) at 1:01 PM.

J.J Miranda asked the Committee to approve the minutes of the July 9th, 2026 meeting.

- **The minutes were approved unanimously.**

J.J Miranda reminded the Committee of the Conflict of Interest Policy and asked all members to confirm that there were no conflicts of interest with regard to any of the protocols to be discussed at the meeting.

- **P. Muranski acknowledged their individual conflict of interest and abstained from voting on their respective protocols.**

DURC Review

- No protocols requiring DURC review were submitted to the Biosafety Officer or to the Committee since the previous meeting.

Human Gene Therapy

- Mapara_IRB-ACYY3055_APM-ACYY0768: A Phase I/II, Open-Label Study of Autologous 19(T2)28z1xx CD19-Directed CAR T Cell Therapy for Desensitization of Highly Sensitized Patients Undergoing Solid Organ Transplantation
 - S. Joussef Pina introduced Dr. Mapara's human use protocol for highly sensitized patients undergoing solid organ transplantation.
 - Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
 - No concerns were identified by the Committee Human Gene Transfer Experts.
 - The Appendix M was voted upon and approved unanimously.
- Reshef_IRB-ACYY1706_APM-ACYY0770: A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy
 - S. Joussef Pina introduced Dr. Reshef's human use protocol for participants with relapsed or refractory large B-cell lymphoma after receiving first-line therapy.



COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE



- Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
- No concerns were identified by the Committee Human Gene Transfer Experts.
- The Appendix M was voted upon and approved unanimously.
- **Schultz_IRB-ACYY1592_APM-ACYY0711: Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL)**
 - S. Joussef Pina introduced Dr. Schultz's human use protocol for patients with relapsed or refractory CD22+ B-cell acute lymphoblastic leukemia (B-ALL).
 - Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
 - No concerns were identified by the Committee Human Gene Transfer Experts.
 - The Appendix M was voted upon and approved unanimously.
- **Sobieszczyk_IRB-ACYY3123_APM-ACYY0771: (HVTN 808), A Phase 1, Open-label, Multicenter clinical trial to examine the safety and immunogenicity of DV700P-RNA in a prime/boost regimen with DV701B1.1-RNA**
 - S. Joussef Pina introduced Dr. Sobieszczyk's human use protocol to examine the safety and immunogenicity of DV700P-RNA in a prime/boost regimen with DV701B1.1-RNA.
 - Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
 - No concerns were identified by the Committee Human Gene Transfer Experts.
 - The Appendix M was voted upon and approved unanimously.
- **Tezel_IRB-ACYY1908_APM-ACYY0769: Phase 2b/3, Multicenter, Randomized, Masked, Sham-controlled Study to Evaluate the Efficacy and Safety of Surabgene Lomparvovec (Suravec) Delivered via Suprachoroidal Space (SCS) Injection Targeting Subjects with Diabetic Retinopathy**
 - S. Joussef Pina introduced Dr. Tezel's human use protocol for subjects with diabetic retinopathy.
 - Details of the study regarding the preparation of the agent, dosage, route of administration, inclusion criteria, quality assurance testing, and informed consent were included in relevant materials distributed to the Committee.
 - No concerns were identified by the Committee Human Gene Transfer Experts.
 - The Appendix M was voted upon and approved unanimously.

rDNA

Four rDNA and infectious agent appendices requiring work at the BSL-1 containment level were presented and discussed. A table describing each BSL-1 Appendix A was shown to the Committee and is available at the Biosafety Office.

- Three appendices were returned to the investigator for further information as shown in a Table presented to the Committee describing the nature of each hold comment.
- After Discussion by the Committee, all BSL-1 Appendices were voted upon collectively and approved unanimously.

Ten rDNA and infectious agent appendices requiring work at the BSL-2 containment level were presented and discussed. A table describing each BSL-2 Appendix A was shown to the Committee and is available at the Biosafety Office.



COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE



- Ten appendices were returned to the investigator for further information as shown in a Table presented to the Committee describing the nature of each hold comment.
- After Discussion by the Committee, all BSL-2 appendices were voted upon collectively and approved unanimously.

Announcements

- There were no new announcements since the last committee meeting.

Report

- There were no new reports since the last committee meeting.

rDNA Incidents

- There were no incidents reported.

Action Items

Action Items from IBC meeting		
Status	Description	Group/Investigator
N/A	N/A	N/A

With there being no further business J.J Miranda adjourned the meeting at 2:06 PM. The next meeting will be held by teleconference on September 10th.

2026 Meeting Calendar

Date
Thursday, January 15, 2026
Thursday, February 12, 2026
Thursday, March 12, 2026
Thursday, April 9, 2026
Thursday, May 7, 2026
Thursday, June 4, 2026
Thursday, July 9, 2026
Thursday, August 6, 2026
Thursday, September 10, 2026
Thursday, October 8, 2026
Thursday, November 5, 2026
Thursday, December 3, 2026



COLUMBIA UNIVERSITY

IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE



IBC Meeting: August 06, 2026
Table 1: Recombinant DNA proposals

Proposals for Work at BSL-1										
	PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	Protocol #	Appendix A
1	Denny, Christine	Cre recombinase under the Glial Fibrillary Acidic Protein (GFAP) promoter, GFP, mCherry	AAV	Mouse	ABSL-1	III-E-1	This project will use viral delivery of a transgenic plasmid for expression in the prefrontal cortex via adeno-associated viruses (AAV). This strategy will require 1 survival surgery in which the AAV is delivered. These viruses do not include helper adenoviruses and are therefore considered biosafety level 1, and do not require the use in a biosafety cabinet.	Y1 M0	LS-ACY0249	BSJW0939
2	Ghosh, Sankar	ECsIT	AAV	Mouse	ABSL-1	III-E-1	To investigate the effect of ECsIT decrease in the establishment of cognitive defects in APP/PS1 transgenic mice, we want to rescue this phenotype by overexpressing ECsIT in the hippocampus, where it is downregulated, before cognitive defects onset. For that, we want to administer an AAV vector encoding ECsIT in the brain of APP/PS1 mice by stereotaxic intracerebral injection.	T2M0	AC-AABG7550	BSJW0880
3	Suh, Yousin	SERPINF1, shSMAD3; shHELB	AAV, mRNA	Mouse	ABSL-1	III-E-1	Since we have observed beneficial effects on cognitive functions, liver pathology, and kidney pathology, we will test the potential therapeutic delivery method (mRNA) to see if this can be translated into human clinical uses. We will use synthetic mRNAs purchased from Trilink Biotechnologies with in vivo-jetRNA®+ (PolyPlus) to deliver the mRNAs.	T1M01	AC-AABU6653	BSJW0632
4	Wu, Xuebing	CRISPR-Cas13d (includes the CasRx protein and its CRISPR RNA array)	AAV	Mouse	ABSL-1	III-E-1	Our lab utilizes adeno-associated virus (AAV) to express the CRISPR/Cas13 system targeting tumor-specific transcripts, wants to eliminate human cancer cells.	T1M0	AC-AABX9651	BSJW0924
	Proposals for work at BSL-2									
	PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	Protocol #	Appendix A
