



INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes  
Thursday, November 6<sup>th</sup>, 2025; 1:00PM

**Teleconference**

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

S. Morse convened the Institutional Biosafety Committee (the **Committee**) at 1:04 PM.

S. Morse asked the Committee to approve the minutes of the October 9<sup>th</sup>, 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.

- **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**

- Bernstein\_IRB-ACY0160\_APM-ACY0064: A Phase 1b, Open-label, Multi-cohort Study of AZD0120, an autologous CD19/BCMA Targeting Chimeric Antigen Receptor T-cell, in Adults with Autoimmune Diseases
  - S. Joussef Pina introduced Dr. Bernstein’s human use protocol for subjects with Autoimmune Diseases. 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.

**rDNA**

Three 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.



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- One appendix was 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.

- Eight 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.

**rDNA Incidents**

- K. Fritz reported a needlestick injury to a CRISPR-Cas9 crRNA guide RNA targeting the zebrafish col12a1a gene. A Postdoctoral fellow working under Dr. Joanna Smeeton was involved in the incident. The Biosafety Office determined the agent was subject to the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules and required an incident report to the National Institutes of Health Office of Science Policy.

**Action Items**

Action Items from 11-06-25 IBC meeting		
Status	Description	Group/Investigator
N/A	N/A	N/A

With there being no further business S. Morse adjourned the meeting at 2:01 PM. The next meeting will be held by teleconference on December 4, 2025.

**2025 Meeting Calendar**

Date
Thursday, January 16, 2025
Thursday, February 13, 2025
Thursday, March 13, 2025
Thursday, April 10, 2025
Thursday, May 8, 2025
Thursday, June 5, 2025
Thursday, July 10, 2025
Thursday, August 7, 2025
Thursday, September 11, 2025
Thursday, October 9, 2025
Thursday, November 6, 2025
Thursday, December 4, 2025



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## INSTITUTIONAL BIOSAFETY COMMITTEE

