SAFETY Meeting Minutes
Biosafety Committee
9/30/2025 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:02 PM
Meeting end time: 1:21 PM

VOTING MEMBER ATTENDANCE

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

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Timothy Burnett
Rich Ellis
Rinosha Majeed
Rivka Schwarcz

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.

GUEST NAMES

DISCUSSION

The minutes from the August, 2025 IBC Meeting were reviewed and approved by the Committee

Preliminary potential exposure report: The committee reviewed the September 12, 2025, needlestick injury involving a graduate student who was collecting blood from a mouse that had been euthanized. This mouse was xenografted with human PC3 cells that were stably transduced with a retroviral vector that allow the cells to express PSMA. and noted that a pre-report to OSP has been filed. The IBC Chair enquired if this individual was from a lab that was involved in recurrent issues. The IBC Administrators indicated that this lab had not been involved in any exposures/injuries/non-compliance previously.

NIH Launches Biosafety Modernization Initiative: The committee discussed a new announcement from the NIH regarding its initiative to modernize biosafety oversight. The intention is to strengthen biosafety oversight over emerging technologies, empower IBCs and reduce unnecessary regulatory burden due to low risk research. As part of this endeavor, listening sessions are being help across the country with the first one being after the IBC Meeting today. A number of IBC members indicate that they would be attending the listening session.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202500016**

Title:	MED25-166: A Phase I/IIa Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of EVM14 as Monotherapy and in Combination with Pembrolizumab in Patients with Selected Solid Tumors
Investigator:	Chrisann Kyi
Submission ID	PROTO202500016

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is a Phase I/IIa, first-in-human, open-label, multiregional study assesses the safety, tolerability, immunogenicity, and preliminary efficacy of EVM14 given by intramuscular injection, alone and with pembrolizumab, in people with selected solid tumors. EVM14 is a mRNA-lipid nanoparticle (mRNA-LNP) cancer vaccine which is formulated by two mRNA drug substances encoding tumor-associated antigens encapsulated in a lipid system. It focuses on safety, immune response, and early signs of benefit, including a comparison of the combination versus pembrolizumab alone in squamous non–small cell lung cancer across multiple centers. 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:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Initial Protocol

2. **Review of PROTO202500015**

Title:	A 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
Investigator:	Heather Landau
Submission ID	PROTO202500015

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is a 1b/2, open-label, multicenter, non-randomized study evaluates the safety, tolerability, and preliminary effectiveness of an autologous dual-targeting CAR T cell therapy in adults with relapsed or refractory AL amyloidosis. The construct is a replication defective self-inactivating 3rd generation lentiviral dual CAR

targeting vector. Phase 1b includes dose escalation and expansion to identify a recommended Phase 2 dose, followed by a larger Phase 2 cohort to further assess efficacy and safety. Participants receive a single intravenous infusion after standard lymphodepletion, with routine clinical sampling for assessments. Follow-up continues for two years, with long-term monitoring thereafter. 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:	12
Against:	0
Recused:	2
Absent:	4
Abstained:	0

Amendment/CR

3. **Review of SAMENDCR202500000033**

Title:	Amendment/CR for PROTO202400015
Investigator:	Miguel-Angel Perales
Submission ID	SAMENDCR202500000033

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a Phase 1, first-in-human, open-label study will evaluate a single dose of TRX103, a CAR-T cell therapy, for safety in people with blood cancers undergoing donor stem cell transplants. 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:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment/CR

4. **Review of SAF03829**

Title:	Amendment/CR for PROTO202400016
Investigator:	Steven Horwitz
Submission ID	SAF03829

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I/II open-label, multicenter study evaluates the investigational therapy CTX131 in adults with previously treated hematologic malignancies. 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:	12
Against:	0
Recused:	2
Absent:	4
Abstained:	0

Amendment

5. **Review of SAF03837**

Title:	Amendment for PROTO202100011
Investigator:	Mark Geyer
Submission ID	SAF03837

a. **Determination:** Approved
b. **Last day of continuing review period:** 10/31/2025
c. **Required modifications:** None
d. **Comments:** This amendment updates personnel and protocol documents and changes in dosing in a Phase 1 first-in-human, open-label, dose escalation and expansion study of UCART22 (Allogeneic Engineered T-cells Expressing Anti-CD22 Chimeric Antigen Receptor) administered to patients with relapsed or refractory B-cell acute Lymphoblastic Leukemia (B-ALL).. 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:	2
Absent:	4

Abstained: 0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

6. **Review of LAB202500091**

Title:	Andy Minn Lab
Investigator:	Andy Minn
Submission ID	LAB202500091

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Minn Lab. Their research explores how the tumor microenvironment, immune interactions, and chronic interferon signaling drive metastasis and resistance to cancer therapies. The Reviewer had no concerns and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-D-3, III-D-4-a, III-F-8; III-F
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Review