5	Chio, Iok In Christine	Oncogenes (KRAS), drug resistance (puromycin resistant, hygromycin resistant, neomycin resistant), reporter genes (luciferase, GFP, mCherry), Gene editing (Cas9)	LV, Pseudorabies, HSV	Mouse	ABSL-1 (Note 3)	III-D-1-a	The goal of our research is to identify therapeutically actionable dependencies in pancreatic cancer. Using a variety of approaches including sequencing, genetic screens, and proteomics, we have identified a number of candidate genes. Candidates validated in both murine and human specimens will be functionally evaluated through CRISPR/Cas9-mediated gene knockout, or short hairpin RNA (shRNA) gene knockdown in patient-derived tumor and metastatic organoids followed by orthotopic transplantation, with priority given to those encoding proteins that may be druggable. To exclude shRNA, sgRNA- or CRISPR-specific effects, we will also validate the effects of candidate expression \ using a cytomegalovirus promoter-driven, lentiviral-encoded vector to ectopically express these proteins in tumor organoids, followed by orthotopic transplantation of the cells to evaluate the impact on pancreatic tumorigenesis.	T1M28	AC-AABK5554	BSJW0834
6	Choi, Eunhee	Insulin receptor, IGF1R	LV	In vitro	N/A	III-D-1-a	The goal of this work is to generate in vitro cultured mammalian cells with knockout or overexpression of insulin receptor (INSR) and/or insulin-like growth factor 1 receptor (IGF1R) to study insulin/IGF signaling, metabolism, phosphorylation signaling, growth, and survival. Replication-incompetent lentiviral and/or retroviral vectors will be used to deliver CRISPR/Cas9 components for knockout or cDNA constructs for overexpression. Vector production, transduction, and handling of vector-containing material will be performed using approved BSL2/BSL-2 enhanced practices in a certified biosafety cabinet with appropriate PPE. Vectors will be produced using separated packaging systems to reduce the risk of replication-competent virus. Materials will be disinfected or autoclaved before disposal. Potential risks include insertional mutagenesis, rare recombination, VSV-G broadened host range if used, and permanent genomic changes from CRISPR editing.	Y1M0	LS-ACY0223	BSJW0914
7	Damoci, Christopher	in progress	plasmid, LNP-mRNA, E. coli, E. coli nissle, S. typhimurium	Mouse	ABSL-2	III-E-1, III-D-1-a, III-F	Mice will be inoculated with E.coli Nissle 1917 bacteria, E. Coli SLIC, or E. Coli SUC-3 to assess the utility of bacteria as a vector for anti-cancer therapies. Bacterial inoculation will occur via intravenous or intratumoral routes of administration	T2M0	AC-AABD2601	BSJW0917
8	Danino, Tal	Hemolysin E (pore-forming, cytolysin/theta toxin) Cytokines that modulate immune function (neoleukin 2/15, IL2, GMCSF, IL7, IL15, IL21, TRAIL, INFα, CXCL16, GFP-PLGF) DNA encoding neoantigen peptides used as vaccines (~100 unique sequences) Synthetic gene circuits (sensing TME, regulating growth, capsule expression) Clostridium perfringens enterotoxin (Rho GTPase) Pseudomonas Exotoxin (ADP rybosylating toxins, inhibit protein synthesis) Azurin (induces apoptosis via p53 binding) Heat stable enterotoxin (stimulate guanine cylase) Colicin (bacteriioricin, pore forming, maybe cell cycle or RNAase but unknown) The pX330 vector has single guided RNA(sgRNA) that targets Pten and p53 gene. The Cas9 protein will then use the sgRNA to induce a loss of function	S.typhimurium, Bacillus Calmette-Guérin (BCG), M.marinum, Bacillus Calmette-Guérin (BCG) M.marinum, M.abscessus, L.monocytogenes, S.Marcescens, S.pyogenes, E.coli nissle ,E. coli EV36, E.coli K1 / K5, A. Fischeri MJ1N & ES114, P. Leiognathi KNH6, P. putida, Coxsackievirus B3, Senecavirus A (SVV), Sindbis Virus (SINV), LV	In vitro	N/A	III-E-1, III-D-1-a,	Our goals are to develop safe formulations of microbes that express and effectively deliver diagnostic or therapeutic molecules directly to tumor environments	Y1M0	LS-ACY0212	BSJW0884
9	Dorrello, Nicolino	N, P, H, F, M, and L genes plus cherry or GFP reporter	Measles, Coronaviruses 229E,	Cotton Rat	ABSL-2	III-E-1, III-D-1-a	This proposal will test the prophylactic and therapeutic efficacy fo anti viral inhibitors against Measles and Coronaviruses in cotton rats	Y1M0	AC-ACY0466	BSJW0901
