SAFETY Meeting Minutes
Biosafety Committee
2/24/2026 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:02 PM
Meeting end time: 1:33 PM

VOTING MEMBER ATTENDANCE

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

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Rivka Schwarcz
Timothy Burnett

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
Gary Martin
Abarar Mamoojee
Vasili Koutouratsas

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202600002**

Title:	Trial of BNT113 in Combination with Pembrolizumab versus Pembrolizumab Monotherapy as a First Line Therapy in Patients with Unresectable Recurrent, or Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)
Investigator:	Winston Wong
Submission ID	PROTO202600002

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review for a two-part trial: Part A is an initial non-randomized Safety Run-In Phase to confirm the safety and tolerability at the selected dose range level of a ribonucleic acid-lipoplex (RNA-LPX) vaccine BNT113 in combination with pembrolizumab. Part B, the Randomized Phase of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy to generate pivotal efficacy and safety data in the first line setting in patients with unresectable recurrent or metastatic Human Papilloma Virus 16 positive (HPV16+) HNSCC expressing programmed cell death ligand-1 (PD-L1) with combined positive score (CPS) ≥1. Randomization will be stratified by PD-L1 CPS <20 vs PD-L1 CPS ≥20 and prior chemotherapy (yes vs no). Patients included in the Safety Run-In Phase of the trial (Part A) will not be randomized to Part B and will continue on-trial treatment (BNT113 in combination with pembrolizumab) within Part A. 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:	0
Absent:	7
Abstained:	0

Initial Protocol

2. **Review of PROTO202600007**

Title:	MED26-024: A Phase 1/2, First-in-human Study of VNX-202 Gene Therapy in Patients with HER2-Positive Cancer (SENTRY-HER2)
Investigator:	Nick Mai
Submission ID	PROTO202600007

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments:** This is the initial review for a first-in-human (FIH) phase 1/2 study to test the safety, PK, pharmacodynamics (PD), and anti-cancer efficacy of VNX-202 in human subjects with HER2-positive solid tumors. VNX-202 is an investigational adeno-associated virus (AAV) gene therapy product. Part 1 is a dose-escalation study evaluating the safety, PK, immunogenicity, pharmacodynamics, and preliminary anti-tumor activity of VNX-202 across a range of dose levels. Part 2 will enroll cohorts of subjects with specific solid tumors to receive VNX-202 at the recommended Phase 2 dose (RP2D) identified in Part 1. The Reviewer did not have any concerns and recommended approval. The Committee discussed the production of the product and viral and antibody titers but did not have any concerns and 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:	0
Absent:	7
Abstained:	0

Initial Protocol

3. **Review of PROTO202600003**

Title:	MED26-006 A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, a CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy in Participants with Aggressive B-Cell Non-Hodgkin Lymphoma
Investigator:	Gilles Salles
Submission ID	PROTO202600003

a. **Determination:** Deferred
b. **Last day of continuing review period:**
c. **Required modifications:** None
d. **Comments:** This is the initial review for a phase 1/2, multicenter, open-label study evaluating the safety and efficacy of LYL314, a dual-targeting chimeric antigen receptor (CAR) targeting cluster of differentiation (CD)19 and CD20 in participants with aggressive B-cell NHL (defined as Diffuse Large B-Cell Lymphoma (DLBCL), DLBCL arising from follicular lymphoma [tFL], follicular lymphoma Grade 3B/large cell FL (FL 3B), Primary Mediastinal B-cell Lymphoma (PMBCL), and High-grade B-cell lymphoma (HGBL)). The Committee deferred the protocol discussion to the next meeting.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For:
Against:
Recused:
Absent:
Abstained:

Initial Protocol

4. **Review of PROTO202600001**

Title:	MED26-005: Phase 1/2 Study of mRNA-4359 Administered Alone and in Combination With Immune Checkpoint Blockade in Participants with Advanced Solid Tumors
Investigator:	James Smithy
Submission ID	PROTO202600001

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the initial review of an open-label, multicenter, first-in-human phase 1/2 study of mRNA-4359 as monotherapy and in combination with immune checkpoint blockade in adults in 3 arms. The primary objective of is to assess the safety and tolerability of mRNA-4359 either alone or in combination with systemic immune checkpoint blockade. 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-2
g. **Votes:**
For: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Initial Protocol

