SAFETY Meeting Minutes
Biosafety Committee
8/26/2025 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:02 PM
Meeting end time: 1:34 PM

VOTING MEMBER ATTENDANCE

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

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Timothy Burnett
Rich Ellis
Rinosha Majeed
Wendy He
Shuchi Agarwal

QUORUM INFORMATION

Number of SAFETY members on the roster: 17
Number required for quorum: 9

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 committee discussed the IBC policy for confirming of training for individuals added to IBC registrations. Members suggested that new students be provided a copy of the policy and ensuring that all graduate students are properly informed.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202500014**

Title:	MED25-117: A Phase II Trial of Obecabtagene Autoleucel Consolidation in Adult Patients with Acute Lymphoblastic Leukemia in First Complete Remission Without Measurable Residual Disease
Investigator:	Jae Park
Submission ID	PROTO202500014

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This Phase II, multi-center trial evaluates the effectiveness of obe-cel, a CD19-targeted CAR T-cell therapy, as a consolidation treatment for adults with high-risk B-cell acute lymphoblastic leukemia (ALL) who are in MRD-negative remission and ineligible for upfront transplant. The study includes patients with both Philadelphia chromosome-negative and positive disease. Key objectives are to measure relapse-free survival, event-free survival, safety, and overall survival, along with exploratory assessments of quality of life, remission depth, CAR T-cell persistence, and molecular factors related to outcomes. 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: 0

Absent: 5
Abstained: 0

Amendment/CR

2. **Review of SAF03777**

Title:	Amendment/CR for PROTO202000028
Investigator:	Jae Park
Submission ID	SAF03777

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I, open-label, multicenter trial evaluating FT819, an allogeneic CAR T-cell therapy derived from a clonal iPSC line engineered to target CD19, in patients with relapsed or refractory B-cell malignancies (BCL, CLL, and B-ALL). The trial includes dose-escalation and dose-expansion stages for each disease type, aiming to identify safe dosing levels, assess tolerability, and detect early signs of anti-tumor activity. 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: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Amendment/CR

3. **Review of SAF03776**

Title:	Amendment/CR for PROTO201900015
Investigator:	Kevin Curran
Submission ID	SAF03776

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
a. **Comments:** This is the amendment and annual review for a Phase II, single-arm, open-label, multicenter trial evaluating the efficacy and safety of *tisagenlecleucel*, a CD19-directed CAR T-cell therapy, in pediatric and young adult patients with high-risk B-cell acute lymphoblastic leukemia (B-ALL) who remain minimal residual disease (MRD) positive at the end of first-line consolidation therapy. The primary

objective is to assess 5-year disease-free survival. Patients will undergo screening, pre-treatment, infusion, and follow-up phases, with efficacy monitored regularly and a second infusion offered based on MRD status and B-cell recovery. Long-term safety monitoring for lentiviral vector effects will continue under a separate protocol. 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.

b. **Applicable section of NIH Guidelines:** Section III-C-1
c. **Containment level:** BSL-2
d. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

4. **Review of SAF03769**

Title:	Amendment/CR for PROTO202400005
Investigator:	Geoffrey Ku
Submission ID	SAF03769

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I trial evaluating the safety and maximum tolerated dose of intraperitoneal mesothelin-targeted CAR T-cell therapy in patients with mesothelin-positive esophagogastric adenocarcinoma and peritoneal carcinomatosis. CAR T cells are administered via peritoneal catheter across escalating dose levels. Patients undergo leukapheresis after progression on first-line therapy, with bridging therapy permitted during the 3–4-week manufacturing period. 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:	5
Abstained:	0

Amendment/CR

5. **Review of SAF03783**

Title:	Amendment/CR for PROTO202000007
Investigator:	Roisin O'Cearbhaill
Submission ID	SAF03783

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I, single-arm, open-label trial assessing the safety and maximum tolerated dose of intrapleural administration of genetically engineered autologous CAR T cells targeting mesothelin in patients with malignant pleural mesothelioma. The CAR T cells incorporate an anti- PD-1 component. Using a 3+3 dose-escalation design, the trial will treat patients across five escalating dose levels to evaluate safety and tolerability. 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:	5
Abstained:	0