10	Mace, Emily	multiple genes of interest, multiple fluorescent reporters	CRISPR, LV	In vitro	N/A	III-D-1-a	CRISPR editing or lentiviral gene expression of fluorescent reporters or gene knockouts in human iPSC, primary lymphocytes, or lymphocyte cell lines.	Y1M0	LS-ACY0222	BSJW0913
11	Palomero, Teresa	RHOA G17V	LV	Mouse	ABSL-1 (Note 3)	III-D-1-a	To study the therapeutic effects of targeted therapies, we will test the effect of drug treatments in vivo in mice transplanted with Patient Derived Xenografts (PDXs) obtained from biopsies from Peripheral T-cell Lymphoma patients. PDXs will be purchased from public repositories	T2M0	AC-AABG4576	BSJW0907
12	Shawber, Carrie	Notch1, Notch4, CELSR1, PIK3CA, KRAS, GATA2, FOXC2	LV	In vitro	N/A	III-D-1-a	Propagation and mutagenesis of genes: Genes are cloned into lentiviral vectors with and without puromycin and variants identified in patient studies introduced by PCR based site directed mutagenesis. DNA is propagated in non-virulent E.COLI (DH5alpha and HST08). All media exposed to bacteria are treated with Bleach or agarose plates are disposed of in biological waste (red bags). -Introduction into tissue culture cells. Plasmids are introduced into cells via calcium phosphate transfection and lentiviral infect (non-replicative). The lentiviral system used 4 plasmids, 1 is an expression vector and the rest are packaging plasmids. All tissue culture work is performed in a certified biological safety cabinet and staff wear	Y1M0	LS-ACY0243	BSJW0920
13	Simpson, Eleanor	Cre, A bacterial recombinase enzyme for site specific recombination. GCaMP6f/m/s, jRGECO fluorescent proteins for imaging calcium neuronal activity. DLight, SLight, GAcH, fluorescent biosensor proteins for imaging dopamine, serotonin and acetylcholine release. hM4D(Gi), hM3D(Gq), KORRD (DREADDs - designer receptors activated by designer drugs). GFP, MCitrine, mCherry: fluorophore markers eNpHR3.0, ClV1, for	AAV, HSV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	This project involves multiple methods to investigate the role of serotonin, opioid and dopamine signalling in aspects of cognition and motivation. We will use regionally restricted transgene expression in the mouse brain using recombinant viral vectors. Specifically, viral vectors will be injected intracranially into mice for the purpose of either altering or monitoring neural activity. Mice will be Wild-type, receptor Knock out or those carrying the cre allele to direct viral expression to specific cell types.	Y1 M0	LS-ACY0217	BSJW0912
14	Yamashita, Masahiro	Gag, Pol, Env, CPSP6 and cyclophilin A, fluorescent proteins (e.g., GFP and related variants) and luciferase genes, shRNAs, sgRNAs	LV (HIV, EIV, FIV, SIV, BIV), MLV (eco/ampho), HTLV	In vitro	N/A	III-D-1-a	The objective of research performed in our lab is to understand how virus-infected cells differ between each other in their ability to transmit the virus. We will also study how the viral capsid affect various intracellular events to promote HIV-1 infection	Y1M0	LS-ACY0213	BSJW0891

Note1: The Biosafety Office allows Stereotaxic injections to be designated as ABSL-1

Note2: The Biosafety Office allows Transduced cell injections that are free from virus to be designated as ABSL-1

Note3: The Biosafety Office allows the administration of replication deficient vectors or attenuated strains to be designated as ABSL-1

Note 4: BSL-2 practices for Fish procedures: store rVSV-infected fish within BSL1 satellite facility, in sealed disposable containers on a designated rack clearly labeled for PI handling only. Following euthanasia, water and containers will be decontaminated with >10% bleach

Note 5: BSL-2 agent handled with risk mitigation measures