SAFETY Meeting Minutes
Biosafety Committee
3/31/2026 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:02 PM
Meeting end time: 1:25 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		Present
Paul Zel		Present
Philip Hauck		Present
Hillary Frommer		Absent
Zainab Shahid		Absent
Geoffrey Ku		Absent
Rui Gardner		Present
Marc Kramer		Present
Sham Mailankody		Present
Paul O'Brien		Present
Andrea Ventura		Absent
Christine Iacobuzio-Donahue		Absent
Shuchi Agarwal		Absent

NON-VOTING ATTENDEES/GUESTS

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

QUORUM INFORMATION

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

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

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

DISCUSSION

The Committee approved the Minutes from the January 2026 meeting and discussed adding standard language for future Minutes.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202600009**

Title:	RESTORE: A Phase 1/2 Study of nula-cel in Autologous CD34+ Hematopoietic Stem Cells to Convert HbS to HbA for Treating Severe Sickle Cell Disease
Investigator:	Jaap Jan Boelens
Submission ID	PROTO202600009

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/30/2027

c. **Required modifications:** None

d. **Comments:** This is the initial review for a first-in-human, single-arm, open-label, single-dose, Phase 1/2 study in participants who have severe Sickle cell disease (SCD). Nula-cel is an investigational drug product (DP) intended for the treatment of severe SCD. The primary objectives are to evaluate the safety, efficacy, and pharmacodynamics (PD) of treatment with nula-cel in participants with severe SCD. [redacted] 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: 6
Abstained: 0

Initial Protocol

2. **Review of PROTO202600008**

Title:	A Phase 1/2, Open-label, Multicenter Study of mRNA-2808 in Participants with Relapsed or Refractory Multiple Myeloma
Investigator:	Alexander Lesokhin
Submission ID	PROTO202600008

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review for a First-in-human Phase 1/2, open-label, multicenter, dose-escalation study to determine the safety, PK, PD, and preliminary efficacy of mRNA-2808 in participants with relapse and refractory Multiple Myeloma. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the protocol.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-1
g. **Votes:**
For: 11
Against: 0
Recused: 1
Absent: 6
Abstained: 0

Continuing Review

3. **Review of SAF03975**

Title:	Continuing Review for PROTO202300001
Investigator:	Vinod Balachandran
Submission ID	SAF03975

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** The is the annual review for a Phase II, open-label, multicenter, randomized study evaluating the efficacy and safety of adjuvant autogene cevumeran plus atezolizumab and mFOLFIRINOX versus mFOLFIRINOX in patients with resected PDAC who have not received prior systemic anti-cancer treatment for Pancreatic ductal adenocarcinoma (PDAC) and have no evidence of disease after

surgery. No changes, accidents, or loss of containment were reported. The Committee voted to approve the annual renewal.

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

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

g. **Votes:**

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

Amendment/CR

4. **Review of SAF03965**

Title:	Amendment/CR for PROTO202500006
Investigator:	James Smithy
Submission ID	SAF03965

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment of a prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate the efficacy, tolerability, and safety of treatment with IMA203, an investigational, autologous T-cell receptor (TCR) T-cell therapy targeting the PRAME protein administered at the recommended Phase II dose vs. investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma. The primary efficacy endpoint of the trial is progression-free survival (PFS) centrally assessed by a blinded independent central review (BICR1) using Response Evaluation Criteria in Solid Tumors (RECIST)1.1. Overall survival (OS) will serve as the key secondary endpoint. No changes, accidents or loss of containment were reported. The purpose of the amendment was to update protocol documents. The Committee voted to approve the annual renewal and amendment.

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

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

g. **Votes:**

For:	10
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

5. **Review of SAF03957**

Title:	Amendment/CR for PROTO201600012
Investigator:	Sham Mailankody
Submission ID	SAF03957

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for an open-label, dose escalating, nonrandomized, single-center, phase I study of chimeric antigen receptor T cells (CAR T cells) engineered to target B-cell maturation antigen (BCMA) using a receptor with 4-1BB (CD137) co-stimulatory and CD3 zeta (CD3ζ) signaling domains, and co-express a truncated epidermal growth factor receptor (EGFRt) (EGFRt/BCMA-41BBz CAR T) cells in patients with advanced multiple myeloma (MM). The primary objective is to assess the safety of intravenously administered EGFRt/BCMA-41BBz CAR T cells in patients with MM, with and without concomitant Lenalidomide. The general approach is to conduct an open-label, dose escalating, nonrandomized, single-center, phase I study of EGFRt/BCMA-41BBz CAR T cells in patients with advanced MM. No changes, accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Committee voted to approve the annual renewal and amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For:	10
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

