SAFETY Meeting Minutes
Biosafety Committee
4/28/2026 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		Absent
Hillary Frommer		Present
Zainab Shahid		Present
Geoffrey Ku		Absent
Rui Gardner		Absent
Marc Kramer		Present
Sham Mailankody		Present
Paul O'Brien		Absent
Andrea Ventura		Absent
Christine Iacobuzio-Donahue		Present
Shuchi Agarwal		Present

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Rivka Schwarcz
Gary Martin
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.

GUEST NAMES
Gabriella Lugo
Mariam Mustafa

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202600011**

Title:	MED26-061: A Phase 1 Study to Evaluate the Safety of KLN-1010, a Novel, In Vivo Gene Therapy to Generate Anti-BCMA CAR-T Cells in Patients with Relapsed and Refractory Multiple Myeloma
Investigator:	Sham Mailankody
Submission ID	PROTO202600011

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027

c. **Required modifications:** None

d. **Comments:** This is the initial review for a multi-center, first-in-human dose escalation and dose expansion study designed to evaluate the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of the *in vivo* CAR-T therapy KLN-1010, in patients with relapsed and refractory multiple myeloma. The primary objectives are to determine the safety, tolerability, maximum tolerated dose (MTD), and/or recommended Phase 2 dose (RP2D) of KLN-1010. The secondary objectives are to characterize the pharmacokinetics (PK) and pharmacodynamics of KLN-1010 and to determine the preliminary antitumor activity of KLN-1010. The Committee noted that administration of this product requires procedures that differ from the institution's standard use of closed-system transfer devices. The Committee reviewed and discussed the controls outlined in the SOP developed by the BSO for this product, including the measures intended to support appropriate handling and administration under the proposed process.

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

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

g. **Votes:**

For:	12
Against:	0
Recused:	1
Absent:	5
Abstained:	0

Initial Protocol

2. **Review of PROTO202600012**

Title:	MED26-049: A Phase 1b 2a, Randomized, Double-blind Study to Investigate Safety, Tolerability, PK, PD, and Efficacy of SNIPR001 in Patients with Heme Malignancy Scheduled for Allo-SCT Receiving FQ-P and Harboring FQ-R E.coli Pre-Transplant
Investigator:	Ying Taur
Submission ID	PROTO202600012

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027

c. **Required modifications:** None

d. **Comments**: This is the initial review for a phase 1b/2a, randomized, double-blind, placebo-controlled study to assess the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary efficacy of oral SNIPR001 (genetically modified bacteriophages targeting *E. coli*) in patients with hematologic malignancy scheduled for allo-Hematopoietic Stem-Cell Transplantation (HSCT) receiving standard of care (SoC) Fluroquinolone (FQ) prophylaxis and harboring FQ resistant E. coli in the gut pre-transplant. The primary objective of the study is to assess the safety and tolerability of SNIPR001 in all patients who receive SNIPR001 or placebo in combination with standard of care (SoC) levofloxacin prophylaxis. The Reviewer did not have any concerns and recommended approval. The Committee discussed the novelty of the approach and the method of targeting of the product. There were no concerns and the Committee voted to approve the trial.

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

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

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Initial Protocol

3. **Review of PROTO202600010**

Title:	MED26-052: Randomized Open Label Study of the Bria IMT Regimen and Check Point Inhibitor vs Physicians Choice in Advanced Metastatic Breast Cancer (BRIA - ABC)
Investigator:	Shanu Modi
Submission ID	PROTO202600010

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is a phase 3, randomized, open label study designed to compare the Bria-IMT regimen in combination with check point inhibitor vs physician's choice in metastatic breast cancer. The Bria-IMT regimen includes: cyclophosphamide infusion and intradermal inoculation of SV-BR-1-GM (an experimental tumor cell line stably transfected to secrete GM-CSF *in vivo*). The Primary Objective is to evaluate the effect of the Bria-IMT regimen in combination with Check Point Inhibitor (CPI) on overall survival (OS). The Committee discussed considerations related to product preparation and administration. The study team was advised that any operational requirements should be appropriately addressed and resolved prior to product administration and voted to approve the trial.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

4. **Review of SAF04016**

Title:	Amendment/CR for PROTO202000001
Investigator:	Jae Park
Submission ID	SAF04016

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for a phase I study to assess the safety and tolerability of intravenously administered 19(T2)28z1XX chimeric antigen receptor (CAR) T cells in patients with relapsed or refractory large cell lymphoma. Secondary objectives include assessing the anti-tumor efficacy and *in vivo* persistence of the CAR T cells. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol

documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review and amendment.

