SAFETY Meeting Minutes
Biosafety Committee
6/26/2025 4:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 4:02 PM
Meeting end time: 4:33 PM

VOTING MEMBER ATTENDANCE

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

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Timothy Burnett
Rinosha Majeed

QUORUM INFORMATION

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

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

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

REVIEW OF CLINICAL SUBMISSIONS

Initial Protocol

1. **Review of PROTO202500011**

Title:	A Phase 1/2 Trial of ADI-270 (Engineered gamma delta Chimeric Receptor [CAR] variable delta-1 T Cells Targeting CD70) in Adults with Relapsed or Refractory (R/R) Clear Cell Renal Cell Carcinoma (ccRCC)
Investigator:	Ritesh Kotecha
Submission ID	PROTO202500011

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This is a Phase 1/2 multicenter, open-label, dose escalation, and dose expansion study of ADI-270 in patients with Relapsed or Refractory (R/R) Clear Cell Renal Cell Carcinoma (ccRCC). ADI-270 is an engineered allogeneic Vδ1 γδ CAR T cell product that targets CD70 and expresses a dominant negative form of the TGFβ receptor II (dnTGFβRII). Phase 1 will assess the safety, tolerability, and Maximum Tolerated Dose (MTD)/ Maximum Administered Dose (MAD)MTD/MAD of ADI-270, enrolling up to 30 patients to select a Phase 2 dose. Phase 2 will evaluate anti-tumor activity at the Recommended Phase 2 Dose (RP2D), determined from clinical, pharmacologic, and translational data from Phase 1. The Specialist's questions were addressed. 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: 9
Against: 0
Recused: 2
Absent: 6
Abstained: 0

Initial Protocol

2. **Review of PROTO202500012**

Title:	MED25-045: An Open-Label, Phase 1/2 Study of JCAR017 in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (017004)
Investigator:	Jae Park
Submission ID	PROTO202500012

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This is a Phase 1/2, open-label, multicenter study to determine the efficacy and safety of JCAR017 in adult subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma (R/R CLL or SLL). The study will include a Phase 1 dose-finding part followed by a Phase 2 expansion to further evaluate the efficacy and safety of JCAR017 monotherapy administered at the recommended dose. In a separate Phase 2 Double-Exposed Monotherapy Expansion (DEME) cohort the efficacy and safety of JCAR017 monotherapy will be evaluated in subjects with R/R CLL or SLL who have received at least 2 prior lines of therapy including a BTK inhibitor and a BCL2 inhibitor. Separate Phase 1 cohorts will assess the combination of JCAR017 and concurrent ibrutinib or venetoclax. In all subjects, the safety, efficacy, and PK of JCAR017 will be evaluated. The Specialist's questions were addressed. 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Initial Protocol

3. **Review of PROTO202500010**

Title:	MED25-056: A First-in-Human, Open-Label Trial to Evaluate the Combination of ACTengineTM IMA203 with mRNA-4203 in Previously Treated, Unresectable or Metastatic Cutaneous Melanoma or Synovial Sarcoma Patients (ACTengineTM IMA203-102)
Investigator:	James Smithy
Submission ID	PROTO202500010