6. **Review of SAF03962**

Title:	Amendment/CR for PROTO202300012
Investigator:	Alan Ho
Submission ID	SAF03962

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is annual renewal and amendment for an open-label, phase I, dose-escalation study evaluating the safety of Tumor Necrosis Factor Alpha and Interleukin-2 Coding Oncolytic Adenovirus (TILT-123) when given in combination with anti-Programmed Death Ligand-1 (anti-PD-L1). The primary objective of this study is to evaluate the safety of TILT-123 when given as intratumoral and

intravenous injections in combination with avelumab to patients with solid tumors (melanoma and Squamous Cell Carcinoma of head and neck) refractory to or progressing after anti-PD(L)1 immunotherapy. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. [redacted] The Committee voted to approve the annual renewal and 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

7. **Review of SAF03984**

Title:	Amendment for PROTO202500018
Investigator:	Michael Scordo
Submission ID	SAF03984

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is an amendment to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.

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

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

g. **Votes:**

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

Amendment

8. **Review of SAF03982**

Title:	Amendment for PROTO202400008
Investigator:	Ritesh Kotecha
Submission ID	SAF03982

a. **Determination:** Approved
b. **Last day of continuing review period:** 5/31/2026
c. **Required modifications:** None
d. **Comments:** This is an amendment to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

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

Amendment

9. **Review of SAF03986**

Title:	Amendment for PROTO202500020
Investigator:	Maximilian Merz
Submission ID	SAF03986

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is an amendment to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

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

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

10. **Review of LAB202600012**

Title:	Mengtong Li Lab
Investigator:	Mengtong LI
Submission ID	LAB202600012

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Li lab. Their research aims to define how the nervous system regulates immune function through specific brain–body circuits. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the initial review.
e. **Applicable section of NIH Guidelines:** III-D-3, III-F-8, Appendix C-I
f. **Containment level:** BSL-2
g. **Votes:**

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

Initial Protocol

11. **Review of LAB202600014**

Title:	Ivan Maillard Lab
Investigator:	Ivan Maillard
Submission ID	LAB202600014

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review for the Maillard lab. Their lab studies how Notch signaling influences T and B cell immunity. The Reviewer requested the addition of information about plasmids. This information was added and the Reviewer did not have any concerns and recommended approval. The Committee voted to approve the initial review.
e. **Applicable section of NIH Guidelines:** N/A
f. **Containment level:** BSL-1
g. **Votes:**

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

Triennial Protocol

12. **Review of LAB202600015**

Title:	Ronan Chaligne Lab
Investigator:	Ronan Chaligne
Submission ID	LAB202600015

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Chaligne lab. Their work focuses on single-cell genomics and technology development across a variety of biological contexts, working with fresh and frozen clinical biospecimens. 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: 6
Abstained: 0

Triennial Protocol

13. **Review of LAB202600007**

Title:	Anna-Katerina Hadjantonakis Lab
Investigator:	Anna-Katerina Hadjantonakis
Submission ID	LAB202600007

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Hadjantonakis lab. The long-term goal of their work was to understand the events underlying cell lineage development, tissue patterning and morphogenesis in the early mammalian embryo. 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
14. **Review of LAB202600017**

Title:	Viviane Tabar Research
Investigator:	Viviane Tabar
Submission ID	LAB202600017

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Tabar lab. Their laboratory studies human stem cells both for their application in treating nervous system disorders as well as for their use as a platform to model brain tumors. They also study cell populations, including putative cancer stem cells and immune cells, in primary human brain tumors. The Reviewer requested clarifications to the decontamination methods. This issue was addressed, and 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
15. **Review of LAB202600004**

Title:	Anthony Daniyan Lab
Investigator:	Anthony Daniyan
Submission ID	LAB202600004

