SAFETY Meeting Minutes
Biosafety Committee
6/30/2026 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:02PM
Meeting end time: 1:44PM

VOTING MEMBER ATTENDANCE

Name	Substituting For	Attendance
Mark Klang		Present
Andy Koff		Present
Xiuyan Wang		Absent
Kevin Curran	Prasad Adusumilli	Present
Justin Laracy		Present
Lauren Wood		Present
Paul Zel		Present
Philip Hauck		Absent
Hillary Frommer		Absent
Zainab Shahid		Present
Geoffrey Ku		Absent
Rui Gardner		Present
Marc Kramer		Present
Sham Mailankody		Present
Paul O'Brien		Present
Andrea Ventura		Present
Christine Iacobuzio-Donahue		Present
Shuchi Agarwal		Present

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Rivka Schwarcz
Gary Martin
Richard Ellis
Patricia Thomas
Rene Celeste
Sunipa Pramanik

QUORUM INFORMATION

Number of SAFETY members on the roster: 18
Number required for quorum: 10

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE STATUS AND VOTING KEY	
ABSTAIN:	Present for the vote, but not voting "For" or "Against."
ABSENT:	Absent for discussion and voting for reasons other than a conflicting interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflicting interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member substitutes for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

GUEST NAMES
Sharon Samuel

DISCUSSION

The Minutes from the April meetings were approved. The IBC discussed a balanced approach to managing proprietary information in the meeting minutes, ensuring transparency while protecting patient privacy and sponsor confidentiality.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202600020**

Title:	MED26-136: A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy
Investigator:	Gunjan Shah
Submission ID	PROTO202600020

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review for a Phase 3 study evaluating the efficacy of KITE-753 versus axicabtagene ciloleucel (axi-cel) in adult participants with relapsed or refractory large B-cell lymphoma (LBCL) after one line of systemic therapy. The investigational Chimeric Antigen Receptor (CAR) T-cell therapy is KITE-753. The primary objective is to evaluate the efficacy of KITE-753 versus axicabtagene ciloleucel. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the clinical trial.
e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Initial Protocol

2. **Review of PROTO202600021**

Title:	MED26-148: Phase 1, Multicenter, Open-Label, FIH Study of ITI-5000 (Self-Amplifying RNA Vaccine) Alone and in Combo with Pembrolizumab in Participants with Stage II-III TNBC Who Have Completed Standard Curative-Intent Therapy
Investigator:	Tiffany Traina
Submission ID	PROTO202600021

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** Change biosafety level from BSL-1 to BSL-2.

d. **Comments:** This is the initial review for a phase I first-in-Human Study of ITI-5000 (Self-Amplifying RNA Vaccine) alone and in combination with Pembrolizumab in participants with Stage II-III Triple Negative Breast Cancer (TNBC) who have completed standard Curative-Intent Therapy (VITAL-TNBC Study). The primary objective is to assess the safety and tolerability of ITI-5000 in participants with TNBC. Immunogenicity of ITI-5000 will also be explored to support the design of potential future clinical studies. The Reviewer did not have any concerns and recommended approval. The Committee determined that this protocol should be classified as Biosafety Level 2 (BSL-2). The Committee voted to approve the initial protocol.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Initial Protocol

3. **Review of PROTO202600018**

Title:	PED26-009: A Phase 2 Study of WU-CART-007 (soficabtagene geleucel), an Anti-CD7 Allogeneic CAR-T Cell Therapy, in Patients with Relapsed or Refractory T-Cell Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma (T-RRex)
Investigator:	Kevin Curran
Submission ID	PROTO202600018

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review of a Phase 2 study to evaluate the efficacy of WU-CART-007 for patients with Relapsed/Refractory (R/R) T-Cell Acute Lymphoblastic Leukemia (T-ALL)/Lymphoblastic Lymphoma (LBL) as a therapy to induce complete Minimum Residual Disease (MRD) negative response. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the initial protocol.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	2
Absent:	4
Abstained:	0

Initial Protocol

4. **Review of PROTO202600019**

Title:	MED26-126: An Open-Label, Multicenter Phase 1/2 Study to Evaluate the Safety and Efficacy of AB-3028 in Patients With Castration Resistant Prostate Cancer (CRPC)
Investigator:	Susan Slovin
Submission ID	PROTO202600019

