



INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes  
Thursday, April 9<sup>th</sup>, 2026; 1:00PM

**Teleconference**

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

S. Morse convened the Institutional Biosafety Committee (the **Committee**) at 2:04 PM.

S. Morse asked the Committee to approve the minutes of the March 12<sup>th</sup>, 2025 meeting.

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

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**

- Bhatia\_IRB-ACY1300\_APM-ACY0464: RESTORE: A Phase 1/2 Study of nula-cel in Autologous CD34+ Hematopoietic Stem Cells to Convert HbS to HbA for Treating Severe Sickle Cell Disease.
  - S. Joussef Pina introduced Dr. Bhatia’s human use protocol for pediatric patients with severe sickle cell disease. 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.

**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.



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### rDNA

Fourteen 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.

- Nine 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.

Sixteen 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.

- Eleven 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

### Report

- There were no new reports.

### rDNA Incidents

- There were no incidents reported.

### Action Items

Action Items from 04-09-26 IBC meeting		
Status	Description	Group/Investigator
N/A	N/A	N/A

With there being no further business S. Morse adjourned the meeting at 2:32 PM. The next meeting will be held by teleconference on May 7<sup>th</sup>, 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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IBC Meeting: April 09, 2026

Table 1: Recombinant DNA proposals

Proposals for Work at BSL-1								
PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	
1	Agalliu, Dritan	alpha-synuclein and GFP	AAV	Mouse	ABSL-1	III-E-1	We will inject wild-type B6/J mice with AAV-SYN or AAV-GFP. We will inject 6 x 10 <sup>9</sup> viral genomes per injection. The animal will either receive either unilateral or bilateral injections of the AAV in the substantia nigra. Two weeks after stereotaxic injection of the appropriate AAV, the mice will be transferred to the protocol.	T2M0
2	Cheng, Ke	Nppa, Fluc	LNP-saRNA	Mouse	ABSL-1	III-E-1	RNA will be loaded into lipid nanoparticles(LNP); we will mix RNA and lipids in a flask in a BSL2 hood and evaporate the organic solvent using a rotary evaporator in a chemical hood. The prepared RNA/LNP will be used for animal studies immediately.	Y1M0
3	Christiano, Angela	Alopecia Areata-related proteins, IL-2, IL-10, TGF-beta	Plasmid	Mouse	ABSL-1	III-F	Recombinant DNA encoding for immunomodulatory molecules as well as Alopecia Areata-related proteins will be subcutaneously injected in C3H/HeJ mice and the subsequent prevention of Alopecia Areata development will be monitored over the course of 22 weeks. Recombinant DNA used in this protocol is a regular plasmid for protein overexpression, NOT a Viral vector. Human skin will be grafted into mice. Human T cells will be injected into human grafted skin in scid mice.	Y1M0
4	Benny, Christine	RAM-mKate2, c-Fos-tTA, TRE-mCherry	AAV	Mouse	ABSL-1	III-E-1	This work will use viral delivery of a transgenic plasmid for expression in various subregions of the brain via adeno-associated viruses (AAV). This strategy will require one survival surgery in which the AAV is delivered. The viruses do not include helper adenoviruses	Y1M0