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** IMA203-102 trial is a new first-in-human trial that evaluates the combination of TCR T cell IMA203 with mRNA-4203—an mRNA-based vaccine targeting the tumor-associated PRAME antigen—in patients with unresectable and metastatic cutaneous melanoma (CM) or synovial sarcoma (SS).
IMA203is an autologous TCR-T cell therapy targeting PRAME, a cancer/testis antigen, currently under investigation in the Phase 1/2 IMA203-101 trial. As of August 2024, 68 patients had received IMA203 monotherapy in Phase 1 with acceptable safety profile and approved to move to phase 3 with established RP2D: 1 to 10 x 10^9 TCR-T cells.
mRNA-4203 is a lipid nanoparticle (LNP)-formulated mRNA encoding a concatemer of PRAME peptides recognized by IMA203. It is designed to boost or re-activate previously infused IMA203 T cells by enhancing PRAME presentation on HLA-A*02:01-positive antigen-presenting cells following intramuscular (IM) injection. The technology platform is consistent with that used in other Moderna mRNA products, include COVID-19 vaccine, RSV vaccine, and investigational cancer vaccines mRNA-4157 and mRNA-4359.
The phase 1 trial is divided into 1A-mRNA vaccine dose escalation cohort (DL1 of 0.5mg and DL2 of 1mg, with a dose DL-1 of 0.1mg) and 1B-expansion cohort. 18 patients for phase 1A and 10 patients for phase 1B. The maximum study duration per patient is 3 years (1 year of treatment, 2 years of follow-up).
Patients will receive: A single infusion of IMA203 TCR-T cells at RP2D (1.0–10.0 x 10^9 CD8+ transduced viable cells), followed by subcutaneous low-dose IL-2 (1 million IU) daily for 5 days (Days 2–6), then twice daily for 5 more days (Days 7–11), then followed by Intra-muscular administration of mRNA-4203 for up to 12 cycles (28-day cycles).
Based on the sponsor's platform experience with similar LNP mRNA vaccines, low-dose intramuscular mRNA-4203 poses no genotoxic or secondary malignancy risks. The overall safety profile for IMA203 monotherapy has been deemed acceptable. Although potential more severe adverse effects from the combination regimen of IMA203 and mRNA-4203 is possible, the combination therapy does not appear to pose additional biosafety concern. The Reviewer asked for confrmation that recipients will be followed up for 15 years post-infusion. This was confirmed and the reviewer did not have 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

4. **Review of SAMENDCR202500000024**

Title:	Amendment/CR for PROTO202100009
Investigator:	Sergio Giralt
Submission ID	SAMENDCR202500000024

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a phase II multi-center, single arm, clinical trial to assess the ability of B Cell Maturation Antigen (BCMA) directed chimeric antigen receptor (CAR) T cell therapy to improve response in Multiple Myeloma (MM) patients who have failed to achieve at least very good partial response (VGPR) after first-line therapy (induction followed by high-dose melphalan, autologous stem cell transplant and maintenance lenalidomide). Eligible patients must have undergone autologous hematopoietic cell transplant (HCT) and started lenalidomide maintenance with less than a VGPR. They will receive leukapheresis, LD chemotherapy, and BCMA CAR-T therapy, followed by resumption of lenalidomide at least 30 days post-infusion if recovery criteria are met. Patients will be followed for one year. No accidents or loss of containment were reported. The purpose of the amendment is to update administrative documents. 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:	10
Against:	0
Recused:	1
Absent:	6
Abstained:	0

Amendment/CR

5. **Review of SAF03753**

Title:	Amendment/CR for PROTO202400014
Investigator:	Sridevi Rajeeve
Submission ID	SAF03753

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for a Phase 2, randomized, open-label, global, multicenter study to determine independently in 2 cohorts the efficacy and safety of cilta-cel therapy when combined with fix-duration sequential combinations of daratumumab and bispecific antibodies (Tal-D and Tec-D) either before or after cilta-cel infusion in the fit or intermediate-fit adult participants, aged ≤70 years diagnosed with standard-risk Newly Diagnosed Multiple Myeloma (NDMM) per the International Myeloma Working Group (IMWG) criteria. This study evaluates the safety and efficacy of sequencing bispecific antibody–daratumumab combinations and cilta-cel after Daratumumab, Velcade, Revlimid, Dexamethasone (DVRd) induction in multiple myeloma. Cilta-cel is a BCMA-targeting CAR-T therapy, while teclistamab and talquetamab are bispecific antibodies targeting B Cell Maturation Antigen (BCMA) and G protein-coupled receptor, class C, group 5, member D (GPRC5D), respectively. The primary goal is to assess curative potential and progression-free survival at 3 and 5 years. Secondary objectives include evaluating overall efficacy and safety. Cohorts are not designed for comparison. No accidents or loss of containment were reported. The purpose of the amendment is to update administrative documents. The Reviewer did not express 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

6. **Review of SAMENDCR202500000017**

Title:	Amendment/CR for PROTO201900009
Investigator:	Michael Scordo
Submission ID	SAMENDCR202500000017

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a Phase 1, open label, non-randomized, multi-center, dose escalation study of AB-205 in adult subjects with Hodgkin or non-Hodgkin lymphoma who are in a chemo-sensitive remission undergoing high-dose therapy, with or without radiation, and autologous stem cell transplantation (HDT-ASCT). Secondary objectives include assessing grade ≥3 adverse events, mucosal toxicities, and time to neutrophil and platelet engraftment. AB-205, developed by Angiocrine Bioscience to aid vascular recovery post-chemotherapy, will be given 4 hours after ASCT in three dose-escalation cohorts (5, 10, and 20 million cells/kg). Subjects will be followed through day +100. No accidents or loss of containment were reported. The purpose of the amendment is to update personnel and inform the committee that this trial is closed to accrual. The Committee voted to approve the amendment and annual review.

