SAFETY Meeting Minutes
Biosafety Committee
11/25/2025 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:04 PM
Meeting end time: 1:18 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		Absent
Zainab Shahid		Present
Geoffrey Ku		Present
Rui Gardner		Present
Marc Kramer		Absent
Sham Mailankody		Absent
Paul O'Brien		Present
Andrea Ventura		Present
Christine Iacobuzio-Donahue		Present
Shuchi Agarwal		Present

NON-VOTING ATTENDEES/GUESTS

Rivka Schwarcz
Timothy Burnett
Rene Celeste
Yuky Lam
Gary Martin

QUORUM INFORMATION

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

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

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

DISCUSSION

The IBC Committee discussed the recently released memo from Janssen Pharmaceutical. Institutional Biosafety Committee (IBC) review and approval are not required for the use of FDA-authorized Ciltacabtagene autoleucel (cilta-cel) products that are out-of-specification (OOS) for commercial release when administered under the FDA expanded access program (EAP) for patients with multiple myeloma. This position is based on recent NIH guidance, which states that such therapeutic use outside of clinical trials or research is not subject to NIH Guidelines or IBC review. However, institutions may still require IBC oversight based on their own policies, and it is recommended to periodically check for changes in applicable NIH Guidelines. The Committee agreed with the FDA recommendations and will revisit it in another year.

Updated Exposure Report: The Committee discussed the final report for the exposure that occurred on 10/10/25, which was sent to OSP with Committee recommendations. All corrective actions were instituted.

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202500020**

Title:	MED25-185: A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel - CARTITUDE-10
Investigator:	Maximilian Merz
Submission ID	PROTO202500020

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is a Phase 2 study evaluating the impact of changes in the administration of Ciltacabtagene autoleucel (cilta-cel) in different settings with newly diagnosed multiple myeloma (NDMM) who are currently in their first line of therapy, for whom autologous stem cell transplant (ASCT) is not intended as initial therapy.

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. 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:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

2. **Review of SAF03792**

Title:	Amendment/CR for PROTO202000030
Investigator:	Maria Palomba
Submission ID	SAF03792

a. **Determination:** Approved

b. **Last day of continuing review period:** 11/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a nonconforming lisocabtagene maraleucel in subjects with relapsed and/or refractory large B-cell lymphoma (LBCL) per the approved prescribing information. This is an expanded access protocol that will be conducted at sites qualified under the Sponsor's risk evaluation and mitigation strategy (REMS) program and approved for commercial administration of lisocabtagene maraleucel and where the EAP is authorized to be conducted for use of nonconforming lisocabtagene maraleucel. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to provide the list of the out of specification (OOS) products administered and the reason for it, update personnel and administrative documents. All the products were OOS because their T-cell lineage purity was less than the commercial specification. 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:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

3. **Review of SAF03839**

Title:	Amendment/CR for PROTO202400020
Investigator:	Sandra D'Angelo
Submission ID	SAF03839

a. **Determination:** Approved

b. **Last day of continuing review period:** 11/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for an expanded access protocol (EAP) that provides controlled access to nonconforming (NC) afamitresgene autoleucel (afami-cel), a suspension for intravenous infusion that does not meet commercial release specifications. Conducted at authorized treatment centers (ATCs) administering TECELRA, the EAP defines NC or out-of-specification (OOS) products as those failing at least one batch release test against TECELRA's commercial standards. No accidents, exposures or loss of containment were reported. The purpose of the amendment is to update personnel, regional locations, and administrative documents. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment and annual review.

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

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

g. **Votes:**

For: 12
Against: 0
Recused: 2
Absent: 4
Abstained: 0

Amendment/CR

4. **Review of SAF03885**

Title:	Amendment/CR for PROTO201800007
Investigator:	Sham Mailankody
Submission ID	SAF03885

a. **Determination:** Approved

b. **Last day of continuing review period:** 11/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a Phase I, open-label, dose escalating, nonrandomized, single-center trial of g protein-coupled receptor class c group 5-member d (gprc5d) targeted MCARH109 chimeric antigen receptor (CAR) modified t cells for the treatment of multiple myeloma. 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:	13
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment/CR

5. **Review of SAF03869**

Title:	Amendment/CR for PROTO202300025
Investigator:	Chrisann Kyi
Submission ID	SAF03869

a. **Determination:** Approved

b. **Last day of continuing review period:** 11/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for an open-label, randomized phase I/II clinical trial that assesses the safety, optimal dosing, and efficacy of adding IMNN-001(IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) to standard carboplatin/paclitaxel chemotherapy plus bevacizumab (BEV) compared to chemotherapy plus BEV alone, with a structured multi-cycle regimen and a safety lead-in phase monitored by a DSMB. The primary goal is to assess whether adding IMNN-001 to chemotherapy and bevacizumab reduces the rate of minimal residual disease (MRD) at second-look laparotomy compared to standard treatment. 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-1

g. **Votes:**

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

Amendment/CR

6. **Review of SAF03881**

Title:	Amendment/CR for PROTO202300028
Investigator:	Sham Mailankody
Submission ID	SAF03881

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase 1 multicenter, open-label study to evaluate the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of Arlocabtagene Autoleucel (BMS-986393) in combination with alnuctamab, mezigdomide, or iberdomide in participants with relapsed or refractory multiple myeloma (RRMM). 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: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment/CR

7. **Review of SAF03886**

Title:	Amendment/CR for PROTO202100014
Investigator:	Sham Mailankody
Submission ID	SAF03886