Amendment/CR

6. **Review of SAF03809**

Title:	Amendment/CR for PROTO202300024
Investigator:	Jae Park
Submission ID	SAF03809

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is an amendment and annual review for a Phase I clinical trial that tests a new CD19-targeted CAR T cell therapy designed to secrete interleukin-18 for patients with relapsed or refractory acute lymphoblastic leukemia. The study uses a dose-escalation approach across several patient groups, with or without chemotherapy, to evaluate safety and identify the best dose for future trials based on

patient outcomes and CAR T cell activity.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:	0
Absent:	5
Abstained:	0

Amendment/CR

7. **Review of SAF03770**

Title:	Amendment/CR for PROTO202400011
Investigator:	Roisin O'Cearbhaill
Submission ID	SAF03770

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This amendment and annual review is for a Phase I, multicenter trial testing the safety and effectiveness of FT825, an engineered cell therapy, in patients with advanced solid tumors. The study evaluates FT825 both alone and in combination with cetuximab following chemotherapy in various cancer types, including those with and without established HER2-targeted therapies. It also examines new treatment approaches for EGFR-expressing tumors and considers retreatment strategies for patients whose disease progresses. The trial is structured with dose-escalation and expansion phases, enrolling patients across different regimens and tumor groups. 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:	5
Abstained:	0

Amendment/CR

8. **Review of SAF03808**

Title:	Amendment/CR for PROTO202300019
Investigator:	Adam Schoenfeld
Submission ID	SAF03808

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is an amendment and annual review for a Phase I clinical trial testing a new DLL3-targeted CAR T-cell therapy in patients with extensive-stage small cell lung cancer (SCLC) and large cell neuroendocrine carcinoma (LCNEC). The study's main goals are to evaluate safety and establish the recommended dose for future trials. It includes an initial dose-escalation phase followed by a cohort expansion phase. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel, DL7 dose level, 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: 5
Abstained: 0

Amendment/CR

9. **Review of SAF03778**

Title:	Amendment/CR for PROTO202300032
Investigator:	Alexander Shoushtari
Submission ID	SAF03778

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a Phase 1/2 clinical trial investigating a novel tumor-infiltrating lymphocyte (TIL) therapy that expresses IL-15 for patients with advanced melanoma resistant to immune therapies, and select cases of refractory non-small cell lung cancer. The study is evaluating safety, efficacy, and tolerability in a multi-stage format. The first phase focuses on determining the optimal dose, while the second phase further assesses the treatment's effectiveness at that dose. 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:	0
Absent:	5
Abstained:	0

Amendment/CR

10. **Review of SAF03780**

Title:	Amendment/CR for PROTO202200019
Investigator:	Mark Geyer
Submission ID	SAF03780

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is an amendment and annual review for a Phase I clinical trial investigating a novel CAR T-cell therapy targeting CD371 for patients with relapsed or refractory acute myeloid leukemia (AML). The CAR T cells are engineered with a human CD371-targeting motif, a mutated CD28 costimulatory domain (YSNV), and interleukin-18 (IL-18) to boost immune activation. The study uses a dose-escalation approach to evaluate safety, determine the recommended Phase II dose, and closely monitor toxicity, CAR T-cell persistence, and myeloid recovery. Patients receive lymphodepleting chemotherapy prior to CAR T-cell infusion, and are enrolled across multiple dosing cohorts using a 3+3 design.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:	0
Absent:	5
Abstained:	0

Amendment

11. **Review of SAF03819**

Title:	Amendment for PROTO202400022
Investigator:	Adam Schoenfeld
Submission ID	SAF03819

a. **Determination:** Approved
b. **Last day of continuing review period:** 1/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment includes updates to study personnel, supplemental toxicity management guidelines, 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: 5
Abstained: 0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

12. **Review of LAB202500054**

Title:	Juan Osorio Lab
Investigator:	Juan Osorio
Submission ID	LAB202500054

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Osorio Lab. Their lab investigates the mechanisms of antibody-mediated immunity and how these insights can be applied to develop durable and effective antibody-based immunotherapies. Using mouse models, antibody engineering, and high-dimensional immune profiling, the research aims to uncover the cellular and molecular pathways driving therapeutic antibody activity. This integrated approach supports the rational design and optimization of next-generation antibody therapies with lasting clinical benefit. The Reviewer's questions were addressed and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-D-3, III-D-3-b, III-F-8, Appendix C-I, III-F-8, Appendix C-II
f. **Containment level:** BSL-2

g. **Votes:**
For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Initial Protocol
13. **Review of LAB202500044**