5. **Review of PROTO202600006**

Title:	MED25-231: FORTRAS: Phase I, Investigator Initiated, Dose-escalation Clinical Trial Evaluating a CD8 Alpha/Beta Armored RAS G12D/HLA-A*11:01-specific T-cell Receptor Therapy (MSK-TCR5) in Patients with Advanced Solid Tumors
Investigator:	Adam Schoenfeld
Submission ID	PROTO202600006

a. **Determination:** Deferred
b. **Last day of continuing review period:**
c. **Required modifications:** None
d. **Comments:** This is the initial review for a phase I dose escalation trial to evaluate the safety and identify the optimal biologic dose (OBD) of the MSK T-Cell receptor 5 (MSK-TCR5) for patients with solid tumors. The Committee deferred the discussion of the trial to the next meeting.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For:
Against:
Recused:
Absent:
Abstained:

Initial Protocol

6. **Review of PROTO202500023**

Title:	MED25-248: A Phase I Trial for R/R MetAstatic DLL3+ Cancers utilizing Armored CAR T cells (ARMADA)
Investigator:	Adam Schoenfeld
Submission ID	PROTO202500023

a. **Determination:** Deferred

b. **Last day of continuing review period:**
c. **Required modifications:** None
d. **Comments:** This is the initial review for phase I dose-escalation study with a primary objective to evaluate the toxicity of Delta-like protein 3 (DLL3) targeting armored Chimeric Antigen Receptor (CAR) T cells in patients with DLL3+ relapsed/refractory small cell lung cancer (R/R SCLC) and other DLL3+ neuroendocrine tumors. The Committee deferred discussion of the trial until the next meeting.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For:
Against:
Recused:
Absent:
Abstained:

Continuing Review

7. **Review of SAF03953**

Title:	Continuing Review for PROTO202500003
Investigator:	Jamie Chaft
Submission ID	SAF03953

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal for a phase 3 trial to evaluate the addition of an investigational personalized mRNA cancer vaccine, V940 to adjuvant pembrolizumab in participants with resectable Stages II-IIIB(N2) Non-small cell lung cancer (NSCLC) who did not achieve a pathological complete response after neoadjuvant pembrolizumab with platinum-doublet chemotherapy followed by surgery. No changes, accidents, or loss of containment were reported. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual renewal.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-1
g. **Votes:**
For: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Continuing Review

8. **Review of SAF03960**

Title:	Continuing Review for PROTO202100019
Investigator:	Kevin Curran
Submission ID	SAF03960

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal for a phase 2 trial to study early reinfusion of tisagenlecleucel to promote durable B-cell aplasia in pediatric and young adult patients with relapsed/refractory CD-19-positive B-cell Acute Lymphoblastic Leukemia. The primary objective is to decrease the loss of peripheral blood B-cell aplasia (BCA) rate at 6-months post-infusion below 10%. The secondary objectives of this study are assessments of toxicity with early reinfusion of tisagenlecleucel. No accidents or loss of containment were reported. Changes to personnel were indicated. The Reviewer did not have any concerns and recommended approval. 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: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Continuing Review

9. **Review of SAF03956**

Title:	Continuing Review for PROTO202200001
Investigator:	Sameer Farouk Sait
Submission ID	SAF03956

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal for a phase I trial to determine the safety of administering autologous Human Epidermal Growth Factor Receptor 2 (HER2) CAR T cells after lymphodepletion in pediatric patients with HER2+ ependymoma and to evaluate the multicenter feasibility of administering up to three infusions of HER2CAR T cells after lymphodepletion. No changes, accidents, or loss of containment were reported. The Reviewer did not have any concerns and recommended approval. 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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment/CR

10. **Review of SAF03941**

Title:	Amendment/CR for PROTO202400001
Investigator:	Robert Motzer
Submission ID	SAF03941

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a phase 2, randomized, double-blind, placebo- and active-controlled, parallel-group, multicenter safety and efficacy study of an investigational personalized mRNA cancer vaccine, V940 plus pembrolizumab versus placebo plus pembrolizumab in the adjuvant treatment of participants with Renal cell carcinoma (RCC) post nephrectomy. No accidents or loss of containment were reported. Changes to personnel and protocol documents were completed in the accompanying amendment. The Reviewer did not have any concerns and recommended approval. 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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment/CR