5	Kellendonk, Christoph	Genetic sensor for Ca (GCaMP)	AAV	Mouse	ABSL-1	III-E-1	The goal is to understand how a genetic risk mutation for Parkinson affects neuronal Ca2+ activity in dopamine neurons	Y1M0
6	Konofagou, Elisa	Green fluorescent protein (GFP), Glial derived neurotrophic factor (GDNF), CRISPR-Cas9 Neurturin (NTRN), pACE/R, pTRPA1, GCAMP6f	AAV, CRISPR, PEG-DNA micelle, mRNA	Mouse	ABSL-1 (Note 2)	III-E-1	We are interested in delivery rDNA and rAAV through the blood-brain barrier using focused ultrasound. We plan to work with AAV for gene transduction and gene editing (CRISPR-Cas9). We will not make any of the rAAV in-house. They will be procured commercially or through collaborations.	T2M0
7	Ferrera, Vincent	DREADDS, GFP, GRAB-Ach, GRAB-NE, GRAB-DA	AAV	Macaque	ABSL-1	III-E-1	Monkey Optogenetics and DREADDS and Neurotransmitter reporters. We study central nervous system neurophysiology in primates using a combination of electrophysiology, neuropharmacology, MRI and focused ultrasound. standard optogenetics/DREADDS/nt reporter procedures, neural tissue graft (pathogen free)	T1M13
8	Leong, Kam	CRISPR effector and gRNA	AAV	Mouse	ABSL-1	III-E-1	In our lab, we have designed a few different approaches for somatic gene editing, including CRISPR-encoding AAVs and nanoparticles, and CRISPR-edited cell. We will test those approaches in mice to evaluate their gene editing efficacy.	Y1M0
9	Moy, Ryan	CCNE1, ERBB2, Cas9, sgRNA	Plasmid	Mouse	ABSL-1	III-E-1	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.	Y1M0
10	Ozcan, Lale	Gfp, Cre, shRNA against Rap1a, shRNA against Lgals1	AAV	Mouse	ABSL-1	III-E-1	The goal is to study the role of Rap1 and its downstream effectors in cholesterol metabolism and atherosclerosis. We will investigate this by acutely silencing or overexpressing them in the liver. We will achieve this by tail vein injection of adeno-associated viruses (AAVs). We will not produce these vectors in the lab—we will order them from Penn Vector Core or Viraquest.	T1M0
11	Siegelbaum, Steven	CAMKII, GCAMP6f, GCAMP7f, JRGECO1a	AAV	Mouse	ABSL-1	III-E-1	We aim to understand neural functional connectivity and its corresponding vascular responses in both "normal" and affected states. To investigate the neurovascular relationship, we use imaging, recording, and neuronal manipulation techniques, which are based on transgenic or viral expression of calcium indicator proteins during behavior. Viruses that will be used are: AAV	Y1M0
12	Targoff, Kimara	NKX2-5, GFP	Plasmid	Fish	ABSL-1	III-E-1	To generate transgenic animals or rescue mutant embryos, we will inject DNA samples into embryos at the 1-cell stage. For transgenesis, the DNA constructs will be stably integrated into the germline of injected embryos. For mutant rescue, we will evaluate whether cDNA introduction can rescue the mutant phenotype, validating that the mutant version of a particular gene is responsible for the mutant phenotype	T1M09
13	Tsang, Stephen	AAV8-Pde6a, AAV8-RFP, H2BEGFP	AAV, LV	Mouse	ABSL-1	III-E-1	We hypothesize that recessive forms of retinal degeneration can be treated using an AAV-based gene augmentation therapy that delivers a good copy of the gene and restore vision in mice.	Y1M0
14	Yang, Tingting	Best1, Best2, Best3, Best4, Ano1, Ano2, GS, GOT1, GOT2, GAD65, GAD67, GDH1, GLS2	AAV, BEV	In vitro	N/A	III-E-1	We study ion channels of interest by whole-cell patch clamp and solving their structures.	Y1M0