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review of an open-label, multicenter Phase 1/2 study evaluating the safety, efficacy, cellular kinetics, immunogenicity, and pharmacodynamics of AB-3028 in adult subjects with progressive metastatic castration-resistant prostate cancer (mCRPC). The Reviewer requested additional information about off target sites. These issues were resolved, and the Reviewer recommended approval. The Committee voted to approve the protocol.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Continuing Review

5. **Review of SAF04054**

Title:	Continuing Review for PROTO202500011
Investigator:	Ritesh Kotecha
Submission ID	SAF04054

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review for the Phase 1/2 multicenter, open-label, dose escalation, and dose expansion study of ADI-270 in patients with Relapse/Refractory clear cell Renal Cell Carcinoma (ccRCC). ADI-270 is an engineered allogeneic CAR T cell product that targets Cluster of Differentiation (CD)70. The primary objectives are to characterize the safety and tolerability of ADI-270, to define the maximum tolerated dose/maximum assessed dose (MTD/MAD) of ADI-270, to select a dose of ADI-270, and to characterize the anti-tumor activity of ADI-270 at the recommended phase 2 dose (RP2D). No changes, accidents, or loss of containment were reported. The Committee voted to approve the annual renewal.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

6. **Review of SAF04027**

Title:	Amendment/CR for PROTO202500012
Investigator:	Jae Park
Submission ID	SAF04027

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review and amendment for a Phase 1/2, open-label, multicenter study to determine the efficacy and safety of JCAR017 in adult subjects

with R/R Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL). The study will include a Phase 1 dose-finding part to determine the recommended dose (RD) of JCAR017 monotherapy, followed by a Phase 2 expansion to further evaluate the efficacy and safety of JCAR017 monotherapy administered at the RD. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual renewal.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

7. **Review of SAF03916**

Title:	Amendment/CR for PROTO202400014
Investigator:	Sridevi Rajeeve
Submission ID	SAF03916

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a Phase 2, randomized, open-label, global, multicenter study to independently determine the efficacy and safety of cilta-cel therapy when combined with fix-duration sequential combinations of daratumumab and bispecific antibodies (Tal-D and Tec-D) either before or after cilta-cel infusion in participants with Newly Diagnosed Multiple Myeloma (NDMM). No changes, accidents, or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual renewal.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

8. **Review of SAF04047**

Title:	Amendment/CR for PROTO201900013
Investigator:	Sergio Giralt
Submission ID	SAF04047

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for a Phase 3, multicenter, open-label study designed to examine the safety and efficacy of bb2121, a CAR-T cell therapy, compared to standard of care therapy options for patients with relapsed and refractory multiple myeloma (RRMM). No accidents, or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual renewal.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment

9. **Review of SAF04051**

Title:	Amendment for PROTO202400022
Investigator:	Adam Schoenfeld
Submission ID	SAF04051

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** The purpose of this amendment is to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment/CR

10. **Review of SAF04032**

Title:	Amendment/CR for PROTO202300008
Investigator:	Sham Mailankody
Submission ID	SAF04032

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a Phase 1, multicenter, open-label study to evaluate the safety and emerging efficacy of CB-011 in patients with relapsed/refractory multiple myeloma (r/r MM). CB-011 is a product of (CRISPR)-based gene editing designed to create an allogeneic human T cell product with specific capacity to target multiple myeloma cells. No changes, accidents, or loss of containment were reported. The purpose of the amendment was to update personnel. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review and amendment.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment/CR

11. **Review of SAF04064**

Title:	Amendment/CR for PROTO202400009
Investigator:	Susan Slovin
Submission ID	SAF04064

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a Phase I/II, open label study to evaluate the safety, tolerability, and antitumor activity of AZD0754 CAR T-cell therapy in participants with metastatic prostate cancer. The study will evaluate AZD0754 in participants with metastatic castration-resistant prostate cancer (mCRPC) who have previously received treatment with a novel hormonal agent (NHA) and taxane. No accidents or loss of containment were reported. The purpose of the amendment is to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review and amendment.

