COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
Thursday, March 12th, 2026; 1:00PM
Teleconference

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

S. Morse convened the Institutional Biosafety Committee (the **Committee**) at 1:08 PM.

S. Morse asked the Committee to approve the minutes of the February 12th, 2025 meeting.

- **The minutes were approved unanimously.**

S. Morse 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.

- M. Underwood acknowledged his individual conflict of interest and abstained from voting on the 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

- Lonier_IRB-ACYY1093_APM-ACYY0404: A Phase 2, Multicenter, Open-Label Study Of CC-97540 (BMS-986353), CD19-Targeted NEX-T Chimeric Antigen Receptor (CAR) T Cells, in Participants with Active Systemic Lupus Erythematosus (SLE) (Including Lupus Nephritis) with Inadequate Response.
  - S. Joussef Pina introduced Dr. Lonier's human use protocol for participants Active Systemic Lupus Erythematosus (SLE) (Including Lupus Nephritis) with Inadequate Response. 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-ACYY1396_APM-ACYY0485: A Phase 2, Multicenter, Open-Label Study Of CC-97540 (BMS-986353), CD19-Targeted NEX-T Chimeric Antigen Receptor (CAR) T Cells, in Participants with Active Systemic Lupus Erythematosus (SLE) (Including Lupus Nephritis) with Inadequate Response.
  - S. Joussef Pina introduced Dr. Schultz's human use protocol for patients with Active Systemic Lupus Erythematosus (SLE) (Including Lupus Nephritis) with Inadequate Response. 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.
  - Additional information regarding the investigational product was requested from the investigator.

- The Appendix M was approved unanimously following a request for additional information provided by the trial sponsor.

- Sobieszczyk_IRB-ACYY1174_APM-ACYY0344: HVTN 322: A phase 1 clinical trial to evaluate the safety and immunogenicity of the V2 apex–directed immunogens DV201P-RNA and DV202B1-RNA in adult participants without HIV.
  - S. Joussef Pina introduced Dr. Sobieszczyk's human use protocol for patients with adult participants without HIV. 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.
  - Additional information regarding the investigational product was requested from the investigator.
  - The Appendix M was approved unanimously following a request for additional information provided by the trial sponsor.

Biosafety Office Reviews

- No renewals for Coronavirus Research have been submitted to the Biosafety Office since the last meeting.

Coronavirus Research

- No new Coronavirus research proposals were received by the Biosafety Office since the previous meeting.

rDNA

Twelve 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.

- Seven 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 twelve BSL-1 Appendices were voted upon collectively and approved unanimously.

Fourteen 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.

- Seven 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

- C. Aston informed the committee of the upcoming appointment of JJ Miranda as the Institutional Biosafety Committee Chair.

Report

- There were no new reports.

rDNA Incidents

- There were no incidents reported.

Action Items

Action Items from 03-12-26 IBC meeting		
Status	**Description**	**Group/Investigator**
N/A	**N/A**	**N/A**

With there being no further business S. Morse adjourned the meeting at 2:16 PM. The next meeting will be held by teleconference on April 9th, 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

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INSTITUTIONAL BIOSAFETY COMMITTEE