11. **Review of SAF03957**

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

a. **Determination:** Deferred

b. **Last day of continuing review period:** 2/28/2026

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a phase I trial to assess the safety of a preparation of autologous T lymphocytes transduced with a retroviral vector expressing a chimeric antigen receptor (CAR) specific for the tumor-associated antigen (TAA) human B-cell maturation antigen (BCMA; tumor necrosis factor receptor superfamily member 17; TNFRSF17) fused to the co-stimulatory domain of 4-1BB (CD137) and the CD3-zeta (CD3z) T-cell signaling domain, and a truncated form of the human epidermal growth factor receptor (EGFRt), with potential immunostimulating and antineoplastic activities in patients with multiple myeloma (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 Reviewer did not have any concerns and recommended approval. The Committee deferred the discussion of the trial to the next meeting.

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

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

g. **Votes:**
For:
Against:
Recused:
Absent:
Abstained:

Amendment/CR

12. **Review of SAF03958**

Title:	Amendment/CR for PROTO202400027
Investigator:	Christian Grommes
Submission ID	SAF03958

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a phase I open label study designed to determine the safety and tolerability of MVR-C5252. Patients diagnosed with recurrent high-grade glioma, wild-type Isocitrate Dehydrogenase (IDH) or mutated IDH, WHO grade 3 or grade 4, based on radiographic findings may be enrolled in the dose-escalation portion of this study. No changes, accidents, or loss of containment were reported. The purpose of the amendment was to update protocol documents. The Reviewer did not have any concerns and recommended approval. 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: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Amendment/CR
13. **Review of SAF03913**

Title:	Amendment/CR for PROTO202100010
Investigator:	Ritesh Kotecha
Submission ID	SAF03913

a. **Determination:** Deferred
b. **Last day of continuing review period:** 1/31/2026
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for a phase 1 dose escalation study using a modified 3+3 design, followed by expansion to characterize safety and tolerability and assess antitumor activity of autologous genetically modified T cells (ADP-A2M4CD8) in subjects with human leukocyte antigen (HLA) class I allele (HLA-A*02) and Melanoma-associated antigen-A4 (MAGE-A4) positive inoperable locally advanced or metastatic tumor types. No changes, accidents, or loss of containment were reported. The purpose of the amendment was to update the PI and PI's CV. The Committee deferred the amendment discussion to the next meeting.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**
For:
Against:
Recused:
Absent:
Abstained:

Amendment/CR
14. **Review of SAF03939**

Title:	Amendment/CR for PROTO202200020
Investigator:	Maria Palomba
Submission ID	SAF03939

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None

d. **Comments:** This is the annual renewal and amendment for a phase I first-in-human, open-label, dose-escalation, nonrandomized multicenter study to evaluate the safety and tolerability of combination cluster of differentiation 19 (CD19) autologous chimeric antigen receptor T cell therapy (CART), SYNCAR-001 + STK-009, in subjects with relapsed/refractory (r/r) CD19+ hematologic malignancies. 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 renewal and amendment.

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

f. **Containment level:**

g. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment

15. **Review of SAF03942**

Title:	Amendment for PROTO202400015
Investigator:	Miguel-Angel Perales
Submission ID	SAF03942

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is an amendment to update 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:	0
Absent:	7
Abstained:	0

Amendment

16. **Review of SAF03964**

Title:	Amendment for PROTO202300019
Investigator:	Adam Schoenfeld
Submission ID	SAF03964

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is an amendment to correct an error in the risk group. The trial materials were handled under the appropriate containment. 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: 0
Absent: 7
Abstained: 0

Amendment

17. **Review of SAF03901**

Title:	Amendment for PROTO202500010
Investigator:	James Smithy
Submission ID	SAF03901

a. **Determination:** Deferred
b. **Last day of continuing review period:** 3/5/2027
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 deferred discussion of the amendment to the next meeting.
e. **Applicable section of NIH Guidelines:** Section III-C-1
f. **Containment level:** BSL-2
g. **Votes:**

For:
Against:
Recused:
Absent:
Abstained:

REVIEW OF LABORATORY SUBMISSIONS

Triennial Protocol

18. **Review of LAB202600006**

Title:	Ingo Mellinghoff Lab
Investigator:	Ingo Mellinghoff
Submission ID	LAB202600006