e. **Applicable section of NIH Guidelines:** Section III-C-1

f. **Containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

12. **Review of LAB202600041**

Title:	Molecular Microbiology Facility (MMF) (Jonathan Peled)
Investigator:	Jonathan Peled
Submission ID	LAB202600041

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the initial review for the Molecular Microbiology Core Facility (MMF). The goal is to conduct research on infections in cancer patients, microbial causes of cancer, and infection-induced inflammation. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the initial review.

e. **Applicable section of NIH Guidelines:** N/A

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

13. **Review of LAB202600035**

Title:	Lydia Finley Lab
Investigator:	Lydia Finley
Submission ID	LAB202600035

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments**: This is the triennial review for the Finley Lab protocol. They investigate how cellular metabolic pathways regulate cell fate decisions in stem cells and cancer cells. The goal is to combine genetic and metabolomic approaches to investigate cell-

type specific growth requirements and elucidate how flux through central metabolic pathways regulates key cellular activities, including self-renewal and differentiation. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** III-D-3-b, III-D-3-a, III-F-8 Appendix C-II, III-F-8 Appendix C-I

f. **Containment level:** BSL-1 and BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

14. **Review of LAB202600036**

Title:	Michael McDevitt Lab
Investigator:	Michael McDevitt
Submission ID	LAB202600036

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Michael McDevitt Lab. The research involves development of antibody drug platform technology for medical use to treat cancer and disease. The Reviewer requested additional information about transport. These issues were resolved, and the Reviewer recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

15. **Review of LAB202600032**

Title:	Arvin Dar Lab
Investigator:	Arvin Dar
Submission ID	LAB202600032

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Dar Laboratory. The primary goal of the research is to develop tools that enable researchers to modulate cell signaling networks, allowing for in-depth mechanistic exploration of disease and potential therapeutic applications. The focus of the work is the development of chemical tools and probes to target cancers driven by dysregulated enzymes, receptors, cellular communication pathways, and the tumor microenvironment. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8 Appendix C-II, III-D-3-b

f. **Containment level:** BSL-1 and BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

16. **Review of LAB202600034**

Title:	Precision Pathology Biobanking Center (PPBC) (Joachim Silber)
Investigator:	Joachim Silber
Submission ID	LAB202600034

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Precision Pathology Biobanking Center. The center functions through the acquisition and banking of human biologic specimens to be used in studying the causes, detection, prevention, and treatment of cancer. The MSKBiobank and Pathology Core Facility serves to procure, process, store and distribute well-characterized neoplastic and nonneoplastic human tissue to suit specific research needs. The Reviewer requested post exposure procedures and specific contact time requirements be addressed. Once addressed, the Reviewer recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** None

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol
17. **Review of LAB202600018**

Title:	Jennifer Zallen Lab
Investigator:	Jennifer Zallen
Submission ID	LAB202600018

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Jennifer Zallen Laboratory. The laboratory uses multidisciplinary approaches from cell and developmental biology, physics, engineering, and computer science to study how tissue architecture is dynamically established and remodeled throughout development. The Reviewer requested clarification on the listed PPE to be used. Once addressed, the Reviewer recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8 Appendix C-I, III-F-8 Appendix C-II, III-D-3-b
f. **Containment level:** BSL-1 and BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
18. **Review of LAB202600039**

Title:	Nikola Pavletich Lab
Investigator:	Nikola Pavletich
Submission ID	LAB202600039

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Nikola Pavletich Laboratory. The group is interested in understanding, at the structural and mechanistic level, the functions of key proteins and macromolecular complexes that are altered in cancer. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8 Appendix C-I, III-F-8 Appendix C-II
f. **Containment level:** BSL-1 and BSL-2
g. **Votes:**
For: 14
Against: 0

Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
19. **Review of LAB202600023**

Title:	Jayanta Chaudhuri Lab
Investigator:	Jayanta Chaudhuri
Submission ID	LAB202600023