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I open-label, dose-escalating, nonrandomized, single-center trial investigating the concurrent administration of GPRC5D-targeted CAR T Cell MCARH109 and BCMA-targeted CAR T Cell MCARH125 in patients with relapsed or refractory multiple myeloma. 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: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment

8. **Review of SAF03883**

Title:	Amendment for PROTO202400011
Investigator:	Roisin O'Cearbhaill
Submission ID	SAF03883

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment updates administrative documents and personnel. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For: 12
Against: 0
Recused: 2
Absent: 4
Abstained: 0

Amendment

9. **Review of SAF03897**

Title:	Amendment for PROTO202200013
Investigator:	Jae Park
Submission ID	SAF03897

a. **Determination:** Approved
b. **Last day of continuing review period:** 10/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment updates 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: 13

Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment
10. **Review of SAF03896**

Title:	Amendment for PROTO202500012
Investigator:	Jae Park
Submission ID	SAF03896

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This amendment updates administrative documents and personnel. 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: 13
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment
11. **Review of SAF03884**

Title:	Amendment for PROTO202400022
Investigator:	Adam Schoenfeld
Submission ID	SAF03884

a. **Determination:** Approved
b. **Last day of continuing review period:** 1/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment updates administrative documents and personnel. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For: 12
Against: 0

Recused: 2
Absent: 4
Abstained: 0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

12. **Review of LAB202500106**

Title:	Christina Gladkova Lab
Investigator:	Christina Gladkova
Submission ID	LAB202500106

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Gladkova Lab which investigates the molecular principles that determine organelle architecture (shape, distribution, and movement) to elucidate how this supports cellular function. The Reviewer had no concerns and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-D-3-b, III-F-8 Appendix C-II, III-E
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol

13. **Review of LAB202500102**

Title:	Dimitar Nikolov Lab
Investigator:	Dimitar Nikolov
Submission ID	LAB202500102

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Nikolov lab which aims to characterize the molecular mechanisms underlying cell-to-cell interactions and signal transduction across the cell membrane. 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-E
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
14. **Review of LAB202500100**

Title:	Maria Jasin Lab
Investigator:	Maria Jasin
Submission ID	LAB202500100

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Jasin lab which focuses on the repair of one lesion in DNA, the double-strand break (DSB). The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8 Appendix C-II, III-D-3-b, III-D-1-a
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
15. **Review of LAB202500105**

Title:	Michael Glickman Lab
Investigator:	Michael Glickman
Submission ID	LAB202500105

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None

d. **Comments:** This is the triennial review for the Glickman lab which focuses on the pathogenesis of mycobacterial infection to discover new therapies or vaccination strategies. The Reviewer had questions about sample inactivation, decontamination, and transportation, which were addressed. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8 Appendix C-II, III-D-3-b, III-D-1-a
f. **Containment level:** BSL-2+
g. **Votes:**

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

Triennial Protocol
16. **Review of LAB202500098**

Title:	Gynecology GMT Research Lab (Britta Weigelt)
Investigator:	Britta Weigelt
Submission ID	LAB202500098

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Weigelt laboratory which employs advanced genomics techniques to investigate the causes and complexities of rare gynecologic cancers, focusing on the clinical and biological significance of tumor heterogeneity. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Protocol
17. **Review of LAB202500101**

Title:	Eric Lai Lab
Investigator:	Eric Lai
Submission ID	LAB202500101

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Lai lab which focuses on diverse topics in gene regulation, including at transcriptional and post-transcriptional levels. The Reviewer had questions regarding the usage of human tissues, which were addressed. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8 Appendix C-II, III-F-8 Appendix C-III, III-D-1-a, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

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

Commented [HL1]: Word missing?

Triennial Protocol

18. **Review of LAB202500103**

Title:	Kenneth Marians Lab
Investigator:	Kenneth Marians
Submission ID	LAB202500103

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Marians lab which is interested in how human replisome progression is regulated and what happens when the replisome is stalled. 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-III, III-E
f. **Containment level:** BSL-2
g. **Votes:**

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

Triennial Protocol
19. **Review of LAB202500099**

Title:	Joseph Sun Lab
Investigator:	Joseph Sun
Submission ID	LAB202500099

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Sun lab which focuses on the cellular and molecular mechanisms that govern innate lymphocyte development and function. 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-II, III-D-1-a, III-D-3-a,
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Triennial Protocol
20. **Review of LAB202500104**

Title:	John Humm lab
Investigator:	John Humm
Submission ID	LAB202500104

a. **Determination:** Approved
b. **Last day of continuing review period:** 11/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Humm lab which focuses on combining DNA repair inhibitors with targeted radiopharmaceutical therapies to enhance treatment effectiveness in metastatic prostate cancer. The Reviewer had questions about funding source and tissue biosafety notation, which were addressed. 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: 14
Against: 0
Recused: 0

Absent: 4
Abstained: 0

Amendment
21. **Review of SAF03898**

Title:	Amendment for LAB202500048
Investigator:	Craig Thompson
Submission ID	SAF03898

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for updating the CRISPR/cas9 gene manipulation system. 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-b
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment
22. **Review of SAF03843**

Title:	Amendment for LAB202400004: Title: Lentiviral shRNA Knockout Study in Mouse Lip Tissue
Investigator:	Luc Morris
Submission ID	SAF03843

a. **Determination:** Approved
b. **Last day of continuing review period:** 5/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for adding Replication-deficient lentiviral vectors. 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-b
f. **Containment level:** BSL-2
g. **Votes:**
For: 14
Against: 0
Recused: 0

Absent: 4
Abstained: 0