Title:	Karlo Perica Lab
Investigator:	Karlo Perica
Submission ID	LAB202500044

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Perica Lab. They work on innovative cell-based cancer therapies, particularly CAR T cell approaches. Their research aims to make these treatments more accessible and effective through off-the-shelf allogeneic cells and advanced gene editing. The lab's efforts range from basic science in animal models, to translational studies with patient samples, and developing new cell therapies. Key areas include creating cells that can avoid immune rejection, improving CAR T cell function, studying patient responses, and advancing direct, in vivo gene editing techniques. The Reviewer's questions were addressed and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-D-3**,** III-D-3a, III-D-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**
For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Initial Protocol
14. **Review of LAB202500012**

Title:	Mariia Akhmanova Lab
Investigator:	Mariia Akhmanova
Submission ID	LAB202500012

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None

d. **Comments:** This is an initial review for the Akhmanova Lab. Their lab explores the mechanisms of cell migration and invasion in confined in vivo environments, focusing on how interactions between migrating cells and surrounding tissues regulate tissue penetration. Using Drosophila, mouse and human organoids, and mathematical modeling, the research aims to understand how immune and metastatic cancer cells distribute through tissues and influence morphogenesis, immune responses, and aging. Their goal is to develop strategies to manipulate cellular infiltration for therapeutic applications.The Reviewer's questions were addressed and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-D-3, III-D-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

15. **Review of LAB202500031**

Title:	Minkui Luo Lab
Investigator:	Minkui Luo
Submission ID	LAB202500031

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Luo lab. Their lab focuses on annotating and manipulating protein methylation events and their downstream effects in epigenetic regulation. Using recombinant DNA technologies, the team expresses and assays protein targets in various biological contexts to better understand their functional roles and therapeutic potential. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

16. **Review of LAB202500069**

Title:	Nai-Kong Cheung Lab
Investigator:	Nai-Kong Cheung
Submission ID	LAB202500069

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Cheung lab. Their lab focuses on developing chimeric and humanized antibodies against tumor-associated antigens. Their research includes T-cell engaging bispecific antibodies, pretargeted radioimmunotherapy using SADA platforms, and innovative antibody technologies. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review

17. **Review of LAB202500071**

Title:	Joan Massague Lab
Investigator:	Joan Massague
Submission ID	LAB202500071

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Massague lab. Their lab investigates how growth factors, signaling pathways, and gene expression programs regulate normal cell proliferation and drive cancer metastasis. Building on foundational work in TGFβ signaling and its dual role in tumor suppression and metastasis promotion, the research takes a broad approach to uncover the biological, molecular, and genetic mechanisms underlying metastatic progression. 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-3-a, III-D-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review

18. **Review of LAB202500048**

Title:	Craig Thompson Lab
Investigator:	Craig Thompson
Submission ID	LAB202500048

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Thompson lab. Their lab investigates how metabolic pathways regulate cellular responses to growth factors and nutrients, comparing normal and cancer cells to identify therapeutic targets. Using mouse and human cell cultures, recombinant DNA techniques, and genetically modified mouse models, the research aims to uncover differences in metabolic regulation that could inform novel cancer treatments. 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, IIID-1-a, III-D-3, III-D-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review

19. **Review of LAB202500063**

Title:	Phillip Niethammer Lab
Investigator:	Philipp Niethammer
Submission ID	LAB202500063

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Niethammer lab which studies how inflammatory signals develop and spread in living zebrafish tissue following injury or infection. Using fluorescent biosensors and advanced microscopy, they visualize real-time immune responses to study how different cell types (endothelial, epithelial, and leukocytes) react to inflammation and shape tissue-level immune activity.
e. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
f. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
g. **Containment level:** BSL-2
h. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

20. **Review of LAB202500067**

Title:	Daniel Bachovchin Lab
Investigator:	Daniel Bachovchin
Submission ID	LAB202500067