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

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

g. **Votes:**

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

Amendment/CR

7. **Review of SAF03714**

Title:	Amendment/CR for PROTO202400009
Investigator:	Susan Slovin
Submission ID	SAF03714

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a first-in-human Phase I/II open label study to evaluate the safety, cellular kinetics, and efficacy of AZD0754, a chimeric antigen receptor (CAR) T-cell therapy directed against Six Transmembrane Epithelial Antigen of Prostate 2 (STEAP2), in adult participants with metastatic prostate cancer. Substudy 1 focuses on metastatic castration-resistant prostate cancer (mCRPC) who have previously received treatment with a novel hormonal agent (NHA) and taxane. Part A (dose escalation) identifies the recommended dose; Part B (dose expansion) confirms safety. Participants undergo screening, apheresis, lymphodepletion, and AZD0754 infusion, with follow-up for up to 15 years. Up to 36 participants may be enrolled in Part A and 20 in Part B. The purpose of the amendment is to update personnel and administrative documents. No accidents or loss of containment were reported. 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

8. **Review of SAMENDCR202500000015**

Title:	Amendment/CR for PROTO202300008
Investigator:	Sham Mailankody
Submission ID	SAMENDCR202500000015

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a Phase 1, multicenter, open-label evaluation of safety and emerging efficacy of CB-011 in patients with relapsed/refractory multiple myeloma (r/r MM). CB-011 is a product of (CRISPR)-based gene editing designed to create an allogeneic human T cell product with specific capacity to target multiple myeloma cells. This approach to cancer therapy aims to provide treatment for patients with limited treatment options for r/r MM. No accidents or loss of containment were reported. The purpose of the amendment is to update 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment/CR

9. **Review of SAF03751**

Title:	Amendment/CR for PROTO201900013
Investigator:	Sergio Giralt
Submission ID	SAF03751

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:**
d. **Comments:** This is the amendment and annual review for a Phase 3, Multicenter, Randomized, Open-label Study to Compare the Efficacy and Safety of bb2121 Versus Standard Triplet Regimens in Subjects with Relapsed and Refractory Multiple Myeloma (RRMM) (KarMMa-3) (CAR-T). This study evaluates the safety and efficacy of bb2121, a CAR T-cell therapy using a patient's own modified immune cells, in treating relapsed and refractory multiple myeloma (RRMM) after failure of two prior treatments. Modified cells are manufactured off-site and infused back into the patient, with outcomes compared to standard care. No accidents or loss of containment were reported. The purpose of the amendment is to update personnel and to incorporate the new guidelines for secondary primary malignancies. 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:	10
Against:	0
Recused:	1
Absent:	6
Abstained:	0

Amendment

10. **Review of SAF03734**

Title:	Amendment for PROTO202300034
Investigator:	Adam Schoenfeld
Submission ID	SAF03734

a. **Determination:** Approved
b. **Last day of continuing review period:** 1/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment includes updates to study personnel and a revised Investigator's Brochure (IB), which incorporates preliminary safety data and new guidance on hyper-inflammatory syndrome—specifically, Immune Effector Cell-associated Hemophagocytic Lymphohistiocytosis-like Syndrome (IEC-HS).
The protocol has also been updated for greater clarity, with additional safety stopping parameters included. A voluntary clinical hold has been initiated while further information is gathered and the FDA conducts its review, following a recent serious adverse event involving IEC-HS in a patient.
None of the changes introduce new safety concerns for participants. 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