IBC Meeting: March 12, 2026

Table 1: Recombinant DNA proposals

Proposals for Work at BSL-1

	PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Campus
1	Arancio, Ottavio	Human tau protein transgene with proline-to leucine point mutation at amino acid 301 and enhanced green florescent protein transgene.	AAV	Mouse	ABSL-1	III-E-1	Components for the construction of the AAV-phSYN1-FLEX-tau and AAVphSYN1-FLEX-EGFP were assembled from existing vectors and PCR products by standard molecular cloning techniques and amplified in recombinase deficient E. coli (STBL3 cells). Purified plasmid was then sent to the Penn Vector Core for preparation on AAV particles.The vectors will be sterotaxically injected in the hippocampus of animals that express the Cre recombinase in the CA3 or the CA1 or astrocytic cells in the hippocampus. Our goal is to examine how expression of mutant tau in these specific areas of the hippocampus affects synaptic plasticity and memory formation.	CUIMC
2	Bauer, Robert	Cre recombinase, Trib1, Stk40	AAV	Mouse	ABSL-1	III-E-1	Our lab utilizes adeno-associated virus (AAV) to manipulate genes in the livers of mice to investigate their role in lipid metabolism. This usually takes the form of overexpressing a transgene to determine its function, overexpressing a mutant form of the gene to test the effect of the mutation, or overexpressing Cre recombinase to knockout a gene in the livers of conditional knockout mice.	CUIMC
3`	Haeusler, Rebecca	FoxO1-LoxP flanked; FoxO3-LoxP flanked; FoxO4-loxP flanked; Fxr-loxP flanked; alpha1-antitryspin-Cre; Slc30a10-loxP flanked; Slc39a8 loxP-flanked Does the gene(s) of interest have a	AAV	Mouse	ABSL-1 (Note 3)	III-E-1	Many of the mice we use contain LoxP sites, knockouts, or the Cre transgene. These mice were made in other labs and shared with us. We will use purified adeno-associated viruses that are replication incompetent and noninfectious.	CUIMC
4	John, Simon	Either a florescent protein (green, red, yellow, etc., XFP), beta-catenin protein (CTNMB1), or Cre recombinase.	AAV	Mouse	ABSL-1	III-E-1	We aim to understand the structural and functional roles of Schlemm's canal and the trabecular meshwork in the regulation of aqueous humor outflow, IOP sensing and control, and the development of glaucoma as well as the factors contributing to retinal degeneration during glaucoma pathogenesis. We use approaches based on imaging, molecular assays, labeling, fluid tracing, and targeted manipulation of protein expression, facilitated by viral expression of recombinases, reporter proteins, receptors, cellular adhesion factors, and transcriptional regulators.	MS
5	Maxim, Demetri	GFP, Cas9, Cre	AAV	Mouse	ABSL-1	III-E-1	The goal of our project is to develop in vivo CRISPR-Cas editing as a novel gene therapy approach for treating genetic kidney diseases. We will package CRISPRCas base editors into adeno-associated virus (AAV) vectors and deliver them to the kidney in vivo. The AAV viruses will be produced without helper adenovirus. Our initial indication is polycystic kidney disease and we will use CRISPR-Cas to edit mutations and regulatory regions associated with the PKD1 and PKD2 genes. We will produce AAV via standard triple transfection in HEK293T/HEK293 cells. Plasmids needed for the triple transfection will be amplified in E Coli and extracted using Maxiprep kits following by endotoxin removal. In the event of an exposure (needle stick or mouse bite), we will seek medical attention at Mount Sinai Morningside or Columbia Medical Center.	CUIMC/MS
6	Mentis, George	fluorescent proteins (eGFP, TdTomato)	AAV	Mouse	ABSL-1	III-E-1	Use of AAVs to label neuronal populations	CUIMC
7	Moy, Ryan	CCNE1, ERBB2, Cas9	Plasmid	Mouse	ABSL-1	III-F	Mice will be injected with human cancer cells to form tumor xenografts through either subcutaneous injection, splenic injection, or intra-gastric injection. For EPO-GEMM experiments, the plasmid mix containing expression plasmid for oncogene and/or sgRNA plasmid for tumor suppressor genes with Cas9 gene will be injected into the epithelial compartment in the corpus/antrum region. The CRISPR/Cas9 plasmid encodes the Cas9 nuclease, which induces site-specific double-strand DNA breaks at genomic loci specified by the co-delivered sgRNA. The oncogene expression plasmid contains a cDNA encoding a defined oncogenic driver under the control of a mammalian promoter.	CUIMC