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Bachovchin lab. Their lab explores the role of serine proteases in regulating cancer progression and immune system signaling. 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, III-D-1-a,III-D-3, III-D-3-b, III-F-8, Appendix C-I.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

21. **Review of LAB202500058**

Title:	Alexandros Pertsinidis Lab
Investigator:	Alexandros Pertsinidis
Submission ID	LAB202500058

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Pertsinidis lab. Their lab aims to uncover the molecular mechanisms of gene regulation with high precision and relate these findings to medically relevant processes. By developing advanced optical imaging tools, the team visualizes gene activity in real time at the single-cell level. They also use in vitro systems with purified human transcription factors and single-molecule techniques to dissect the transcription initiation process, combining in vivo and in vitro approaches for deeper insight into gene regulation. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

22. **Review of LAB202500066**

Title:	Irene Orlow lab
Investigator:	Irene Orlow
Submission ID	LAB202500066

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Orlow lab. Their lab focuses on understanding how genetic, epigenetic, and phenotypic factors influence cancer prognosis and survivorship, particularly in melanoma and breast cancer. The lab supports large-scale epidemiologic studies by processing and analyzing human biospecimens, including blood, tissue, saliva, and urine. Techniques used include

DNA/RNA extraction, PCR-based genotyping, expression analysis, and high-throughput omics testing. No animal, live virus, or radioactive work is conducted. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Commented [AK1]: Why is it BSL2+? Check and have them correct as needed

Commented [TB2R1]: Their lab was working with covid contaminated samples, which is the reason for the high BSL. We have asked the to fix this.

Triennial Review

23. **Review of LAB202500064**

Title:	Danwei Huangfu Lab
Investigator:	Danwei Huangfu
Submission ID	LAB202500064

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Huangfu lab. Their lab uses human pluripotent stem cells (hPSCs) to explore how insulin-producing β cells in the pancreas develop and function, with the goal of better understanding and treating diabetes. The lab applies genome editing tools like CRISPR and TALENs, gene transduction, directed differentiation, chemical screening, and mouse models to uncover key developmental regulators and improve 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-D-3, III-D-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

24. **Review of LAB202500073**

Title:	Justin Perry Lab
Investigator:	Justin Perry
Submission ID	LAB202500073

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Perry lab. Dead cells are cleared by macrophages through efferocytosis, which helps prevent autoimmunity and inflammation. Disease may result from issues with how macrophages digest dead cells, not just from engulfment. This team aims to study rapid response circuits (RRCs) in macrophages to understand their role in disease and identify new diagnostic and therapeutic targets. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Review

25. **Review of LAB202500043**

Title:	Alex Kentsis Lab
Investigator:	Alex Kentsis
Submission ID	LAB202500043

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Kentsis lab. Their lab investigates the molecular mechanisms driving refractory childhood cancers, including leukemias and solid tumors. Using retroviral and lentiviral vectors to perform experiments, the lab aims to uncover how genetic changes promote cancer cell growth and survival, with the goal of informing more effective 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2
g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Treinnial Review
26. **Review of LAB202500059**

Title:	Adam Schmitt Lab
Investigator:	Adam Schmitt
Submission ID	LAB202500059

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Schmitt lab. Their study explores how noncoding genomic elements influence the cellular response to DNA damage and cancer development. Using viral vectors and recombinant DNA, the lab modifies human and animal cells to study gene function and employs transgenic mouse models and human tumor samples to identify key noncoding elements involved in cancer progression. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.
f. **Containment level:** BSL-2+
g. **Votes:**
For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Commented [AK3]: Why is it BSL2+? Please check and ask them to correct as needed.

Commented [TB4R3]: Their lab was working with covid contaminated samples, which is the reason for the high BSL. We have asked the to fix this.

Triennial Review
27. **Review of LAB202500036**

Title:	Etay Ziv Lab
Investigator:	Etay Ziv
Submission ID	LAB202500036

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Ziv lab. Their lab focuses on understanding the molecular and biological changes that occur in tumors following

interventional radiology treatments such as ablation and embolization. Using *in vitro* experiments and patient tissue samples, the lab also investigates how different drugs interact with these procedures to identify therapies that could be translated into clinical use. 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, and III-F-8, Appendix C-II.