IBC Meeting: October 9, 2025

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	Cheng, Ke	Nppa mRNA loaded liposome: Artrial natriuretic peptide/factor; Foxo3 mRNA loaded liposome: Foxo3 protein; miR21 loaded liposome: miRNA-21-5p; siBRD4 loaded LNP	LNP	Pig	ABSL-1	III-F	Human lung tissue provided by The University of North Carolina at Chapel Hill. We isolated lung derived spheroid cells in a BSL2 hood in the lab. Cell supernatant will be sent to a third company for endotoxin and mycoplasma test before usage. Lastly, cell derived secretomes/exosomes will be sterile filtered in a BSL2 hood before usage.	Y1 M9	AC-AABY0651	BSJW0022
2	Vickovic, Sanja	Cas13 (or Cas13 + guide RNAs). Fluorescent proteins (including ECFP, YFP, EGFP, mCherry, mRuby, etc). Custom RNA segments reverse complement to endogenous transcripts of interest.	AAV	Mouse	ABSL-1	III-E-1	The goal of the project is to understand the causal role the transcriptome plays in fundamental cellular processes involved in aging, particularly in the brain. To explore this question, we will use custom molecular tools to perturb specific cellular populations. In particular, we will use AAVs to knockdown specific transcripts of interest.	Y1 M1	AC-AACE0752	BQVF4817
Proposals for work at BSL-2										
PI	Insert	Vector	Host	Animal Biosafety Level	NIH category	Use/Comments	Year	Protocol #	Appendix A	
3	Abate-Shen, Cory	Gene inserts include: Nkx3.1, G9a, Glp, Suv39h1, Ezh2 - these are growth promoting but not highly oncogenic; we also express shRNAi vectors which knock-down expression.	AV, LV	Mouse	ABSL-1 (Note 3)	III-D-1-a	The goal of my research is to understand the mechanisms of human cancer with the ultimate goal of developing new, more effective strategies for prognosis and treatment of the disease. We use mice to investigate these issues since mice are amenable to genetic manipulation and since many processes of human cancer are conserved in mice and therefore can be studied in mice. We use adenoviruses and lentivirus to introduce genes into mice to achieve Gene recombination.	Y1 M0	AC-AABT1620	BQVF7809
4	Abate-Shen, Cory	Nkx3.1, G9a, Glp, Suv39h1, Ezh2, shRNAi vectors which knock-down expression.	AV, LV	Mouse	ABSL-1 (Note 3)	III-D-1-a	The goal of my research is to understand the mechanisms of human cancer with the ultimate goal of developing new, more effective strategies for prognosis and treatment of the disease. We use mice to investigate these issues since mice are amenable to genetic manipulation and since many processes of human cancer are conserved in mice and therefore can be studied in mice. This protocol describes the use of adenoviruses and lentivirus to introduce genes into mice to achieve Gene recombination	T1 M0	AC-AABT3650	BQVF7807
5	Farber, Donna	Hes4	LV	In vitro	N/A	III-D-1-a	The goal is to use non replicating viral vectors to perturb gene function in primary human B cells. Methods include cell culture, transfection, and exposure of cells to replication incompetent lentiviral vectors with self inactivating long terminal repeats. Work will be performed at Biosafety Level 2 in a Class II biological safety cabinet, with centrifugation in sealed rotors and use of personal protective equipment including coats, gloves, and eye or face protection. Waste and disposables in contact with vectors or potentially infectious materials will be decontaminated using approved methods, and surfaces will be disinfected after use and spills. Additional risks include VSV G pseudotyped vectors that broaden host range and present aerosol hazards. These will be mitigated by cabinet handling, sealed centrifugation, and limiting volumes. CRISPR introduces risks of double strand breaks and off target effects, addressed with validated designs and transient delivery.	Y1 M0	LS-AAAD5152	BQVF5806
6	Ferrante, Anthony	cre-dependent tet tox and GFP	AAV, AV	Mouse	ABSL-1 (Note 3)	III-D-1-a	The goal of these studies is to test whether signaling in several neuron populations (parabrachial nucleus, arcuate, parasubthalamic nucleus, et al) is required to prevent against weight gain following overfeeding. 6-8 week old Adeno-associated viruses that express Cre under the control of distinct promoters, eg CGRP, TAC1, CRH, mice will undergo bilateral stereotaxic injection of an adeno-associated viral vector containing the light chain of the tetanus toxin into the relevant nuclei. As only the light chain of the tetanus toxin is used, this virus is non-toxic and will act in a Cre mediated manner to silence targeted neurons in the presence of DCZ. Conversely, AAV vector with activating Gs protein will be injected and activate targeted neurons in a Cre and DCZ dependent manner. Although infectious exposure to these virus is not known to cause disease, if such an exposure were to occur, the person would go to W&H (or CUIMC Emergency Department after-hours) for evaluation.	Y1 M03	AC-AABR6604	APA-AWEA8771
7	Kim, Arianna	BRD7, BRD9, CCL8, CCL25, CCL28	LV	Mouse	ABSL-1 (Note 2)	III-D-1-a	The objective of this study is to assess the in vivo roles of epigenetic regulators (BRD7, BRD9) and select chemokines (CCL8, CCL25, CCL28) in BCC pathogenesis and resistance, utilizing a well-established skin reconstitution method. A silicon chamber will be placed on the dorsum, and equal numbers of dermal fibroblasts and tumor keratinocytes transduced with a third-generation lentiviral vector carrying specific shRNAs or overexpressing plasmids will be mixed as a slurry and added to the silicon chamber (implantation) at one to two sites on the mouse.	Y1 M0	AC-AABT2658	BQVF7803
8	Ren, Bing	SYFP2, CREs, and synthetic barcode sequences	AAV, LV	Mouse	ABSL-1 (Note 3)	III-E-1, III-D-1-a	Cis-regulatory elements (CREs) will be synthesized and ordered from commercial vendors (IDT, Twist Bioscience). These CREs are cloned into an AAV plasmid backbone via Gibson assembly to create plasmid libraries. Plasmid libraries are eventually used for packaging into AAV particles through external vendors (e.g., VectorBuilder) or used directly for transient transfections in cultured cells. In addition, CREs may be cloned into lentiviral transfer plasmid backbones. These plasmids will be used in lab to transfect HEK293T cells (ATCC) along with packaging vectors (psPAX2, Addgene) and envelop vectors (pMD2.G, Addgene) for lentivirus production. Lentivirus will be used to transduce cultured human HCT116 cells (ATCC). In all cases, transfected or transduced samples will be fixed for imaging. All viral vectors used are replication incompetent.	Y1 M0	AC-AACJ5950	BQVF7811
9	Yan, Kelly	Wnt3a, RSPO1, Znf3	AV	Mouse	ABSL-1 (Note 3)	III-D-1-a	Mice will be injected with replication deficient adenovirus to induce hepatic infection leading to systemic circulation of soluble proteins for the perturbation and manipulation of stem cells.	Y1 M0	AC-AACJ3953	BQVF5802

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 prior to c

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