

SAFETY Meeting Minutes
 Biosafety Committee
 1/27/2026 1:00 PM
 Zoom

MEETING TIME RECORDS

Meeting start time: 1:03 PM
Meeting end time: 1:23 PM

VOTING MEMBER ATTENDANCE

Name	Substituting For	Attendance
Mark Klang		Present
Andy Koff		Present
Xiuyan Wang		Present
Prasad Adusumilli		Absent
Justin Laracy		Absent
Lauren Wood		Present
Paul Zel		Absent
Philip Hauck		Present
Hillary Frommer		Present
Zainab Shahid		Present
Geoffrey Ku		Absent
Rui Gardner		Absent
Marc Kramer		Absent
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
Timothy Burnett
Gary Martin
Rene Celeste
Richard Ellis
Abarar Mamoojee

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 substitute 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.

DISCUSSION

The Minutes from the November 2025 and December 2025 Meeting were approved.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. Review of PROTO202500024

Title:	MED25-236: An Open-label, Phase 1, Multi-Center Master Protocol to Evaluate the Safety and Preliminary Anti-Tumor Activity of TCR-engineered T cells Recognizing KRAS Mutations in Adult Subjects with Unresectable, Advanced, and/or Metastatic Solid Tumors
Investigator:	Adam Schoenfeld
Submission ID	PROTO202500024

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is a phase 1 study to investigate TCR-Engineered T cells recognizing KRAS mutations in adult participants with unresectable, advanced and/or metastatic solid tumors. The investigational T-cell products are NT-112 and AZD0240. The study has 2 arms, Part A Dose Escalation and Part B Dose Expansion. The primary objective of Part A is to evaluate the safety of KRAS TCRTs and evaluate the MTD and recommended dose for expansion (RDE). The primary objective of Part B is to further evaluate the safety of KRAS TCRTs at the RDE in participants. The Reviewer did not express any concerns and recommended approval. The Committee voted to approve the trial.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	11
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Against: 0
Recused: 1
Absent: 6
Abstained: 0

Initial Protocol

2. Review of PROTO202500025

Title:	MED25-229: Phase 1/2 Study Evaluating Genetically Modified Autologous T-cells Expressing a T-cell Receptor Recognizing a Cancer/germline Antigen as Monotherapy or in Combination with Nivolumab in Patients with Recurrent and/or Refractory Solid Tumors
Investigator:	Alexander Shoushtari
Submission ID	PROTO202500025

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is a phase 1/2 Study Evaluating Genetically Modified Autologous T-cells Expressing a T-cell Receptor Recognizing a Cancer/germline Antigen as Monotherapy or in Combination with Nivolumab in Patients with Recurrent and/or Refractory Solid Tumors. The Reviewer did not express any concerns and recommended approval. The Committee voted to approve the trial.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	11
Against:	0
Recused:	1
Absent:	6
Abstained:	0

Continuing Review

3. Review of SAF03904

Title:	Continuing Review for PROTO202300030
Investigator:	Michael Postow
Submission ID	SAF03904

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the annual review for a Phase 3, randomized, placebo- and active-controlled, parallel-group, multicenter, double-blind safety and efficacy study of adjuvant V940 plus pembrolizumab (Arm A) versus adjuvant placebo plus

pembrolizumab (Arm B) in participants with completely resected high-risk (Stage II-IV [including clinical Stage II] per AJCC eighth edition) cutaneous melanoma. The primary objective is to compare V940 plus pembrolizumab to placebo plus pembrolizumab with respect to recurrence-free survival (RFS). No changes, accidents, exposures or loss of containment were reported. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review.

- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-1
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Continuing Review

4. Review of SAF03949

Title:	Continuing Review for PROTO202400028
Investigator:	Alexander Shoushtari
Submission ID	SAF03949

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the annual review for a Phase 2/3, Randomized, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab (Control Arm). No changes, accidents, exposures or loss of containment were reported. [REDACTED]

[REDACTED]
[REDACTED] The Committee agreed with the reviewer’s recommendation and voted to approve the annual review.

- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Continuing Review

5. Review of CR20250000006

Title:	Continuing Review for PROTO202300029
Investigator:	Jamie Chافت
Submission ID	CR202500000006

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the annual review for a Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Study of Adjuvant V940 (mRNA-4157) & Pembro vs Adjuvant Placebo & Pembro in Participants with Resected Stage II, IIIA, IIIB (N2) NSCLC. No changes, accidents, exposures or loss of containment were reported. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-1
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Continuing Review

6. Review of SAF03902

Title:	Continuing Review for PROTO201900027
Investigator:	Sandra D'Angelo
Submission ID	SAF03902

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the annual review for a master protocol to assess the safety and Antitumor Activity of Genetically Engineered T Cells in NY-ESO-1 and/or LAGE-1a positive solid tumors. No changes, accidents, exposures or loss of containment were reported. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Amendment/CR**7. Review of SAF03925**

Title:	Amendment/CR for PROTO202400026
Investigator:	Ivan Kotchetkov
Submission ID	SAF03925

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and annual review for a Phase I Study of MB-CART19.1 Cellular Therapy for Relapsed/Refractory Primary and Secondary Central Nervous System Lymphoma (CNSL) using on-site manufacturing with the clinimacs prodigy device. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel and administrative documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	11
Against:	0
Recused:	1
Absent:	6
Abstained:	0

Amendment/CR**8. Review of SAF03923**

Title:	Amendment/CR for PROTO202200010
Investigator:	Jae Park
Submission ID	SAF03923

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and annual review for a Phase I Study of T-cell receptor α constant (TRAC) Locus Integrated CD19-Targeted 19(T2)28z1xx Chimeric Antigen Receptor (CAR) Modified T Cells in Adult Patients with Relapsed or Refractory Large B-Cell Lymphoma. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** Section III-C-1
- f. **Containment level:** BSL-2
- g. **Votes:**

For: 11
Against: 0
Recused: 1
Absent: 6
Abstained: 0

Amendment

9. Review of SAF03934

Title:	Amendment for PROTO202500012
Investigator:	Jae Park
Submission ID	SAF03934

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 6/30/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for updating administrative 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:** 11
 - Against:** 0
 - Recused:** 1
 - Absent:** 6
 - Abstained:** 0

Amendment

10. Review of SAF03932

Title:	Amendment for PROTO202300024
Investigator:	Jae Park
Submission ID	SAF03932

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 8/31/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for updating the committee about two reversible, non-fatal dose-limiting toxicities at the initial dose. The protocol has been revised to test a lower dose both with and without lymphodepleting chemotherapy to ensure safety, without changing recruitment or increasing patient numbers. 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: | 11 |
| Against: | 0 |
| Recused: | 1 |
| Absent: | 6 |
| Abstained: | 0 |

Amendment

11. Review of SAF03933

Title:	Amendment for PROTO202400008
Investigator:	Ritesh Kotecha
Submission ID	SAF03933

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 5/31/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for updating administrative 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: | 12 |
| Against: | 0 |
| Recused: | 0 |
| Absent: | 6 |
| Abstained: | 0 |

Amendment

12. Review of SAF03937

Title:	Amendment for PROTO202500002
Investigator:	Jae Park
Submission ID	SAF03937

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 4/30/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for updating personnel and administrative 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:** 11
 - Against:** 0
 - Recused:** 1
 - Absent:** 6
 - Abstained:** 0

Amendment

13. Review of SAF03935

Title:	Amendment for PROTO202400011
Investigator:	Roisin O'Cearbhaill
Submission ID	SAF03935

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 8/31/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for updating personnel and administrative 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:** 11
 - Against:** 0
 - Recused:** 1
 - Absent:** 6
 - Abstained:** 0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

14. Review of LAB202500117

Title:	The Microbiology Research Lab
Investigator:	Lauren McVoy
Submission ID	LAB202500117