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Proposals for work at BSL-2								
PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	
15 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 ubiquitin 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.	Y1M0	
16 Ansoorge, Mark	hm3d, hm4d, hmgas: g-protein coupled receptors responsive to clozapine-N-oxide CHR2, Arch, NpHR: light activated ion channels GCaMP6: genetic calcium indicator	AAV, HSV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	we will use recombinant DNA to make mice in which we can modulate the activity of specific neuronal subpopulations	Y1M0	
17 Basso, Katia	BCL2, BCL6, MYC	MMLV	In vitro	N/A	III-D-1-a	Following published protocols (Caesar R. et al., Nature Protocols 2021; <a href="https://doi.org/10.1038/s41596-021-00506-4">https://doi.org/10.1038/s41596-021-00506-4</a> ), we plan to immortalize human germinal center (GC) B cells which are routinely isolated from de-identified and discarded lymphoid tissue collected upon tonsillectomies performed at CUIMC. In order to achieve ex-vivo expansion of non-malignant GC B cells, primary cells will be grown on a monolayer of feeder cells expressing chemokines (IL21 and CD40L) and will be transduced with non-replicative retroviruses expressing oncogenes (BCL6, BCL2, and/or MYC). The transduced cells remain dependent on feeder cells and grow in-vitro for several weeks.	Y1M0	
18 Bradshaw, Elizabeth	the pLKO.1 vector expresses Puromycin N-acetyltransferase and beta-lactamase	LV, HSV-1	In vitro	N/A	III-D-1-a	This project investigates neurodegeneration mechanisms using an in vitro human microglia (MDMi) model. MISSION® lentiviral shRNA (replication-incompetent) is used to reduce expression of genes associated with neurodegenerative risk to assess functional effects on microglial responses. Vectors are third-generation and lack genes required for replication. HSV-1 (ATCC VR-733) is used to infect MDMi to study host-virus interactions. Work is performed under BSL-2 conditions in a Class II biosafety cabinet, with wearing appropriate PPE (gloves, lab coat, goggles). Pipet tips are disposed of immediately in puncture-resistant containers containing 10% bleach.	Y1M0	
19 Cheng, Ke	Nppa, sFlt-1	LNP-mRNA, AAV, AV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	Human plasma will be purchased from commercial vendor. The vendor will provide the certificate of pathogen free, including HIV, Hepatitis B and etc. We will isolate plasma derived exosomes in a BSL2 hood. The isolated exosomes will be sent to a third company for pyrogenicity test and sterile filtered before usage. AAV and mRNA will be purchased from commercial vendor. We will dilute AAV/mRNA to a determined concentration in a BSL2 hood. AAV will be administered to animals directly. mRNA will be loaded into lipid nanoparticles (LNP): we will mix mRNA and lipids in a flask in a BSL2 hood and evaporate the organic solvent using a rotary evaporator in a chemical hood. The prepared mRNA/LNP will be used for animal studies immediately.	Y1M22	
20 Chung, Hachung	EGFP, ADAR1, PKR, IFIH1, DDX58, RNASE V, gRNA, Cas9, recombinase	LV, CRISPR, PB	In vitro	N/A	III-D-1-a, III-F	We will transfect Gag-pol, VSVG, and the transfer vector into 293T HEK cells to produce lentiviruses carrying our gene of interest. For transfection, X-tremeGENE 9 (Roche) will be used. We will transfect Gag-pol, VSVG, and the transfer vector into 293T HEK cells to produce lentiviruses carrying our gene of interest. For transfection, X-tremeGENE 9 (Roche) will be used. We will use 2nd generation lentiviral systems, a widely used and safe method to produce replication-defective lentiviruses.	Y1M0	
21 Ho, David	SARS-CoV-2 Spike	LV, VSV, Human Coronavirus 229E and OC43	In vitro	N/A	III-D-1-a, III-F	Construct the S gene so that it could be used to construct pseudoviruses so that it could be used to look for neutralizing antibodies. Express S protein to use to screen for monoclonal antibody.	Y1M0	
22 Hough, Rebecca	UCP2, BioITA, Citron, siRNA	AV, LV, Pseudomonas aeruginosa strain K	Mouse	ABSL-2	III-D-1-a, III-F	To understand the specific proteins regulating basic mechanisms of Acute Lung Injury in live animals, we use plasmid and viral vector-based gene transduction and knockdown strategies. Following gene expression or knockdown, we carry out imaging studies in intact alveoli or capillaries of live lungs excised from mice	Y1M0	