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

g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Protocol

28. **Review of LAB202500068**

Title:	Daniel Heller Lab
Investigator:	Daniel Heller
Submission ID	LAB202500068

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Heller lab. Their lab focuses on developing nanomaterials to detect and treat cancer by targeting specific biomarkers. The lab creates polymer-based and fluorescent carbon nanomaterials, tests them in cell cultures, and evaluates their effectiveness in mouse models for both therapy and diagnosis. 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-3-b, III-F-8, Appendix C-I, and III-F-8, Appendix C-II.

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

g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Treinnial Review

29. **Review of LAB202500065**

Title:	Babak Mehrara Lab
Investigator:	Babak Mehrara
Submission ID	LAB202500065

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Mehrara lab. Their study focuses on understanding the biological processes that lead to lymphedema and developing potential drug and surgical treatments. By studying lymphatic biology, the lab aims to improve care for patients affected by this chronic condition. 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
f. **Containment level:** BSL-2
g. **Votes:**
For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review
30. **Review of LAB202500055**

Title:	Govindaswami Ragupathi Lab
Investigator:	Govind Ragupathi
Submission ID	LAB202500055

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Ragupathi lab. Their lab focuses on developing monoclonal antibodies, optimizing vaccines that induce antibody responses, and producing and testing new immunological adjuvants to augment these responses. 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
f. **Containment level:** BSL-2
g. **Votes:**
For: 11
Against: 0
Recused: 1
Absent: 5
Abstained: 0

Commented [AK5]: This is wrong- The description sounds like it is from Babak Mehrara's lab
Commented [TB6R5]: Resolved

Triennial Review

31. **Review of LAB202500060**

Title:	Christine Iacobuzio Lab
Investigator:	Christine Iacobuzio-Donahue
Submission ID	LAB202500060

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Iacobuzio-Donahue lab. Their lab investigates how genetic changes within pancreatic tumors drive metastasis, the spread of cancer to other organs, which causes most cancer deaths. Using sequencing, bioinformatics, and tissue models, the researchers aim to identify key genes and pathways involved in this process. The goal is to improve treatment strategies by targeting the metastatic traits of cancer cells rather than individual genes. 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-3-b, III-F-8, Appendix C-I & C-II

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review

32. **Review of LAB202500072**

Title:	Milind Rajadhyaksha Lab
Investigator:	Milind Rajadhyaksha
Submission ID	LAB202500072

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Rajadhyaksha lab. Their lab focuses on designing and building confocal microscopes for imaging skin cancer. The work involves engineering hardware and software, and testing is done on human skin tissue using chemical contrast agents like acridine orange and acetic acid. 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

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennnial Review

33. **Review of LAB202500047**

Title:	Genomics Core Lab (Neeman Mohibullah)
Investigator:	Neeman Mohibullah
Submission ID	LAB202500047

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Genomics Core Lab (Neeman Mohibullah) lab. This core prepares material for next-generation sequencing, starting with nucleic acid extraction and pathology, followed by DNA library preparation and sequencing. 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

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

g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Review

34. **Review of LAB202500056**

Title:	Xuejun Jiang Lab
Investigator:	Xuejun Jiang
Submission ID	LAB202500056

a. **Determination:** Approved

b. **Last day of continuing review period:** 8/31/2026

c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Jiang lab. Their study explores the molecular mechanisms of programmed cell death, a key process in maintaining tissue health and preventing disease. The goal is to translate these findings into new 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-b; III-D-3; 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:	5
Abstained:	0

Continuing Review
35. **Review of SAF03818**

Title:	Continuing Review for LAB202400009
Investigator:	Xinbo Yang
Submission ID	SAF03818

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Yang Lab. Their lab uses structure-based protein engineering to understand how the immune system distinguishes between self and foreign antigens. This knowledge is applied to develop precise and effective new therapies. 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-II; III-F-8 Appendix C-I; III-F-8 Appendix C-III.
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Continuing Review
36. **Review of SAF03817**

Title:	Continuing Review for LAB202300048
Investigator:	Neal Rosen
Submission ID	SAF03817

