Minutes
Thursday, July 10th, 2025; 1:00PM
Teleconference

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

S. Morse convened the Institutional Biosafety Committee (the **Committee**) at 1:02pm.

S. Morse asked the Committee to approve the minutes of the June 5th, 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

- Lentzsch_IRB-AAAV7829_APM-AAAW6250: Phase 1b/2 Study of AZD0120 (also known as GC012F), a Chimeric Antigen Receptor T Cell Therapy Targeting CD19 and B cell Maturation Antigen in Participants with Relapsed or Refractory AL Amyloidosis.
    - S. Joussef Pina introduced Dr. Lentzsch's human use protocol for subjects with relapsed refractory AL amyloidosis. 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 Commitee.
    - 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

Two 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.

- Two 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, both BSL-1 Appendices were voted upon collectively and approved unanimously.

Two 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.

- No 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, both BSL-2 appendices were voted upon collectively and approved unanimously.

NIH Compliance

In response to the June 18th notice from NIH-OSP, the Biosafety Office reached out to investigators and performed a joint review of their ongoing and proposed research activities, determining that no applicable notifications to NIH were warranted. The IBC was presented with the reviews and confirmed that no applicable notifications were warranted.

Announcements

- Anthony Donatich, a voting member, is departing from the Institutional Biosafety Committee.

Reports

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

rDNA Incidents

- There were no incidents reported to the Biosafety Office.

Action Items

Action Items from 07-10-25 IBC meeting		
Status	**Description**	**Group/Investigator**
N/A	**N/A**	**N/A**

With there being no further business S. Morse adjourned the meeting at 1:43 pm. The next meeting will be held by teleconference on August 7th, 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

IBC Meeting: July 10, 2025

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	Egli, Dietrich	SLC30A8, INS, GCK, KCNJ11, WFS-1, CFTR, HLA	CRISPR	Mouse	ABSL-1	III-E-1	We study the maturation and functional development of stem cell derived beta cells (sc-beta cells). We use these to for disease modeling by transplantation of control and mutant cells. We will be able to conduct functional analysis of these transplanted cell in mice by performing intraperitoneal glucose stimulation test, monitoring cpeptide/insulin/proinsulin level after transplantation. The stem cell core takes patient fibroblasts, reprograms them into iPSCs then CRISPR corrects the cells so that we have control and mutant lines. These cells are differentiated using a protocol established in house and published (Sui et al "Pancreatic beta cell differentiation from human pluripotent stem cells." Current Protocols in Human Genetics). To fully differentiate the cells we implant them into	Y1 M4	AC-AABK4552	BQAE0006
2	Olive, Kenneth	E.coli cea - Colicin E1 - Toxin (pore forming) cylE - -Hemolysin - Toxin (pore forming) hylE - Hemolysin E - Toxin (pore forming) pfo - -Toxin - Toxin (pore forming) - from C.perfringens azu - Azurin - Toxin (apoptosis inducing) sta1 - Heat Stable Enterotoxin 1 - Toxin (apoptosis inducing) magainins - Magainin - Anti-cancer peptide ple1 - Pleurocidin - Anti-cancer peptide histone H2A - Buforin IIb - Anti-cancer peptide EcN-SLC-CXCR7nb - CXCR7 specific nanobody. AAV Kras G12D sgRNA	AAV, E. coli Nisle	Mouse	ABSL-1	III-E-1	Mice will be inoculated with E.coli Nissle 1917 bacteria to assess the utility of bacteria as a vector for anti-cancer therapies. Bacterial inoculation will occur via intravenous, intraperitoneal or oral gavage routes of administration. Mice will receive donor RNA via adeno-associated virus (AAV) vectors for the purpose of genomic incorporation by a constitutive Cas9 transgene system. Viral inoculation will occur via intrapancreatic injection.	Y1 M0	AC-AABS3610	BQVE7860
3	Yuste, Rafael	Opsins, voltage indicators, and cre recombinase	AAV	Mouse	ABSL-1	III-E-1	Here we inject nonreplicative, non-genome integrative virus directly into the CNS of mice in order to insert voltage indicators	Y1 M5	AC-AABN3562	APA-BQVE7802
	Proposals for work at BSL-2									
	PI	**Insert**	**Vector**	**Host**	**Animal Biosafety Level**	**NIH category**	**Use/Comments**	**Year**	**Protocol #**	**Appendix A**
4	Fidock, David	Plasmodium falciaprum k13 gene	Plasmodium falciparum, plasmid	In vitro	N/A	III-F, III-E-1	Generation of Plasmodium falciparum parasite lines expressing point mutations in the k13 gene that are associated with partial resistance to artemisinin.	Y1 M0	LS-AAAD5000	BQVE8807
5	Sternberg, Samuel	Various nuclease and transposase genes, including TnpA, TnpB, TnsA, TnsB, TnsC, or guide RNAs, and/or combinations thereof	AAV, AV, LV	In vitro		III-E-1, III-D-1-a	We will be generating lentiviral, adenoviral, and adeno-associated viral (AAV) vectors using standard approaches, with the goal of transducing human cell lines and performing lentivirus-based gene integration. Viral vectors will be generated by co-transfecting packaging cells derived from mammalian cell lines, with a plasmid vector containing a portion of the viral genome and additional packaging plasmids. The packaging plasmids encode essential viral proteins (such as Gag, Pol, and Rev for lentivirus, or Rep and Cap for AAV) required for the assembly and packaging of the viral particles. Transfected packaging cells then produce lentiviral, adenoviral, or AAV particles, which are released into the cell culture supernatant. The viral particles, containing the desired genetic material, will be harvested and purified from the supernatant using various techniques, such as ultracentrifugation or filtration, to concentrate and purify the viral particles for	Y1 M0	LS-AAAD4751	APA-BQVE4811
6	Cardoso, Wellington	pitx1	LV	In vitro	N/A	III-D-1-a	Overexpression of Genes in Mouse Cells via Lentivirus	Y1 M0	LS-AAAD4651	BQSE8763

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 disposal.

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