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

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

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

5. **Review of SAF03994**

Title:	Amendment/CR for PROTO202400004
Investigator:	Gunjan Shah
Submission ID	SAF03994

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a randomized, open-label, global, multicenter, Phase 3 study in adult participants with newly diagnosed multiple myeloma (NDMM) for whom high-dose therapy and autologous stem cell transplant (ASCT) are part of the intended treatment plan. The study compares daratumumab, bortezomib, lenalidomide and dexamethasone (DVRd) followed by Ciltacabtagene Autoleucel (Cilta-cel) versus DVRd followed by autologous stem cell. Cilta-cel is an autologous chimeric antigen receptor T-cell (CAR-T) therapy that targets B-cell maturation antigen (BCMA), a molecule expressed on the surface of mature B-lymphocytes and malignant plasma cells. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review and amendment.

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

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

g. **Votes:**

For:	12
Against:	0
Recused:	1
Absent:	5
Abstained:	0

Amendment/CR

6. **Review of SAF03991**

Title:	Amendment/CR for PROTO202400003
Investigator:	Heather Landau
Submission ID	SAF03991

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for an open-label Phase 1b dose expansion study exploring the efficacy and safety of Chimeric Antigen Receptor (CAR) T therapy NXC-201 in a population of relapsed or refractory amyloidosis (AL). The primary objectives are to confirm safety, maximum tolerated dose (MTD), and recommended phase 2 dose (RP2D). No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual review and amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:**
g. **Votes:**

For:	12
Against:	0
Recused:	1
Absent:	5
Abstained:	0

Amendment/CR

7. **Review of SAF04000**

Title:	Amendment/CR for PROTO202500004
Investigator:	Steven Horwitz
Submission ID	SAF04000

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for a single arm, two-stage, phase 2, open-label, multicenter study of MB-105, a chimeric antigen receptor (CAR) T-cell therapy that express a cluster of differentiation 5 postive (CD5+) CAR in patients with CD5+ relapsed/refractory T-cell lymphoma (r/r TCL). The primary objectives are to confirm safety and tolerability of the recommended dose. The secondary objectives are to further characterize anti-tumor efficacy of MB-105, assess durability of therapeutic effect, further characterize safety and tolerability of MB-105, and evaluate longer-term impact of MB-105 on patients with r/r TCL. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and protocol documents. The Reviewer did not have any concerns

and recommended approval. The Committee voted to approve the annual review and amendment.

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

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

g. **Votes:**

For:	12
Against:	0
Recused:	1
Absent:	5
Abstained:	0

REVIEW OF LABORATORY SUBMISSIONS

Triennial Protocol

8. **Review of LAB202600019**

Title:	Hedvig Hricak Lab
Investigator:	Hedvig Hricak
Submission ID	LAB202600019

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Hricak lab. The lab is focused on both the development of new molecular probes for cross-sectional, multimodality imaging (MRI, PET and optical) and translational research in molecular imaging. This ranges from basic science to clinical translation, as well as clinical molecular imaging observations to basic science tumor analysis. 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:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Protocol

9. **Review of LAB202600021**

Title:	Kinga Hosszu Lab
Investigator:	Kinga Hosszu
Submission ID	LAB202600021

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Hosszu lab. The lab will conduct experiments to measure drug levels, detect proteins, and identify rare cell types at levels not detectable by conventional clinical instruments. 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: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Triennial Protocol

10. **Review of LAB202600020**

Title:	Immune Discovery & Modeling Service
Investigator:	Jaap Jan Boelens
Submission ID	LAB202600020

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Immune Discovery & Modeling Service (IDMS). This facility provides innovative, state-of-the-art technologies to measure drug levels, detect proteins, and identify rare cell types at levels not detectable by conventional clinical instruments. 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: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Initial Protocol