8	Rustgi, Anil	de-stabilized Cas9, CD73 gRNA, Adora2b gRNA, Enpp3 gRNA, shLIN28b, shCDX2		Mouse	ABSL-1	III-E-1	Cell lines containing a de-stabilized Cas9 and shRNA will be injected in to the Gastroenteral tract. Shield-1 will be given to stabilize the de-stabilized Cas9 protein for gene editing.	CUIMC
9	Rustgi, Anil	GFP, luciferase		Mouse	ABSL-1	III-E-1	This protocol involves the use of human colorectal cancer cell lines (DLD-1 and LoVo), patient-derived colorectal cancer organoids generated from de-identified surgical specimens, and genetically engineered mouse strains containing recombinant DNA alleles (e.g., Villin-CreERT;R26-Pik3ca;KRAS-G12D). The goal of this work is to study colorectal tumor initiation, progression, and metastasis using orthotopic models. Human cell lines and organoids will be cultured under standard BSL-2 tissue culture conditions and prepared as cell suspensions or organoid fragments for transplantation into mice by orthotopic (colonic) injection or portal vein injection under anesthesia. No microorganisms or viral vectors are used in this protocol	CUIMC
10	Sparks, Kally	human muscarinic receptor 4D tagged to mCherry, human muscarinic receptor 3D tagged to mCherry, or mCherry	AAV	Mouse	ABSL-1	III-E-1	We will use DREADDs (designer receptors activated by designer drugs) to activate or silence brain regions. DREADDs are expressed in the brain after injection of AAV viruses under the control of human synapsin gene.	NYSPI
11	Suh, Yousin	synthetic UBE3C mRNA	mRNA	Mouse	ABSL-1	III-F	The primary goal of this protocol is to study the function of UBE3C and its longevity associated variant, and explore the mechanism underlying. Our preliminary data showed that UBE3C declines with age in various human and mouse tissues, and a human longevity associated UBE3C variant could lead to an extended lifespan and health span. Hence, we plan to validate the benefit role of UBE3C and its longevity associated variant in mice by using non-viral in vivo mRNA delivery using liposome-based reagent.	CUIMC
12	Vunjak-Novakovic, Gordana	Nuclear Localization Signal (NLS)-tdTomato, FO32mRNA lipid nanoparticles carrying mcherry mRNA	AAV	Pig	ABSL-1	III-E-1	This protocol uses recombinant nucleic acid delivery materials to evaluate segment-specific pulmonary delivery using a regional ventilation platform. Tested particles include replication-incompetent adeno-associated viral (AAV1) vectors and mRNA lipid nanoparticle formulations (FO32). Materials will be delivered to discrete lung regions either by bronchoscopic instillation or by nebulization through the regional ventilation tube system. All viral vector and nanoparticle preparations will be handled, administered, and disposed of in accordance with Columbia biosafety requirements. Team exposure will be minimized by using a closed nebulization setup with in-line filters, room air HEPA filtration, and appropriate personal protective equipment. Infectious risk is limited because the AAV vectors are replication-incompetent and the mRNA lipid nanoparticles do not replicate. Post experiment waste will be disposed of appropriately.	CUIMC
13	Williams, Samuel		CRISPR	In vitro	N/A	III-F	Aim 1 - Define cell types or subtypes that exhibit altered transcriptional programs in ovary during aging using scRNA-Seq analysis and identify the responsible transcription factors. Aim 1b- Define specific enhancer regions in specific cell types or subtypes that exhibit altered transcriptional programs using scATAC-seq analysis and identify the responsible transcription factors. Aim 1c-Construct single-cell gene regulatory networks in each cell type as well as the temporal aging trajectory trees for each ovarian cell type. Generate CRISPR-engineered knock-in hESCs and differentiate into granulosa cells (dGCs).Characterize molecular phenotypes of dGCs derived from the knock-in hESCs.	CUIMC