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Ingo Mellinghoff lab. Their research focuses on the study of molecular pathways that regulate brain tumor growth. The long-term goal is to develop therapeutic paradigms that target specific properties of primary brain tumors, including genetic alterations in cancer signaling pathways, unique aspects of brain tumor metabolism, or interactions of brain tumor cells with their brain microenvironment. 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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Triennial Protocol

19. **Review of LAB202500123**

Title:	Kenneth Offit Lab
Investigator:	Kenneth Offit
Submission ID	LAB202500123

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Kenneth Offit lab. Their research focuses on identifying novel germline variants that contribute to inherited disease and cancer predisposition and on functionally characterizing these variants to enable targeted therapeutic strategies. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

For:	11
Against:	0

Recused: 0
Absent: 7
Abstained: 0

Triennial Protocol
20. **Review of LAB202600003**

Title:	Ping Chi Lab
Investigator:	Ping Chi
Submission ID	LAB202600003

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Ping Chi lab. Their research focuses on characterizing signal transduction pathway abnormalities in various cancers with an eye toward translational implications. By being able to manipulate genetic materials in the relevant biological systems, they are able to test effects of various genes of interest. 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.
g. **Containment level:** BSL-2
h. **Votes:**
For: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Triennial Protocol
21. **Review of LAB202600002**

Title:	Ming Li Lab
Investigator:	Ming Li
Submission ID	LAB202600002

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial renewal for the Ming Li lab. The main focus of the laboratory is to understand cellular and molecular mechanisms of tolerance and immunity control in health and disease, particularly in cancer, and to exploit regulatory pathways for disease therapy. The Reviewer requested additional

information about the source of the primary cells which was provided and the Reviewer recommended approval. The Committee voted to approve the Triennial renewal.

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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Triennial Protocol

22. **Review of LAB202600001**

Title:	Luis Parada Brain Tumor Center
Investigator:	Luis Parada
Submission ID	LAB202600001

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments**: This is the triennial renewal for the Luis Parada Brain Tumor Center (BTC). They employ patient derived xenografts of malignant brain tumors and primary cultures derived therefrom, to study tumor progression, drug resistance and to evaluate novel therapies. The repertoire of tumor genotypes accumulated in the BTC PDX collection allows for stratification of tumor sub-types and evaluation of drug combinations, two features that are impossible in clinical trials. The Reviewer requested clarification about the description of decontamination methods. The Committee voted to approve the Triennial review.

e. **Applicable section of NIH Guidelines: :** III-F-8, Appendix C-I, III-D-1-a, III-D-3-b

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

g. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Triennial Protocol

23. **Review of LAB202600005**

Title:	Stephen Long Lab
Investigator:	Stephen Long
Submission ID	LAB202600005

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Stephen Long lab. Their research focuses on production and purification of proteins for determining their structures. Analysis of the purified proteins is done using biophysical methods. 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: 11
Against: 0
Recused: 0
Absent: 7
Abstained: 0

Triennial Protocol

24. **Review of LAB202500121**

Title:	Susan Dewolf
Investigator:	Susan Dewolf
Submission ID	LAB202500121

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments**: This is the triennial renewal for the Susan Dewolf lab. The laboratory studies T cell immunology in the context of leukemia and hematopoietic stem cell transplantation both in mouse and human: graft-versus-host disease, graft-versus-leukemia, post-transplant immune reconstitution, and experimental CAR-T cell immunotherapy. These data serve as preclinical data for work being translated into clinical studies. 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: 11
Against: 0

Recused: 0
Absent: 7
Abstained: 0

Continuing Review
25. **Review of SAF03963**

Title:	Continuing Review for LAB202500021
Investigator:	Gerry O'Neill
Submission ID	SAF03963

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal for the Pharmacy Investigational Drug Service (PIDS). They support MSK with the preparation and packaging of investigational drugs for preclinical and clinical use. No changes, accidents, or loss of containment were reported. The Committee voted to approve the annual renewal.
e. **Applicable section of NIH Guidelines:** III-D-1-a
f. **Containment level:** BSL-2
g. **Votes:**
For: 10
Against: 0
Recused: 1
Absent: 7
Abstained: 0

Continuing Review
26. **Review of SAF03948**

Title:	Continuing Review for LAB202500017
Investigator:	Vladimir Ponomarev
Submission ID	SAF03948

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal for the Vladimir Ponomarev lab. Their research aims to develop advanced imaging techniques that enable real-time tracking of immune cell therapies and targeted drug effects in cancer, using multiple modalities for greater precision and insight. They seek to improve the translation of these findings into clinical applications by monitoring cellular and molecular changes before and after treatment. No changes, accidents, or loss of containment were reported. The Committee voted to approve the annual renewal.