Amendment

11. **Review of SAF03690**

Title:	Amendment for PROTO202100003
Investigator:	Sergio Giralt
Submission ID	SAF03690

a. **Determination:** Approved

b. **Last day of continuing review period:** 12/31/2025

c. **Required modifications:** None

d. **Comments:** This is an amendment to a study which is designed to evaluate the safety and efficacy of nonconforming ide-cel in subjects with multiple myeloma per the approved prescribing information. This is an expanded access protocol (EAP) that will be conducted at sites qualified under the Sponsor's risk evaluation and mitigation strategy (REMS) program and approved for commercial administration of ide-cel and where the EAP is authorized to be conducted for use of nonconforming ide-cel. Per the IBC's mandate, this amendment was submitted to update it regarding the Out of specification criteria for patients treated with non-conforming product in the last six months. Additionally, personnel and ICF updates were made. The study team indicated that no subjects were treated in the past six months. The Specialist's questions were addressed. 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:	9
Against:	0
Recused:	2
Absent:	6
Abstained:	0

REVIEW OF LABORATORY SUBMISSIONS

Triennial Review

12. **Review of LAB202500037**

Title:	Andrea Schietinger Lab
Investigator:	Andrea Schietinger
Submission ID	LAB202500037

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Schietinger lab. This research investigates T cell differentiation in tumors, autoimmunity, and infection using genetic mouse models and human samples. It focuses on defining molecular and epigenetic programs through techniques such as flow cytometry, Assay for Transposase-Accessible Chromatin sequencing (ATAC-seq), and RNA-seq, and explores strategies to modulate T cell function in cancer and autoimmune diseases like Type 1 diabetes. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.
e. **Applicable section of NIH Guidelines:** III-D-1-a, III-D-3-b, III-D-3-a, III-F, Appendix C-I, III-E-3, III-D-2,
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing Review

13. **Review of SAF03754**

Title:	Continuing Review for LAB202400008
Investigator:	Agnel Sfeir
Submission ID	SAF03754
Funding:	None
Documents Reviewed:	None

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Sfeir Lab. This lab studies chromosome biology and its role in disease, focusing on telomere maintenance, nuclear DNA repair, and mitochondrial DNA replication and repair. Key areas include telomere dysfunction in cancer, the mutagenic micro-homology mediated end-joining (MMEJ) repair pathway involving polymerase theta, and mitochondrial-nuclear communication during mitochondrial DNA stress. No changes, accidents or loss of containment were reported. The Committee voted to approve the annual review.
e. **Applicable section of NIH Guidelines:** III-D-1-a, III-D-3-b, III-D-3-a, III-F

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

g. **Votes:**

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

Continuing Review

14. **Review of SAF03743**

Title:	Continuing Review for LAB202300047
Investigator:	Nikola Pavletich
Submission ID	SAF03743

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This annual review is for the Pavletich Lab. This research focuses on understanding the structural and mechanistic roles of key proteins and macromolecular complexes altered in cancer. Techniques such as X-ray crystallography and high-resolution electron microscopy are used to reveal how these molecules function and how their changes contribute to cancer development. 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

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

g. **Votes:**

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

Continuing Review

15. **Review of SAF03740**

Title:	Continuing Review for LAB202300030
Investigator:	Michael McDevitt
Submission ID	SAF03740

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This annual review is for the McDevitt Lab. Their research involves development of antibody and nanomaterial drug platform technology for medical use

to treat cancer and disease. No changes, accidents or loss of containment were reported. The Committee voted to approve the annual review.

e. **Applicable section of NIH Guidelines:** III-E

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

g. **Votes:**

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

Continuing review with amendment

16. **Review of SAMENDCR202500000021**

Title:	Amendment/CR for LAB202400012
Investigator:	Alban Ordureau
Submission ID	SAMENDCR202500000021
Funding:	None
Documents Reviewed:	None

a. **Determination:** Approved

b. **Last day of continuing review period:** 7/31/2026

c. **Required modifications:** None

d. **Comments:** This is the amendment and the annual review for the Ordureau Lab. They study how cell signaling pathways, particularly those involving ubiquitin and autophagy, regulate cellular homeostasis and are disrupted in diseases such as neurodegeneration. Using CRISPR, cell biology, biochemistry, and quantitative proteomics, they analyze changes in protein signaling, modification, and trafficking in response to mutations or stress. 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-D-3-b, III-E