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is an initial review for the McVoy Lab. Their lab investigates the development, validation and implementation of cutting techniques for laboratory diagnosis and monitoring of microbial infections. The Reviewer had no concerns and recommended approval. The Committee voted to approve the lab registration.
- e. **Applicable section of NIH Guidelines:** N/A
- f. **Containment level:** BSL-2

- g. **Votes:**
- | | |
|-------------------|----|
| For: | 12 |
| Against: | 0 |
| Recused: | 0 |
| Absent: | 6 |
| Abstained: | 0 |

Initial Protocol

15. Review of LAB202500119

Title:	Therapeutics Bridge Laboratories (Peter Meinke)
Investigator:	Peter Meinke
Submission ID	LAB202500119

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is an initial review for the Therapeutics Bridge Laboratories. Their research focuses on antibody and small molecule discovery for projects related to oncology drug development. The reviewer sought clarification about sharps usage and incident response SOP. These clarifications were addressed and they 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
- f. **Containment level:** BSL-2
- g. **Votes:**
- | | |
|-------------------|----|
| For: | 12 |
| Against: | 0 |
| Recused: | 0 |
| Absent: | 6 |
| Abstained: | 0 |

Triennial Protocol

16. Review of LAB202500124

Title:	Marc Ladanyi Research
Investigator:	Marc Ladanyi
Submission ID	LAB202500124

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the triennial review for the Ladanyi lab which studies molecular profiling of lung cancer and sarcomas to identify targetable vulnerabilities and develop therapy. 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-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Triennial Protocol

17. Review of LAB202500125

Title:	Molecular Cytology Facility (Murray Tipping)
Investigator:	Murray Tipping
Submission ID	LAB202500125

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the triennial review for the Molecular Cytology Facility which studies the detection and analysis of molecules in their natural environment. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
- e. **Applicable section of NIH Guidelines:** N/A
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Triennial Protocol

18. Review of LAB202500122

Title:	Christopher Klebanoff Lab
Investigator:	Christopher Klebanoff
Submission ID	LAB202500122

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the triennial review for the Klebanoff Lab which studies the clinical development of TCR-based immunotherapeutics that can persist and mediate

durable tumor regression in cancer patients. 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-D-3-b
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Triennial Protocol

19. Review of LAB202500107

Title:	Prasad Jallepalli Lab
Investigator:	Prasad Jallepalli
Submission ID	LAB202500107

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the triennial review for the Jallepalli Lab which studies how human cells duplicate and transmit their chromosomes during each round of division. 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, III-D-1-a, III-E
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Triennial Protocol

20. Review of LAB202500118

Title:	Lorenz Studer Lab
Investigator:	Lorenz Studer
Submission ID	LAB202500118

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None

- d. **Comments:** This is the triennial review for the Studer Lab which uses human pluripotent stem cells (hPSCs) to study neural development, aging, and neurodegenerative disease, while developing cell-based therapies. 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-1-a, III-D-3-b
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Triennial Protocol

21. Review of LAB202500112

Title:	Luis Parada Lab
Investigator:	Luis Parada
Submission ID	LAB202500112

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the triennial review for the Parada Lab which uses genetically engineered and PDX mouse models to study neural tumors. The Reviewer expressed concerns about the decontamination of brain tumor specimens which could potentially raise the risk of prions. This issue was addressed 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, III-D-3-a, III-D-3-b
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Continuing Review

22. Review of CR20250000007

Title:	Continuing Review for LAB202500013
Investigator:	Tobias Walther
Submission ID	CR202500000007

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This annual review is for the Walther Lab which aims to investigate disorders of lipid storage and metabolism as well as neurodegeneration. No changes, accidents, exposures, or loss of containment were reported. The Committee voted to approve the annual 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-1-a, III-E
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Continuing Review

23. Review of SAF03929

Title:	Continuing Review for LAB202500001
Investigator:	Omar Abdel-Wahab
Submission ID	SAF03929