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Rosen Lab. Their study uses selective inhibitors to investigate how cancer cells respond to oncoprotein activation and its inhibition. By analyzing feedback and adaptation in signaling pathways, they aim to better understand oncogenic networks and develop more effective cancer therapies. 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-D-3, III-D-3-b; III-D-3, III-D-3-a; 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: 5
Abstained: 0

Continuing Review

37. **Review of SAF03812**

Title:	Continuing Review for LAB202400007
Investigator:	Joo-Hyeon Lee
Submission ID	SAF03812

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Lee Lab. Their lab investigates how cell behaviors regulate organ development, tissue repair, and disease in the respiratory system. Using genetically modified mice, cell cultures, and human lung organoids, they explore how genetic programs and cell communication influence regeneration and disease, including cancer. 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-D-3, III-D-3-b; III-D-3, III-D-3-a ; 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: 5
Abstained: 0

Continuing review with amendment
38. **Review of SAF03803**

Title:	Amendment/CR for LAB202200056
Investigator:	Scott Keeney
Submission ID	SAF03803

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 Scott Keeney Lab. Their lab investigates the mechanism of homologous recombination during meiosis using genetics, molecular biology, biochemistry, cytology, and genomics. The research focuses on yeast (*Saccharomyces cerevisiae*) and mouse models to understand how genetic material is exchanged and maintained during cell division. 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-D-3, III-D-3-b;; III-F-8 Appendix C-II; III-F-8, Appendix C-III, III-F-8 Appendix C-I
f. **Containment level:** BSL-2
g. **Votes:**
For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Continuing review with amendment
39. **Review of SAF03811**

Title:	Amendment/CR for LAB202200064
Investigator:	Richard Wong
Submission ID	SAF03811

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 Richard Wong Lab. Their lab investigates how cancer interacts with the nervous system, focusing on the cellular mechanisms and tumor microenvironment factors that enable nerve invasion.

They use molecular biology tools and animal models to explore these processes. No accidents, exposures or loss of containment have occurred. The purpose of the amendment is to update personnel and for adding *Resiniferatoxin.* The Reviewer requested that the BSC where *Resiniferatoxin* is used has a sign that alerts users about the risks associated with exposure and recommended approval. The Committee voted to approve the amendment and annual review.

e. **Applicable section of NIH Guidelines:** III-D-3, III-D-3-b; III-D-3, III-D-3-a 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:	5
Abstained:	0

Amendment

40. **Review of SAF03815**

Title:	Amendment for LAB202500001
Investigator:	Omar Abdel-Wahab
Submission ID	SAF03815

a. **Determination:** Approved

b. **Last day of continuing review period:** 1/31/2026

c. **Required modifications:** None

d. **Comments:** This amendment is for adding AAV expressing click beetle red luciferase or Murine Interferon beta (Ifnb). 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, III-D-3-b

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

g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment

41. **Review of SAF03816**

Title:	Amendment for LAB202500025
Investigator:	Naama Aviram
Submission ID	SAF03816

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for updating personnel and adding one yeast species (*Saccharomyces cerevisiae*) and one bacterial species (*Staphylococcus epidermidis*) to their registration. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-III
f. **Containment level:** BSL-1
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment

42. **Review of SAF03767**

Title:	Amendment for LAB202500040
Investigator:	Tobias Hohl
Submission ID	SAF03767

a. **Determination:** Approved
b. **Last day of continuing review period:** 5/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for updating personnel and adds several bacterial strains including some that are antibiotic resistant, afungal agent, and human stool samples. Genetically modified microorganisms will also be used. 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-1, III-D-1-a; III-F-8 Appendix C-I
f. **Containment level:** BSL-2
g. **Votes:**

For:	12
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment

43. **Review of SAF03807**

Title:	Amendment for LAB202500042
Investigator:	Kathryn Taylor
Submission ID	SAF03807

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for assigning the location for tetrodotoxin (TTX) reconstitution.. 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: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Amendment

44. **Review of SAF03805**

Title:	Amendment for LAB202200050
Investigator:	David Scheinberg
Submission ID	SAF03805

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for adding the use of oncolytic virus (RP1/RP2, attenuated oncolytic virus). 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, III-D-3a
f. **Containment level:** BSL-2
g. **Votes:**

For: 12
Against: 0
Recused: 0
Absent: 5
Abstained: 0