	Proposals for work at BSL-2							
	PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Campus
14	Ali, Shah	shRNA to Fam220a for project 1. SRP54-CHIP for project 2.	LV	In vitro	N/A	III-D-1-a	Project 1: We are interested in studying the effect of the gene Fam220a on allelespecific gene expression. Therefore, we are going to generate lentiviruses that contain shRNA against Fam220a to turn off endogenous Fam220a expression. Project 2: We are interested in modulating the canonical secretory pathway. Therefore, we will make lentiviruses that can express CHIP-SRP54- which fuses a ubiqutin ligase catalytic domain (CHIP) with a protein that identifies nascent secretory proteins (SRP54). We hypothesize that SRP54 will bind nascent secretory proteins, and CHIP will ubiquitinate them for proteasomal degradation. We will also use an ER-TurboID lentivirus in the same cells to biotinylate secreted proteins to provide a reliable assay to test the functionality of CHIP-SRP54.	CUIMC
15	Colecraft, Henry	tdTomato, a fluorescent protein; and/or Nedd4L, a Nedd4 like E3 ubiquitin protein ligase; and/or nanobody against high threshold calcium channel alpha subunit, beta subunit or Nedd4L E3 ligase	AAV, AV, HSV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	Our laboratory has shown that adeno-associated virus (AAV) expressing our newly developed calcium channel inhibitor CaV-alator (CMV-tdTomato-P2A-F3-Nedd4L) is able to reduce the development of neuropathic pain following spared nerve injury (SNI). We have two additional goals in this study is to test (1) if the drug may reduce established neuropathic pain; (2) if other genetically engineered calcium channel blockers delivered via AAV, Ad or neuron specific HSV-1 may show similar or higher efficacy to reduce the pain. Dr. Chi-Kun Tong and Dr. Papiya Choudhury will administer AAV, Ad and HSV-1.	CUIMC
16	Han, Arnold	PMSCV, PMSGV expression vectors	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	Retroviral vectors may be used to modify autologous mouse T cells prior to adoptive transfer. They will not be used directly in mice. Approximately 10^6 transduce cells will be transferred at a time.	CUIMC
17	Lentzsch, Suzanne	11-1F4 antibody; anti-CD64 antibody; anti-CD89 antibody; 11-1F4-CAR-FcRr-GFP; 11-1F4-CAR-GFP; and CARFcRr-GFP	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	We will s.c. inject AL amyloidosis patient-derived AL amyloid extract into BalB/C mice to establish AL amyloidosis mouse model. We will also produce recombinant bispecific antibodies against AL amyloidosis and macrophages to examine their efficiency on the AL amyloidosis mouse model. In addition, 11-1F4 chimeric antigen receptor engineered macrophages will be produced to assess the amyloid targeting and clearance efficiencies.	CUIMC
18	Liao, Ya Cheng	ANXA11, TDP43, mStayGold, mScarlet	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	The primary goals of using lentivirus is to elucidate gene function, model disease states, or develop therapeutic interventions. Standard laboratory methodologies and manipulations include in vitro cloning into lentiviral vectors, transfection into HEK-293T cells for lentivirus packaging, purify and concentrate the viruses, transduce target cell types, and assess phenotypic changes. To mitigate the risk of accidental exposure or environmental release, specific safety frameworks are employed: Use of replication-incompetent systems where essential replication genes are deleted from the vector and provided in trans on separate plasmids.Chemical disinfection using 10% bleach with a minimum 30-minute contact time or autoclaving at for 30–60 minutes.Surface decontamination with 70% ethanol and disposal in biohazardous sharps containers or bags for incineration. Use of certified Biosafety Cabinets (BSCs) for all aerosol-generating procedures and appropriate PPEs	CUIMC
19	Lu, Chao	H3F3A, H3F3B, NSD1, NSD2, DNMT3A, DNMT3B, Cas9, GFP	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	Lab's research goals are to understand the mechanisms by which mutations in DNA and histone modifying enzymes drive tumor development. To this end, we employ in vitro cultures of mouse and human cancer cell lines and use recombinant DNA technologies, such as lentiviral vector-mediated transgene expression and CRISPR/Cas9 gene editing to genetically modify these cells. Cells are then implanted into mice to study the potential of tumor formation.	CUIMC
20	Marlin, Bianca	Either Channelrhodopsin, GCaMP8, GFP, or RFP	AAV, Sindbis Virus, PRV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	This project aims to understand how trauma and anxiety emerge from our senses, causing changes in the mammalian brain circuitry that can be passed down through generations. More specifically, we will take advantage of the complexity of the mouse olfactory system, alongside this evolutionary conservation, to study how noradrenaline regulates the emergence of trauma and anxiety in our brains. In its essence, this project seeks to understand the functional relationship between a brain region deep in the brainstem (the locus coeruleus, LC) and a peripheral sensory region, namely the main olfactory epithelium (MOE). This requires studying complex circuitry, electrophysiology, and the behavioral outcomes of modulating the activity of both regions. To do that, we will use both recombinant adeno-associated and pseudo-typed rabies virus to either perform synaptic tracing experiments, or to deliver opsins and calcium indicators.	MV