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This annual review is for the Abdel-Wahab Lab which aims to understand the role of genetic alterations in development of leukemias and lymphomas. An amendment was submitted to add materials (mRNA lipid nanoparticles, new AAV constructs) and update personnel. No accidents, exposures, or loss of containment were reported. The Committee voted to approve the annual review.
- e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-1-a, III-D-3-b
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Continuing review with amendment**24. Review of SAF03954**

Title:	Amendment/CR for LAB202500009
Investigator:	Thomas Vierbuchen
Submission ID	SAF03954

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and the annual review for the Vierbuchen Lab. The lab seeks to elucidate fundamental mechanisms governing the production of the myriad neuronal cell types required to build functioning neural circuits. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-1-a, III-D-3-b
- f. **Containment level:** BSL-2+
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Continuing review with amendment**25. Review of SAF03947**

Title:	Amendment/CR for LAB202500011
Investigator:	Jessica Sheu-Gruttadauria
Submission ID	SAF03947

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and the annual review for the Sheu-Gruttadauria Lab. The lab investigates how biomolecular condensates and biological phase transitions shape gene expression in physiology and disease. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-3-b, III-E
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	12
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Against: 0
Recused: 0
Absent: 6
Abstained: 0

Continuing review with amendment

26. Review of SAMENDCR202600000001

Title:	Amendment/CR for LAB202500006
Investigator:	Sohrab Shah
Submission ID	SAMENDCR202600000001

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and the annual review for the Shah Lab. The lab focuses on understanding how tumors evolve over time using multimodal data and computational modeling. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** N/A
- f. **Containment level:** BSL-2
- g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Continuing review with amendment

27. Review of SAF03940

Title:	Amendment/CR for LAB202300077
Investigator:	Xiuyan Wang
Submission ID	SAF03940

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and the annual review for the Gene Transfer Core Facility (Xiuyan Wang). The core manufactures patient cells and genetically modifies these cells with replication defective gammaretroviral and lentiviral vectors as well as gene editing tools. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel, administrative documents, and additional cell lines. The Committee voted to approve the amendment and annual review.

- e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-1-a, III-D-3-a, III-D-3-b
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 11
 - Against:** 0
 - Recused:** 1
 - Absent:** 6
 - Abstained:** 0

Continuing review with amendment

28. Review of SAMENDCR202600000002

Title:	Amendment/CR for LAB202400016
Investigator:	John Maciejowski
Submission ID	SAMENDCR202600000002

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027
- c. **Required modifications:** None
- d. **Comments:** This is the amendment and annual review for the Maciejowski lab. The lab focuses on the pathways leading to clustered mutation and chromosome rearrangements to determine how engagement of these pathways impacts cancer progression, heterogeneity, and response to therapy. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** III-D-3-b, III-F-8 Appendix C-II, III-F-8 Appendix C-I
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Continuing review with amendment

29. Review of SAF03951

Title:	Amendment/CR for LAB202500004
Investigator:	Michael Overholtzer
Submission ID	SAF03951

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 1/31/2027

- c. **Required modifications:** None
- d. **Comments:** This is the amendment and the annual review for the Overholtzer lab. Their lab studies how nutrient signaling pathways are regulated, and how programmed cell death resulting from nutrient deprivation contributes to cancer progression or therapy. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel. The Committee voted to approve the amendment and annual review.
- e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-D-3-b, III-F-8 Appendix C-II, III-D-3-a
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0

Amendment

30. Review of SAF03950

Title:	Amendment for LAB202300059
Investigator:	Joao Xavier
Submission ID	SAF03950

- a. **Determination:** Approved
- b. **Last day of continuing review period:** 9/30/2026
- c. **Required modifications:** None
- d. **Comments:** This amendment is for adding *Klebsiella pneumoniae* to the lab’s IBC registration. The Reviewer’s clarification about *in vivo* use was addressed and they recommended approval. The Committee voted to approve the amendment.
- e. **Applicable section of NIH Guidelines:** N/A
- f. **Containment level:** BSL-2
- g. **Votes:**
 - For:** 12
 - Against:** 0
 - Recused:** 0
 - Absent:** 6
 - Abstained:** 0