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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment/CR

27. **Review of SAF03959**

Title:	Amendment/CR for LAB202500014
Investigator:	Simon Powell
Submission ID	SAF03959

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027

c. **Required modifications:** None

d. **Comments**: The is the annual renewal and amendment for the Simon Powell lab. The major theme of their work is how DNA repair processes are disrupted in human cancers and how this can be exploited therapeutically. They have largely focused on the role of double-strand break repair and homologous recombination in particular. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. The Committee voted to approve the annual renewal and amendment.

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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment/CR

28. **Review of SAF03967**

Title:	Amendment/CR for LAB202400027
Investigator:	Daniel Higginson
Submission ID	SAF03967

a. **Determination:** Approved

b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for the Daniel Higginson lab. The Higginson lab focuses on alternative DNA double strand break repair pathways that become particularly important in tumors deficient in homologous recombination and in tumors relatively deficient in non-homologous end-joining They employ advanced genome editing approaches to measure the full spectrum of repair events at a double strand break to quantify the use of both standard and alternative repair pathways. They seek to understand these pathways better in order to improve the therapeutic response to radiation and other DNA-damaging agents. No changes, accidents, or loss of containment were reported. The purpose of the amendment was to update grants. The Committee voted to approve the annual renewal and amendment.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-F-8, Appendix C-II, III-D-1-a
f. **Containment level:** BSL-2
g. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment/CR

29. **Review of SAF03968**

Title:	Amendment/CR for LAB202500007
Investigator:	Rui Gardner
Submission ID	SAF03968

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for the Flow Cytometry Facility. The aim of the Flow Cytometry Core Facility at MSK is to provide advanced instrumentation as well as high-level technical and scientific expertise in multi-dimensional Flow Cytometry and Cell Sorting, to facilitate science, improve the quality, and advance the scope of MSK research. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel. The Committee voted to approve the annual renewal and amendment.
e. **Applicable section of NIH Guidelines:** III-F-8, Appendix C-I, III-D-3-b
f. **Containment level:** BSL-2
g. **Votes:**

For:	11
Against:	0

Recused: 0
Absent: 7
Abstained: 0

Amendment/CR

30. **Review of SAF03973**

Title:	Amendment/CR for LAB202400017
Investigator:	Chrysothemis Brown
Submission ID	SAF03973

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** This is the annual renewal and amendment for the Chrysothemis Brown lab. They study the role of dendritic cells in regulation of immune responses to foreign antigens, including viruses, bacteria and parasites, self and environmental antigens to help harness mechanisms of immunoregulation for identification of novel drug targets and diagnostics means for treatment of cancer, autoimmunity and infectious diseases. No changes, accidents, or loss of containment were reported. The purpose of the amendment was to add plasmids. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual renewal and amendment.
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: 11
   Against: 0
   Recused: 0
   Absent: 7
   Abstained: 0

Amendment/CR

31. **Review of SAMENDCR202600000004**

Title:	Amendment/CR for LAB202500018
Investigator:	Richard Hite
Submission ID	SAMENDCR202600000004

a. **Determination:** Approved
b. **Last day of continuing review period:** 2/28/2027
c. **Required modifications:** None
d. **Comments:** The is the annual renewal and amendment for the Richard Hite lab. Their research group is focused upon determining the mechanisms of intracellular ion

transport with a particular focus upon the lysosome. They use a variety of structural and biophysical tools including cryo-electron microscopy, X-ray crystallography and electrophysiology to characterize these channels. No accidents or loss of containment were reported. The purpose of the amendment was to update personnel and cell lines. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the annual renewal and amendment.

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:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0

Amendment

32. **Review of SAF03930**

Title:	Amendment for LAB202500001
Investigator:	Omar Abdel-Wahab
Submission ID	SAF03930

a. **Determination:** Approved

b. **Last day of continuing review period:** 1/31/2027

c. **Required modifications:** None

d. **Comments:** This is an amendment to update personnel, and to add lipid nanoparticles and AAV 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-F-8, Appendix C-I

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

g. **Votes:**

For:	11
Against:	0
Recused:	0
Absent:	7
Abstained:	0