7. **Review of LAB202500080**

Title:	Gabrielle Rizzuto Lab
Investigator:	Gabrielle Rizzuto
Submission ID	LAB202500080

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Rizzuto lab. Their study investigates immune tolerance at the maternal–fetal interface. 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, III-E, III-F
f. **Containment level:** BSL-2
g. **Votes:**
For: 14

Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Review

8. **Review of LAB202500081**

Title:	Christopher Lima Lab
Investigator:	Christopher Lima
Submission ID	LAB202500081

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Lima lab which investigates how ubiquitin, SUMO, and related RNA processing pathways function at structural, biochemical, and cellular levels. 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; III-E
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review

9. **Review of LAB202400015**

Title:	Nagavarakishore Pillarsetty Lab
Investigator:	Kishore Pillarsetty
Submission ID	LAB202400015

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Pillarsetty lab which focuses on the development and validation of novel imaging tracers. 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; III-F
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review

10. **Review of LAB202500077**

Title:	Kayvan Keshari Lab
Investigator:	Kayvan Rahimi-Keshari
Submission ID	LAB202500077

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Keshari lab which studies cancer metabolism using imaging and biochemical approaches. 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, III-F
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Review

11. **Review of LAB202500078**

Title:	Charles Rudin Lab
Investigator:	Charles Rudin
Submission ID	LAB202500078

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Rudin lab. Their lab focuses on the development and testing of the novel therapeutic approaches to lung cancer in preclinical models. 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, III-F-8, III-F
f. **Containment level:** BSL-2

g. **Votes:**

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

Triennial Review

12. **Review of LAB202500079**

Title:	Yueming Li Lab
Investigator:	Yueming Li
Submission ID	LAB202500079

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Li lab which studies *γ-secretase* and its roles in neurodegeneration, development, and 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-D-3, III-F-8, III-F

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

g. **Votes:**

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

Triennial Review

13. **Review of LAB202500090**

Title:	Emily Cheng Lab
Investigator:	Emily Cheng
Submission ID	LAB202500090

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Cheng lab which investigates cell death mechanisms to inform cancer 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-D-3, III-D-1, III-F-8
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review

14. **Review of LAB202500075**

Title:	Iestyn Whitehouse Lab
Investigator:	Iestyn Whitehouse
Submission ID	LAB202500075

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Whitehouse lab which studies chromatin-mediated genome compaction, gene expression, and DNA replication. 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
f. **Containment level:** BSL-1
g. **Votes:**

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

Triennial Review

15. **Review of LAB202500086**

Title:	John Petrini Lab
Investigator:	John Petrini
Submission ID	LAB202500086

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Petrini lab which studies how the DNA damage response shapes organ development and 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-D-3, III-F-8, III-F

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

g. **Votes:**

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

Triennial Review

16. **Review of LAB202500085**

Title:	Dirk Remus Lab
Investigator:	Dirk Remus
Submission ID	LAB202500085

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Remus lab which studies mechanisms of eukaryotic DNA replication, using biochemical and genetic approaches. 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

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

g. **Votes:**

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

Triennial Review

17. **Review of LAB202500084**

Title:	Zhirong Bao Lab
Investigator:	Zhirong Bao
Submission ID	LAB202500084

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Bao lab which studies cell lineage and morphogenesis during embryonic development. 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

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

g. **Votes:**

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

Triennial Review

18. **Review of LAB202500074**

Title:	David Scheinberg Lab
Investigator:	David Scheinberg
Submission ID	LAB202500074

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Scheinberg lab. Their research focuses on identifying tumor antigens and exploring ways to modulate regulatory and antigen presentation pathways to advance cancer treatment strategies. 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, III-D-4, III-E-1

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

g. **Votes:**

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

Triennial Review

19. **Review of LAB202500083**

Title:	Richard Kolesnick Lab
Investigator:	Richard Kolesnick
Submission ID	LAB202500083

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Kolesnick lab which investigates sphingolipid stress signaling, focusing on ceramide-mediated responses to

environmental and pharmacologic stress. 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; III-F-8; III-D-1

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

g. **Votes:**

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

Triennial Review

20. **Review of LAB202500088**

Title:	Kojo Elenitoba-Johnson Lab
Investigator:	Kojo Elenitoba-Johnson
Submission ID	LAB202500088

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Elenitoba-Johnson lab which studies hematologic malignancies, defining how novel proteins, fusions, and post-translational modifications drive lymphoma, using genomics/proteomics, cell models, and transgenic mouse models to inform diagnosis and treatment. 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, III-F-8