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Jayanta Chaudhuri Laboratory Protocol. The focus of the lab is to decipher molecular cues that allow a mature B cell to undergo class switch recombination (CSR). The lab's objective is to elucidate the mechanisms by which CSR is regulated to promote immunity while minimizing collateral damage associated with the process. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-D-3-a, III-D-3-b, III-E, III-F-8, Appendix C-I, III-F-8, Appendix C-II
f. **Containment level:** BSL-1 and BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
20. **Review of LAB202600025**

Title:	Caleb Lareau Lab
Investigator:	Caleb Lareau
Submission ID	LAB202600025

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2027
c. **Required modifications: None**
d. **Comments:** This is the triennial review for the Lareau lab. They plan to use genomics readouts to study cell fate changes in response to perturbations. The Reviewer requested additional handling precautions, which were addressed. The Reviewer did not have any further concerns and recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-F-8, Appendix C-III, III-D-3-b, III-D-3-a

f. **Containment level: BSL-2+**

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

21. **Review of SAF04045**

Title:	Amendment for LAB202500092
Investigator:	Andrea Ventura
Submission ID	SAF04045

a. **Determination:** Approved

b. **Last day of continuing review period:** 10/31/2026

c. **Required modifications: None**

d. **Comments:** The purpose of the amendment was to add purified Cholera Toxin and recombinant adeno associated viral (AAV) vectors to the protocol. The Reviewer had minor comments that needed to be addressed. Once addressed, the Reviewer recommended the amendment be approved. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** III-D-1-a

f. **Containment level:** BSL-1 and BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment

22. **Review of SAF04060**

Title:	Amendment for LAB202500045
Investigator:	Sarat Chandarlapaty
Submission ID	SAF04060

a. **Determination:** Approved

b. **Last day of continuing review period:** 7/31/2026

c. **Required modifications: None**

d. **Comments:** The purpose of this amendment is to add personnel and a new lentiviral vector to the protocol. The Reviewer requested consistency in how liquid waste

would be decontaminated. Once addressed, the Reviewer recommended approval of the amendment. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** III-D-3-b

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

23. **Review of SAMEND202600000002**

Title:	Amendment for LAB202500041
Investigator:	Jonathan Peled
Submission ID	SAMEND202600000002

a. **Determination:** Approved

b. **Last day of continuing review period:** 7/31/2026

c. **Required modifications:** None

d. **Comments:** The purpose of this amendment is to update personnel and non-recombinant bacteria. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** None

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Continuing Review

24. **Review of SAF04067**

Title:	Continuing Review for LAB202400008
Investigator:	Agnel Sfeir
Submission ID	SAF04067

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2027

c. **Required modifications: None**

d. **Comments:** This is an annual review for the Sfeir Lab. Their research seeks to understand basic chromosome biology and how their mismanagement manifests in disease. The Committee voted to approve the annual review.

e. **Applicable section of NIH Guidelines:** III-F-8 Appendix C-II, III-D-3-a, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

25. **Review of SAF04070**

Title:	Amendment for LAB202600012
Investigator:	Mengtong Li
Submission ID	SAF04070

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** The purpose of this amendment is to add personnel, mammalian brain tissue, and a new AAV into the protocol. The Reviewer had comments associated with safety practices and PPE requirements for handling brain tissue. Once addressed, the Reviewer recommended the amendment be approved. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I
f. **Containment level:** BSL-1 and BSL-2
g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

26. **Review of SAF04046**

Title:	Amendment for LAB202500014
Investigator:	Simon Powell
Submission ID	SAF04046

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** The purpose of this amendment is to add Adenovirus to the protocol. The Reviewer had comments about how bleach would be used for disinfection and

the procedures for handling spills. Once addressed, the Reviewer recommended the amendment be approved. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** III-D-1-a

f. **Containment level:** BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

27. **Review of SAF04077**

Title:	Amendment for LAB202500042
Investigator:	Kathryn Taylor
Submission ID	SAF04077

a. **Determination:** Approved

b. **Last day of continuing review period:** 7/31/2026

c. **Required modifications:** None

d. **Comments:** The purpose of this amendment is to add new personnel and AAV vectors. The Reviewer requested additional containment for preparation of a separate biohazard. Once addressed, the Reviewer recommended the amendment be approved. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** III-F-8 Appendix C-I

f. **Containment level:** BSL-1 and BSL-2

g. **Votes:**

For:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0