COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
Thursday, July 9th, 2026
Teleconference

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

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 June 4th, 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.

- **There were no conflicts of interest noted.**

DURC Review

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

Human Gene Therapy

- He_IRB-ACYY2434_APM-ACYY0709: IMPACT 31: A Randomized Open-label, Multi-center, Phase II Adjuvant Study of a Personalized Neoantigen DNA Vaccine (GNOS PV02) and Plasmid encoded IL-12 (INO-9012) versus Active Surveillance in Subjects with High-Risk Hepatocellular Carcinoma
    - C. Cameron introduced Dr. He's human use protocol for subjects with high-risk hepatocellular carcinoma. 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.
- Shneider_IRB-ACYY0670_APM-ACYY0144: Phase 1/2 Investigation of Novel Experimental Regimen in Amyotrophic Lateral Sclerosis (PIONEER-ALS): An Open-Label, Uncontrolled, Multicenter Study to Assess the Safety and Tolerability of Two Doses of VTx-002
    - C. Cameron introduced Dr. Shneider's human use protocol to assess the safety and tolerability of VTx-002 in participants with ALS. 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.

Nine 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.

- Six 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 1:46 PM. The next meeting will be held by teleconference on August 6th, 2026.

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

IBC Meeting: July 09, 2026

Table 1: Recombinant DNA proposals

	PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	Protocol #	Appendix A
Proposals for Work at BSL-1										
1	Axel, Richard	GCamP, eArch3, tdTomato, hM3Dq, hM4Di, mCherry	AAV	Mouse	ABSL-1	III-E-1	Viral delivery of recombinant DNA for imaging, optogenetics, and chemogenetics.	T1 M06	AC-AABM8553	BSJW0761
2	Ding, Lei	Cre	AAV	Mouse	ABSL-1 (Note 3)	III-E-1	Replication deficient AAV will be used to induce the expression of Cre in hepatocytes in vivo.	T1 M08	AC-AABQ7591	BSJW0845
3	Guo, Jia	AAV-EF1a-DIO-hChR2(H134R)-EYFP, AAV-EF1a-DIO-hChR2(H134R)-mCherry, AAV-EF1a-DIO-eNpHR 3.0-EYFP, AAV-hSyn-Con/Fon hChR2(H134R)-EYFP-WPRE or mCherry, AAV-hSyn-Con/Fon EYFP-WPRE (control virus), AAV-hSyn-Coff/Fon EYFP-WPRE, AAV-hSyn-Coff/Fon hChR2(H134R)-EYFP-WPRE or mCherry, AAV-hSyn-Con/Foff hChR2(H134R)-EYFP-WPRE or mCherry, AAV-hSyn-Con/Foff EYFP-WPRE or mCherry, AAV-Ef1a-DIO-GCaMP 6f, AV5 pENN.AAV.hSyn.HI.eGFP-Cre, AAV9-CAG-FLEX-jGCaMP8m-WPRE	AAV	Mouse	ABSL-1	III-E-1	AAV vectors are used for cell-specific expression of fluorescent reporters, optogenetic activators, cell activity reporters or local gene induction (cremediated).	Y1 M0	AC-ACYY0593	BBLD8768
4	Marx, Steven	adenine base editor	AAV	Guinea Pig	ABSL-1(Note 3)	III-E-1	Our goals are to perform gene editing. AAV9 to be injected subcutaneously. The DNA is being prepared by gene universal. The DNA will be ligated into a vector. It will then be sent to Franklin Bioloabs for AAV9 creation and amplification.	Y1 M0	AC-ACYY0612	BSJW0829
5	Yan, Shirley ShiDu	mKeima-red (marker), roGFP, synaptophysin, mito-DsRed, EGFP	AAV	In vitro	In vitro	III-E-1	The purpose of using Adeno Associated virus (AAV) vector carrying specific gene products to enhance target gene expression in vitro is to investigate the effects of these genes on cellular function in cultured cells. Viral vectors will be purchased from a commercial supplier and used to transduce cell lines and primary cells.	Y1 M0	LS-ACYY0204	BSJW0858
Proposals for work at BSL-2										
	PI	**Insert**	**Vector**	**Host**	**Animal Biosafety Level**	**NIH category**	**Use/Comments**	**Year**	**Protocol #**	**Appendix A**
6	Bendesky, Andres	GCaMP6x, jGCaMP7x, bReaCher, dLight1, Arch3.0, mCherry, GFP, ChR2, Cre recombinase, TVA, rabies glycoprotein G	AV, AAV, GdRV, LV, PRV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	Stereotaxic injection of viral vectors will be done to infect neurons of interest with markers, activity reporters or optogenetic actuators. Stereotaxic equipment will be sterilized before and after use. No more than 10 ul of viral suspension will be open in the room at any one time. The virus will be injected using a borosilicate glass capillary, which will be bleached immediately following the procedure.	T2 M0	AC-AABH6555	BSJW0835
7	Li, Hao Wei	ampicillin-resistant gene, pig-reactive T cell receptor, Flt3L	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	One of our lab's research goal is to investigate induction of mixed xenogeneic chimerism as an approach to inducing tolerance to xenografts for clinical transplantation. Currently we use a humanized mouse model to study the mechanisms of human cell tolerance to pig xenoantigens induced by mixed chimerism. We will also study the impact of expression of HLA-E and human CD47 on pig cells on NK and monocyte tolerance. Hydrodynamic injection of plasmids encoding human Flt3L is used for induction of human NK cell reconstitution.	Y1 M10	AC-AABY3663	BQAE0008
8	Mentis, George	SMN, fluorescent proteins (eGFP, TdTomato) or other genes (Stasimon, p53, Cre, NT3, P53Serine18)	AAV, GdRV	Mouse	ABSL-1 (Note3)	III-E-1, III-D-1-a	Use of AAVs to induce SMN protein or fluorescent proteins or regulate other genes (Stasimon, p53, Cre, NT3, P53Serine18).	T1 M08	AC-AABR9600	BSJW0866