11. **Review of LAB202600011**

Title:	Paul Romesser
Investigator:	Paul Romesser
Submission ID	LAB202600011

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review for the Romesser lab. The aim of this research is to establish patient-derived tumoroid and organoid cultures from primary rectal tumors and matched normal tissue at multiple time points before, during, and after treatment, in order to study individual tumor characteristics *ex-vivo*, such as chemosensitivity and radiosensitivity. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I
f. **Containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Triennial Protocol

12. **Review of LAB202600022**

Title:	Adriana Haimovitz-Friedman Lab
Investigator:	Adriana Friedman
Submission ID	LAB202600022

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Haimovitz-Friedman lab. This lab studies combination therapies with radiation or chemotherapy to either improve therapy outcome for tumor treatment or protect normal tissues from the side effects of the therapies. The Reviewer requested clarifications to the decontamination practices. These issues were 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
f. **Containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Continuing Review

13. **Review of SAF04013**

Title:	Continuing Review for LAB202500033
Investigator:	Hugo Jhun
Submission ID	SAF04013

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review for the Jhun lab. The Jhun lab focuses on RNA process development/innovation as part of the Olayan Center for Cancer Vaccines. Material generated here will serve as a proving ground to test RNA vaccine technology in preclinical models, and advance methods and designs to the MSKGMP facility for production or RNA-based cancer vaccines for human trials. 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-II
f. **Containment level:** BSL-1
g. **Votes:**
   For: 13
   Against: 0
   Recused: 0
   Absent: 5
   Abstained: 0

Continuing Review

14. **Review of SAF03979**

Title:	Continuing Review for LAB202500028
Investigator:	Martin Weiser
Submission ID	SAF03979

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review for the Weiser lab. This lab studies human gastrointestinal tumors with known abnormalities (over expression and/or gene mutation) in the C-MET proto-oncogene in an animal model that produces human

hepatocyte growth factor (HGF). 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-D-1-a

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

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

15. **Review of SAF04001**

Title:	Amendment/CR for LAB202400005
Investigator:	Jun Hong Choi
Submission ID	SAF04001

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027

c. **Required modifications:** None

d. **Comments:** This is the annual review and amendment for the Choi lab. Their research focuses on developing new genome editing tools to understand cellular development. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel, cell lines, and lentiviral vectors. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve amendment and annual review.

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

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

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

16. **Review of SAF03995**

Title:	Amendment/CR for LAB202500030
Investigator:	Alan Hanash
Submission ID	SAF03995

a. **Determination:** Approved

b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for the Hanash lab. This lab aims to test the mechanisms of action of interleukin 22 (IL-22) on epithelium and the mechanisms of intestinal stem cells (ISC) damage and regeneration post-transplant. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. The Committee voted to approve the amendment and annual review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-1-a, III-D-3-a
f. **Containment level:** BSL-2+
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment/CR

17. **Review of SAF04012**

Title:	Amendment/CR for LAB202500029
Investigator:	David Solit
Submission ID	SAF04012

a. **Determination:** Approved
b. **Last day of continuing review period:** 4/30/2027
c. **Required modifications:** None
d. **Comments:** This is the annual review and amendment for the Solit lab. Their laboratory's efforts have focused on the functional characterization of human tumors, primarily in bladder and skin cancers, using molecular genetics, genetic sequencing, and biochemical techniques with the goal of identifying alterations that drive cancer development and progression. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. The Committee voted to approve the amendment and annual review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-3-a, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	5
Abstained:	0

Amendment

18. **Review of SAF04006**

Title:	Changes to protocol
Investigator:	Ivan Maillard
Submission ID	SAF04006

a. **Determination:** Approved
b. **Last day of continuing review period:** 3/31/2027
c. **Required modifications:** None
d. **Comments:** This an amendment to add mRNA vaccines. 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-I
f. **Containment level:** BSL-1
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Amendment

19. **Review of SAF04008**

Title:	Amendment for LAB202500027
Investigator:	Ross Levine
Submission ID	SAF04008

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 cell lines. 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-I
f. **Containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0

Amendment

20. **Review of SAF04014**

Title:	Amendment for LAB202500068
Investigator:	Daniel Heller
Submission ID	SAF04014

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is an amendment to add human plasma samples from individuals who are positive for HIV. The Reviewer requested additional details regarding precautions for the sample handling and disposal. The necessary details were provided, 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:** N/A

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

g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 5
Abstained: 0