21	Perez-Lorenzo, Rolando	IKZF1, IKZF2, IKZF3, IKZF4, IKZF5, and EGFP	LV	In vitro	N/A	III-D-1-a	The main goal of the project is to determine the role of IKZF Family of transcription factors expression in the development and progression of melanoma and nonmelanoma skin cancers. We will generate stable melanoma and squamous cell carcinoma cell lines with over expression and knock down of IKZF family members. In all cases we will use third generation systems [separated plasmid vector and packaging materials (pMD2.G-VSV-G and psPAX2)] to minimize the generation of replication-competent virus. To minimize the risks of the broadened host range and the environmental stability that using VSV-G carries, we will conduct all the experiments under BSL-2, specific PPE and mandatory training for all personnel. In all cases, 10% bleach will be used in surfaces as well as materials used before processing for disposal as regulated medical waste. No experiments in animals will be conducted, only in vitro procedures are allowed in the scope of this protocol.	CUIMC
22	Sadelain, Michel	Synthetic receptors to target tumor associated antigens	AAV, LV, MMLV	Mouse	ABSL-1 (Note 2)	III-D-1-a	The goal of this work is to engineer human T cells to express synthetic receptors targeting tumor-associated antigens in order to evaluate their functional activity in vitro and in vivo. This involves the use of recombinant DNA (rDNA) constructs delivered via replication-incompetent viral vectors and, where applicable, CRISPR-based gene editing technologies. The viral vectors used are designed to be replication-incompetent. Packaging functions are split across multiple plasmids to reduce the risk of recombination and generation of replication-competent virus. If VSV-G pseudotyping is used, the broad tropism conferred by this envelope protein is acknowledged, and enhanced BSL-2 practices are implemented to mitigate exposure risk. Infectious materials and waste are inactivated using: 10% freshly prepared bleach (minimum 30-minute contact time) Autoclaving prior to disposal Appropriate PPE (lab coat, gloves, eye protection) Biosafety training for all personnel	CUIMC
23	Sawtell, Nathaniel	GFP, channelrhodopsin, archaerhodopsin, halorhodopsin, mCherry, hM4DGi (inhibitory DREADD)	LV, HSV (H129deltaTK-TT)	Mouse	ABSL-1 (Note 3)	III-D-1-a	Viral vectors will be introduced intracranially into the brain of mice using a Nanoject injector device. Vectors will be used to express reporter genes for the purpose of tracing neuroanatomical pathways, and in some cases, will also be used to selectively express opsin genes in particular areas of the brain for subsequent optical manipulation. In experiments involving herpes simplex virus (HSV) vectors, AAV may be used as a helper virus to enable conditional or cell-type-specific expression of the HSV construct, as required by the experimental design.	MV
24	Shen, Michael	cas9, Pten, p53, c-myc, GFP, firefly luc, nanoluc	LV, pT3	Mouse	ABSL-1 (Note 2)	III-D-1-a	Genes of interest (GOIs) will be knocked out using CRISPR/cas9 delivered by lentivirus. GOIs will be overexpressed in lentiviral constructs. Luminescent and/or fluorescent marker genes will be expressed by lentiviral constructs.	CUIMC
25	Sugahara, Kazuki	GFP, mCherry, luciferase, integrin, neuropilin	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	We will use various tumor mouse models to study the tumor-specificity and efficacy of peptide-based drug delivery systems. We will use various pancreatic, breast, gastric, ovarian, and colon cancer cells to generate the tumor mice as described in the animal protocol. Peptides with or without fluorescein will be either synthesized in house or purchased from commercial sources and used in a sterile condition.	CUIMC
26	Wang, Jianlong	Tex10; Zfp281	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	We are interested in studying gene function in embryonic stem cells that are derived from the blastocyst stage of early mouse embryos and in mouse early development. Using affinity purification of critical macromolecules present in stem cells, we have identified several novel genes important for maintaining stem cell identity and early development. To understand how they function in a biological setting, we will study their functions during mouse embryogenesis by modeling embryonic development with embryonic stem cells in culture with increased and decreased expression of these proteins. The consequences of such gene manipulation will be manifested by abnormalities in the engineered stem cell lines, which might mimic certain human and animal developmental diseases or cancers. This will provide a useful in vitro model to understand particular gene functions in early development and genetic diseases.	CUIMC

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 (JLG), in sealed disposable containers on a designated rack clearly labeled for PI handling only. Following euthanasia, water and containers will be decontaminated

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