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

g. **Votes:**

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

Continuing review with amendment

17. **Review of SAF03730**

Title:	Amendment/CR for LAB202300046
Investigator:	Arvin Dar
Submission ID	SAF03730

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for the Dar Lab. Their research combines genetics, biochemistry, structural biology, and small molecule discovery to develop tools that modulate cell signaling. The focus is on creating chemical probes to study and target cancers driven by dysregulated enzymes, receptors, signaling pathways, and the tumor microenvironment. 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-D-3-b, III-F
f. **Containment level:** BSL-2
g. **Votes:**

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

Continuing review with amendment

18. **Review of SAF03729**

Title:	Amendment/CR for LAB202300043
Investigator:	Lydia Finley
Submission ID	SAF03729

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for the Finley Lab. They study how metabolism influences stem and cancer cell fate, focusing on how metabolite levels affect chromatin and gene expression. Using genetic and metabolomic tools, they manipulate mouse and human cells with recombinant DNA to explore growth and differentiation. 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-D-3-b, III-F
f. **Containment level:** BSL-2
g. **Votes:**

For: 11
Against: 0
Recused: 0

Absent: 6
Abstained: 0

Continuing review with amendment

19. **Review of SAMENDCR202500000019**

Title:	Amendment/CR for LAB202300039
Investigator:	Ana Catarina Gradissimo De Oliveira
Submission ID	SAMENDCR202500000019

a. **Determination:** Approved
b. **Last day of continuing review period:** 6/30/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for the Molecular Microbiology Facility (MMF). The Molecular Microbiology Core Facility studies infections in cancer patients and the role of microbes in cancer and inflammation. It focuses on the human microbiota and its potential to prevent infections by antibiotic-resistant microbes. Human fecal samples are collected, and bacterial 16S rDNA (V4–V5) is sequenced and analyzed to characterize microbial communities. The purpose of the amendment was to update administrative documents. The Committee voted to approve the amendment and annual review.
e. **Applicable section of NIH Guidelines:** N/A
f. **Containment level:** BSL-2
g. **Votes:**
For: 11
Against: 0
Recused: 0
Absent: 6
Abstained: 0

Amendment

20. **Review of SAF03749**

Title:	Amendment for LAB202300074
Investigator:	Mara Monetti
Submission ID	SAF03749

a. **Determination:** Approved
b. **Last day of continuing review period:** 12/31/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for updating the IBC registration to include handling of Cerebrospinal fluid (CSF) and brain specimens and updating a new location. The reviewer had questions about handling of specimens obtained from individuals with a confirmed of suspected prion-like disease, e.g., Creutzfeldt-Jakob Disease or

Alzheimer's disease which were addressed and accepted by the reviewer who 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:	11
Against:	0
Recused:	0
Absent:	6
Abstained:	0

Amendment

21. **Review of SAF03707**

Title:	Amendment for LAB202200064
Investigator:	Richard Wong
Submission ID	SAF03707

a. **Determination:** Approved

b. **Last day of continuing review period:** 9/30/2025

c. **Required modifications:** None

d. **Comments:** This amendment is for adding the oncolytic Newcastle Disease Viral (NDV) vector: NDV F3aa which is attenuated to express low virulence (avian and human). The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.

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

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

g. **Votes:**

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

Continuing Review

22. **Review of SAF03741**

Title:	Continuing Review for LAB202300029
Investigator:	Joachim Silber
Submission ID	SAF03741

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This annual review is for the Precision Pathology Biobanking Center (PPBC). The MSK Biobank and Pathology Core provides human tissue resources to support cancer research, including specimen procurement, processing, storage, and

distribution. It banks samples from ~7,000 cancer patients annually and offers histology and immunohistochemistry services, including tissue microarrays, laser capture microdissection, and antibody staining for research use. No changes, accidents or loss of containment were reported. The Committee voted to approve the annual review.

e. **Applicable section of NIH Guidelines:** N/A

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

g. **Votes:**

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

Amendment

23. **Review of SAF03736**

Title:	Amendment for LAB202300029
Investigator:	Joachim Silber
Submission ID	SAF03736

a. **Determination:** Approved

b. **Last day of continuing review period:** 6/30/2026

c. **Required modifications:** None

d. **Comments:** This amendment is for updating safety manuals 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:** N/A

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

g. **Votes:**

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