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23	Izar, Benjamin	CRISPR Library, different gene CRISPR Knockouts	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a, III-F	Different mouse and human tumor cell will be first modified in vitro via CRISPR/CAS9 gene editing, viral transduction of fluorescent proteins or target gene over expression, and once the tumor cells are free of viral particles tumor cells will be injected into the animals for in vivo studies.	T2M0
24	Liu, Shawn	dCas9-Tet1, dCas9-Dnmt3a, GFP	AAV, LV, GdRV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	Our lab aims to study the role of epigenome in brain function and disorders. In order to examine the functional significance of individual epigenetic event such as DNA methylation. We invented a novel molecular tool allowing for editing the DNA methylation. We will apply this tool to study the epigenetic events associated with brain disorder such as Rett syndrome.	Y2M0
25	Mapara, Markus	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 and 1F10 chimeric antigen receptor engineered macrophages will be produced to assess the amyloid targeting and clearance efficiencies.	T1M01
26	Small, Scott	VPS35, VPS26, VPS29, EGFP, CLN5, RhoGEF12 shRNA	AAV, LV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	The aim of the project is to further understand the role of retromer in mouse brain and in particular in the hippocampus. One of the methods used for these studies uses aseptic survival surgical techniques for injection of viral vectors in the regions of the brain that are most vulnerable to disease. This is achieved by use of carefully calibrated stereotactic equipment, that helps us target specific regions of the brain. The viral vectors used are replication deficient and will be injected directly into the brain to minimize the dose/titer needed and also to minimize the off-target effects. The viral vectors express retromer related genes including VPS35, VPS26, VPS29, CLN5, and RhoGEF12 shRNA. Control vectors express the EGFP gene. The overexpression of these retromer components allows us to study the effects of retromer on specific brain regions including function of neurons and glia, in addition to changes in CSF.	Y1M2
27	Sternberg, Samuel	Heterologous expression of genes encoding CRISPR-associated nucleases, antiphage defense proteins, transposases, and associated non-coding RNAs. In some cases, recombination proteins (e.g., lambda Red) or reporter genes such as GFP or RFP may also be expressed.	CRISPR, E. cloacae, E. hormaechei, E. coli, and other species. See attachment for complete list.	In vitro	N/A	III-D-1-a	The Sternberg Lab studies CRISPR-Cas systems, antiphage defense systems, and transposable elements across diverse bacteria and archaea. Our focus is not on applying existing CRISPR- or transposase-based tools, but on understanding the natural functions of these systems in their native biological contexts. Many experiments use heterologous expression systems to study candidate protein-coding genes, non-coding RNAs, and mobile genetic elements in lab-adapted strains of Escherichia coli. Increasingly, we are also examining these systems directly in their native bacterial hosts. These studies involve CRISPR- and transposon-derived elements that may originate from clinical isolates or bacteria associated with human disease. Some isolates are classified as Biosafety Level 2 and therefore require appropriate BSL-2 facilities, equipment, and safety practices.	Y1M0
28	Sternberg, Samuel	Fungal mitochondrial retroplasmid-associated genes (e.g., reverse transcriptase and related open reading frames), gene deletion or tagged variants for functional analysis, and standard selectable markers (e.g., antibiotic resistance markers for laboratory selection). Constructs may also include CRISPR-associated components (e.g., Cas nuclease and guide RNAs) for targeted genome editing in fungi. No toxin, virulence enhancement, or mammalian-active genes will be expressed.	CRISPR, Fusarium/Neurospora/Botryosphaeria/Trichoderma spp. See attachment for complete list.	In vitro	N/A	III-D-1-a	This project will characterize mitochondrial retroplasmids in filamentous fungi (including Fusarium, Neurospora, Epichloë, Botryosphaeria, and Trichoderma). Work will be conducted exclusively in vitro. Fungal isolates will be cultured under standard laboratory conditions, and genomic DNA and RNA will be extracted for sequencing and transcriptomic analysis. Molecular methods will include PCR, cloning, and sequence analysis to define retroplasmid structure and function. Where necessary, targeted genetic modification (e.g., plasmid-based transformation or CRISPR-mediated editing) may be performed to assess gene function. No animal or plant hosts will be used, and no enhancement of pathogenicity or environmental release is planned. All work will follow applicable institutional biosafety guidelines and containment practices.	Y1M0
29	Sugahara, Kazuki	GFP, mCherry, luciferase, integrin, neuropilin	AAV, LV	Mouse	ABSL-1 (Note 2)	III-E-1, 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.	Y1M0
30	Wechsler-Reya, Robert	shRNA directed against target genes including stem cell and developmental signals, cell surface receptors, transcription factors, suppressor genes such as p21, trp53 R172H, trp53 R270H, trp53 S58A, trp53 P275A; fluorescent reporters such as GFP, Luciferase, mCherry, firefly luciferase; oncogenes including Ahcy1, Zbtb7c, Megf10, Rreb1, Top1, ARID1A, CHD7, SNCAIP, PRDM6, cMycT58A, Klf4, Gli2, N-myc, c-myc, Dyn2	Murine Stem Cell Virus (MSCV), LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	Medulloblastoma (MB) and diffuse intrinsic pontine glioma (DIPG) are the most common malignant brain tumors in children. Our goals are to identify the genes that control normal growth and differentiation in the hindbrain, understand how these genes are dysregulated in MB and DIPG, elucidate how tumor cells evade the immune system, and identify novel therapies that specifically target the tumor cells while leaving normal tissue unharmed. This biohazard authorization will include the following methodologies: transplantation of mice with human cancer cells, including cells with target gene knockdown and evaluation of impact on growth of the cancer cells in vivo.	Y1M0

Note 1: The Biosafety Office allows Stereotactic injections to be designated as ABSL-1

Note 2: The Biosafety Office allows Transduced cell injections that are free from virus to be designated as ABSL-1

Note 3: 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

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