9	Sanghvi, Viraj	myc, b-catenin, akt, Nrf2, gfp, rtTA3, SB transposase, Cre recombinase, shRNAs, sgRNAs, Cas9, luciferase, antibiotic resistance, pten, keap1	AV, AAV, LV. MSCV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	We utilize a variety of genetically engineered mouse models, functional genomics and proteomics, genome editing, and innovative screening platforms to: 1) investigate the genetics and pathobiology of related metabolic disorders, such as diabetes, obesity, NAFLD, and liver cancer, 2) understand and target aberrant redox signaling and metabolism in lung and liver malignancies, 3) understand and target non-enzymatic protein glycation in pathobiology. Lentivirus and retrovirus transduction: We use replication deficient human lentiviral and retroviral vectors to over express, knock-down, edit/introduce mutations in mouse and human cells for in vitro and in vivo use. Sleeping beauty transposon: We use sleeping beauty (SB) transposon system (intergrating vector and SB transposase) for somatic gene transfer of cDNA, shRNAs, and/or sgRNAs in mouse hepatocytes in vivo. Transient transfections: We perform transient transfections with rDNA or mRNA to express cDNA, shRNAs, and/or sgRNAs.	T1 M0	AC-AABV8661	BSJW0822
10	Sher, Falak	Plasmids will express CRISPR-Cas9 components (Cas9 nuclease and/or sgRNA) for gene editing. In some experiments, plasmids may express genes of interest relevant to Alzheimer's disease (e.g., SORL1) for functional studies. No pathogenic genes or toxins will be expressed.	CRISPR, LV	In vitro	N/A	III-D-1-a	This project uses CRISPR-Cas9 approaches to study the molecular role of the Alzheimer's disease–associated protein SORL1 in resident immune cells of the brain. Recombinant DNA and gene-editing reagents will be delivered to cell lines including THP-1 cells and iPSCs by transfection of plasmids, synthetic RNA, and/or Cas9 protein, or by transduction with replication-incompetent lentiviral vectors, including Addgene vectors 52962 and 52963. Lentivirus will be produced in HEK293T cells by transfection with psPAX2 packaging plasmid, VSV-G envelope plasmid, and the lentiviral construct of interest, such as guide RNA or Cas9 sequences. Viral supernatants will be collected under a biological safety cabinet and concentrated as needed. Work will follow approved biosafety practices. Surfaces will be disinfected with freshly prepared 70% ethanol or 1% sodium hypochlorite. Tips, pipettes, tubes, and liquid waste will be decontaminated with freshly prepared sodium hypochlorite for at least 20 min.	Y1 M0	LS-ACYY0209	BSJW0875
11	Tall, Alan	LDLR	AV	Mouse	ABSL-2	III-D-1-a	The goal is to assess the mechanism responsible for impaired atherosclerosis regression in JAK2V617F clonal hematopoiesis. This requires using the mouse atherosclerosis regression model, which will be created by administration of replication defective adenovirus into the mouse models in order to induce LDLR expression in liver and lower circulating LDL cholesterol.	T1 M0	AC-AABW3650	BSJW0749
12	Yan, Shirley ShiDu	Tau(P301S), LC3B, Miro1, PINK1, EGFP,	LV	In vitro	N/A	III-D-1-a	The purpose of using lentiviral vector carrying specific gene products to enhance target gene expression in vitro is to investigate the effects of these genes on cellular function in cultured cells. Viral vectors will be purchased from a commercial supplier and used to transduce cell lines and primary cells. These are replication incompetent viral vectors and VSV-G pseudotyped, which made by a company.	Y1 M0	LS-ACYY0200	BSJW0849
13	Yang, Hee Won	Doxycycline-inducible short hairpin RNA (shRNA) targeting PHC2 for knockdown, and CRISPR/Cas9 components (Cas9 and single-guide RNAs) targeting PHC2 for knockout. Some constructs express doxycycline-inducible histone H3.3 variants. Constructs also carry selection markers (e.g., puromycin resistance) and fluorescent/reporter markers for cell tracking and live-cell imaging	CRISPR, LV	Mouse	ABSL-1 (Note2)	III-D-1-a	We will use genetically modified human and mouse cancer cell lines to study CDK4/6 inhibitor resistance in triple-negative breast cancer. Cell lines (human MDA-MB-231 and patient-derived organoids; mouse AT3 and 4T1) are stably modified by lentiviral transduction to express doxycycline-inducible shRNA or CRISPR/Cas9 constructs targeting PHC2, and in some cases inducible histone H3.3 variants. Lentivirus is produced in HEK293T cells using third-generation, replication-incompetent, self-inactivating (SIN) packaging systems and is VSV-G pseudotyped. All viral production and transduction are performed in vitro under BSL-2 containment; only stably modified, virus-free cells are expanded and implanted into animals. CRISPR editing targets a defined endogenous locus (PHC2) with no gain-of-function or oncogenic intent. No replication-competent virus persists in the implanted cells.	Y1 M0	AC-ACYY0621	ACBU8763
14	Zhang, Hanrui	CRISPR gRNAs and Cas proteins, Pcsk9, human LDLR	LV, AAV, AV	Mouse	ABSL-1 (Note 2)	III-D-1-a	Use CRISPR-Cas for perform gene editing in cells.	T1 M08	AC-AABN5558	BSJW0789

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% b

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