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

g. **Votes:**

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

Triennial Review

21. **Review of LAB202500087**

Title:	Laboratory of Comparative Pathology (Juliette Wipf)
Investigator:	Juliette Wipf
Submission ID	LAB202500087

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Laboratory of Comparative Pathology . This core provides clinical and anatomic pathology services for research animals across multiple institutions, handling diverse species and specimens under BSL-2 with hazard disclosure and appropriate containment; the registration also covers rodent breeding service areas for colony management. 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- Not applicable
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review
22. **Review of LAB202500076**

Title:	Jonathan Goldberg Lab
Investigator:	Jonathan Goldberg
Submission ID	LAB202500076

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Goldberg lab which studies vesicular trafficking in mammalian cells, examining how proteins are processed and transported in the secretory pathway and how these processes are altered or controlled in disease, using biophysical and biochemical reconstitution approaches. 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
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review
23. **Review of LAB202500089**

Title:	Asmin Tulpule Lab
Investigator:	Asmin Tulpule
Submission ID	LAB202500089

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Tulpule lab which studies fusion-driven cancers, focusing on receptor tyrosine kinase (RTK) fusion lung cancer and pediatric sarcomas. 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, III-F-8
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Review

24. **Review of LAB202500082**

Title:	Gretchen Diehl Lab
Investigator:	Gretchen Diehl
Submission ID	LAB202500082

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Diehl lab which studies how intestinal microbiota, diet, and tissue factors regulate immune homeostasis, aiming to define pathways that balance defense and repair and how they are disrupted in inflammatory disease. 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-1-a, III-F-8
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing Review

25. **Review of SAF03831**

Title:	Continuing Review for LAB202300059
Investigator:	Joao Xavier
Submission ID	SAF03831

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Xavier Lab which studies the molecular regulation of the biofilm formed by Pseudomonas aeruginosa. No accidents, exposures or loss of containment were reported. An amendment was submitted to add new bacterial and fungal agents and update personnel. The Committee voted to approve the annual review.
e. **Applicable section of NIH Guidelines:** III-D-1, III-E-1, Appendix C-I
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing review with amendment

26. **Review of SAF03825**

Title:	Amendment/CR for LAB202300058
Investigator:	Andrew Kung
Submission ID	SAF03825

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for the Andrew Kung Lab. Thelab uses mouse cancer models to test candidate therapies. No accidents, exposures or loss of containment have occurred. 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; III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

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

Amendment

27. **Review of SAF03832**

Title:	Amendment for LAB202200135
Investigator:	Maria Jasin
Submission ID	SAF03832

a. **Determination:** Approved

b. **Last day of continuing review period:** 11/30/2025

c. **Required modifications:** None

d. **Comments:** This amendment is for adding a new human embryonic cell line to the lab's IBC registration. The Reviewer did not have any concerns and 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: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

28. **Review of SAF03823**

Title:	Amendment for LAB202500050
Investigator:	Alexander Rudensky
Submission ID	SAF03823

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This amendment is for updating personnel and adding retroviral guide RNAs for adoptive transfer and lentiviral guide RNAs for mouse chimera generation. . The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.

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

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

g. **Votes:**

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

Amendment

29. **Review of SAF03830**

Title:	Amendment for LAB202300059
Investigator:	Joao Xavier
Submission ID	SAF03830

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for updating new personnel, administrative documents and adding new fungi (*Candida albicans, Candida paraspilosis*) and bacteria (Enterococcus faecalis, *Bacteroides fragilis, Fusobacterium nucleatum*) used. The Reviewer requested consistency in the bleach concentration used for disinfection and recommended approval upon completion. The Committee voted to approve the amendment.
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

Amendment

30. **Review of SAF03845**

Title:	Amendment for LAB202500066
Investigator:	Irene Orlow
Submission ID	SAF03845

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for making an editorial correction to downgrade containment level for human materials from BSL-2+to BSL-2. The Reviewer did not have any concerns and 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:	14
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

31. **Review of SAF03636**

Title:	Amendment for LAB202300031
Investigator:	Scott Lowe
Submission ID	SAF03636

a. **Determination:** Approved

b. **Last day of continuing review period:** 12/31/2025

c. **Required modifications:** None

d. **Comments:** This amendment is for adding diphtheria toxin administration to transgenic mice bearing the Diphtheria toxin receptor to acutely deplete specific population of cells and assess their role in premalignant pancreatic niches, with intraperitoneal dosing and histologic analysis at defined time points. The Reviewer's questions were addressed and they recommended approval. The Committee voted to approve the amendment.

e. **Applicable section of NIH Guidelines:** IIID-4-b

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

g. **Votes:**

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