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Daniyan lab. The laboratory is focused on developing novel treatment approaches for certain leukemias and lymphomas utilizing the patient's own immune system. Specifically, this work involves the genetic manipulation of patients' immune cells to recognize and kill their own cancer cells. The Reviewer requested more information about the laboratory

structure specifically if this group was embedded within a larger group. This issue was clarified, and the Reviewer had no further concerns and recommended approval. The Committee voted to approve the triennial review.

e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-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 LAB202600016**

Title:	Thomas Norman Lab
Investigator:	Thomas Norman
Submission ID	LAB202600016

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Norman lab. The lab uses high-throughput CRISPR-mediated genetic approaches to investigate cancer and fibrosis in *in vitro* 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-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

Continuing Review

17. **Review of SAF03987**

Title:	Continuing Review for LAB202400002
Investigator:	Adrienne Boire
Submission ID	SAF03987

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review for the Boire lab. Their lab aims to uncover molecular players crucial for leptomeningeal metastasis and suggest rational targets for therapeutic intervention, paving the way for novel approaches to the treatment of leptomeningeal metastasis. No changes, accidents, 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-3-b
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing Review

18. **Review of SAF03976**

Title:	Continuing Review for LAB202500024
Investigator:	Ting Zhou
Submission ID	SAF03976

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review for the Stem Cell Core Facility. The SKI Stem Cell Research Facility uses human pluripotent stem cells, both embryonic stem cells (ES) and induced pluripotent stem cells (iPS cells) that they make with viral vectors. They use genetic technologies to engineer cells and occasionally use lentiviral vectors to make transgenics from these pluripotent stem cells. No changes, accidents, 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-3-b, III-D-1-a
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing Review

19. **Review of SAF03971**

Title:	Continuing Review for LAB202500019
Investigator:	David Jones
Submission ID	SAF03971

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review for the Jones lab. Their research interests are studying the mechanisms through which non-small cell lung cancer (NSCLC) develops drug-resistance and understanding the molecular mechanisms through which NSCLC metastasizes. No changes, accidents, 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-3-a, III-D-3-b

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

g. **Votes:**

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

Amendment/CR

20. **Review of SAF03990**

Title:	Amendment/CR for LAB202500023
Investigator:	Katharine Hsu
Submission ID	SAF03990

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review and amendment for Hsu lab. The laboratory works on the mechanisms of Natural Killer (NK) cells response in cancer and infectious disease. The laboratory uses *in vitro* and *in vivo* approaches in human and mouse models. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. 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-3-a, III-D-3-b, III-D-1-a

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

g. **Votes:**

For: 12

Against: 0
Recused: 0
Absent: 6
Abstained: 0

Amendment/CR

21. **Review of SAMENDCR202600000003**

Title:	Amendment/CR for LAB202500015
Investigator:	Yasuhide Furuta
Submission ID	SAMENDCR202600000003

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for the Mouse Genetics Core Facility. The major services this Core Facility provides are to generate genetically modified mice, such as transgenic and gene targeted mice, for investigators at MSK. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. The Committee voted to approve the annual review.
e. **Applicable section of NIH Guidelines:** 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

Amendment/CR

22. **Review of SAF03983**

Title:	Amendment/CR for LAB202300076
Investigator:	Yu Chen
Submission ID	SAF03983

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for the Chen lab. The major goal of my laboratory is to understand how critical transcription factors mediate prostate cancer oncogenesis. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. 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-3-b, III-D-1-a

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

g. **Votes:**

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

Amendment/CR

23. **Review of SAMENDCR202600000005**

Title:	Amendment/CR for LAB202500025
Investigator:	Naama Aviram
Submission ID	SAMENDCR202600000005

a. **Determination:** Approved

b. **Last day of continuing review period:** 3/31/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review and amendment for the Aviram lab. The Aviram Lab is interested in understanding how bacterial cells protect themselves from invaders, focusing particularly on the CRISPR-Cas adaptive immune system. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. 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-III, III-E

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

g. **Votes:**

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

Amendment

24. **Review of SAF03952**

Title:	Amendment for LAB202500073
Investigator:	Justin Perry
Submission ID	SAF03952

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is an amendment to update bacterial strains and to update viral vector descriptions. The Reviewer requested clarifications to the usage and location. These issues were addressed, and the Reviewer did not have any further concerns and recommended approval. The Committee voted to approve the amendment.

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