SAFETY Meeting Minutes
Biosafety Committee
7/29/2025 1:00 PM
Zoom

MEETING TIME RECORDS

Meeting start time: 1:07 PM
Meeting end time: 1:42 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		Absent
Philip Hauck		Absent
Hillary Frommer		Present
Zainab Shahid		Present
Geoffrey Ku		Present
Rui Gardner		Present
Marc Kramer		Present
Sham Mailankody		Absent
Paul O'Brien		Present
Andrea Ventura		Absent
Christine Iacobuzio-Donahue		Present

NON-VOTING ATTENDEES/GUESTS

Asmita Kumar
Timothy Burnett
Rich Ellis

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 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

DISCUSSION

Meeting minutes: The meeting minutes for May 2025 and June 2025 were reviewed and approved by the Committee

Reevaluation of the handling precautions for PROTO202500010:
The Committee reviewed a protocol involving an mRNA vaccine used alongside a patient's own T cells. The vaccine is made of non-replicating, single-stranded mRNA inside lipid nanoparticles. It was originally approved at BSL-2+, but after further review, it was agreed that BSL-2 precautions are sufficient. Although the vaccine itself is considered low-risk (Risk Group 1), BSL-2 precautions are still needed because it is administered in a clinical setting. The Committee voted to approve the change, and the protocol will be updated accordingly.

Amendment for PROTO202400010:
The annual review for a trial was submitted to the Committee for review. The trial is a randomized, double-blind, phase 2 multicenter study testing the effectiveness and safety of combining [redacted] with [redacted] alone as adjuvant treatment in patients with high-risk muscle-invasive urothelial carcinoma (MIUC). The main goal is to compare clinical outcomes and side effects between the two treatments. The study involves an initial consent for sample collection to facilitate vaccine design for patients diagnosed with MIBC, followed by a second consent and additional screening for those eligible post-surgery, while the vaccine is being manufactured. [redacted] The annual report was approved as no changes had occurred that impacted the biosafety considerations for this study.

Cleaning of Biosafety Cabinets:
New signs are being posted on over 590 biosafety cabinets (BSC) across MSK to educate users about appropriate BSC cleaning practices. The signs explain that ethanol is not effective against all organic matter and recommend using stronger disinfectants like 10% bleach or Peroxigard for deep cleaning.

IBC System Upgrade:
The IBC system was recently updated to include new questions about gain-of-function research and gene drive organisms. These changes are meant to help identify any research that could increase the risk of pathogens becoming more dangerous. Although no labs at MSK are currently doing gene drive work, the questions will help flag any future projects. Some members suggested changes to existing language, which will be made.

IBC Procedures for training verification of personnel listed on IBC Registrations:
A proposed policy was discussed to ensure that all laboratory personnel working with biohazardous materials in MSK labs are appropriately trained. The policy requires individuals to complete initial and annual refresher training. Compliance with training is verified when staff are added to an IBC registration and during annual reviews to ensure continued adherence. If training requirements are not met within seven days, the matter will be escalated and may result in temporary suspension of lab access until compliance is achieved. The Committee determined that additional time is needed to thoroughly review the proposal; therefore, a vote has been postponed to the next meeting.

REVIEW OF CLINICAL SUBMISSIONS

Amendment/CR

1. **Review of SAF03719**

Title:	Amendment/CR for PROTO202200006
Investigator:	Saad Usmani
Submission ID	SAF03719

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase 3 trial that compares two treatments for newly diagnosed multiple myeloma patients not undergoing stem cell transplant: standard therapy (bortezomib, lenalidomide, and dexamethasone) (VRd), then lenalidomide and dexamethasone (Rd) versus VRd followed by cilta-cel (a CAR-T therapy targeting BCMA).Cilta-cel CAR-T cells are manufactured using a third generation, self-inactivating, lentiviral vector. No accidents, exposures 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: 11

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

Amendment/CR

2. **Review of SAMENDCR202500000025**

Title:	Amendment/CR for PROTO202200007
Investigator:	Lara Dunn
Submission ID	SAMENDCR202500000025

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I Human, Open Label, Safety and Tolerability Study of Escalating Multiple Doses of Intratumoral MQ710. Their study evaluates MQ710 monotherapy and combination therapy with pembrolizumab in patients with advanced or metastatic cancer. MQ710 is a non-replicative Modified Vaccinia Virus Ankara-Based virus administered intratumorally. The trial includes dose escalation and expansion phases, enrolling approximately 35–56 patients over 18 months. No accidents, exposures 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: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment/CR

3. **Review of SAMENDCR202500000018**

Title:	Amendment/CR for PROTO201900006
Investigator:	Parastoo Dahi
Submission ID	SAMENDCR202500000018

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a Phase I trial that tests the safety and effectiveness of gene therapy for HIV-positive patients with lymphoma, using their own stem cells genetically modified with an anti-HIV lentiviral vector.

The vector introduces protective genes into CD34+ hematopoietic stem cells to help generate HIV-resistant immune cells after transplantation. The study closely monitors engraftment, gene expression, and immune recovery, aiming to rebuild the patient's immune system to resist HIV infection. 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:	0
Absent:	4
Abstained:	0

Amendment/CR

4. **Review of SAF03757**

Title:	Amendment/CR for PROTO202100007
Investigator:	Miguel-Angel Perales
Submission ID	SAF03757

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is the amendment and annual review for a phase II, multi-center study aims to evaluate MB-CART2019.1 (zamtocabtagene autoleucel), a CAR T-cell gene therapy targeting CD19 and CD20, in patients with diffuse large B cell lymphoma (DLBCL) who have failed at least two prior treatments. The study will measure clinical outcomes including duration of response, progression-free survival, and overall survival over a two-year period. Exploratory objectives include assessing CAR T-cell persistence, correlating it with side effects and efficacy, and examining the relationship between antigen expression and relapse. MB-CART2019.1 is manufactured by enriching patient T cells, then transducing them with a dual-target CAR via a four plasmid lentiviral vector system. The CAR construct uses antibody fragments for both targets linked to human signaling domains, and the manufacturing process has shown strong safety and specificity in preclinical and early clinical trials.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:	12

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

Amendment/CR

5. **Review of SAF03775**

Title:	Amendment/CR for PROTO202100010
Investigator:	Ritesh Kotecha
Submission ID	SAF03775

a. **Determination:** Approved
b. **Last day of continuing review period:** 1/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a phase I trial that investigates the safety and effectiveness of ADP-A2M4CD8, an autologous T-cell therapy engineered to target the tumor antigen MAGE-A4 in patients with certain solid cancers. Eligible patients have tumors positive for MAGE-A4 and appropriate HLA types. Their own T cells (CD4 and CD8) are collected, genetically modified using a self-inactivating lentiviral vector, and expanded. Following lymphodepleting chemotherapy (fludarabine and cyclophosphamide), patients receive the engineered T-cell infusion. The trial may also include immune checkpoint inhibitors (nivolumab or pembrolizumab) as part of the treatment. Participants are closely monitored for both short-term and long-term safety and efficacy, including regular follow-up for potential delayed adverse effects and risks related to the gene modification, in line with regulatory guidance. The aim is to assess whether this approach can improve prognosis in various solid tumors by enhancing the anti-tumor immune response. 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: 11
Against: 0
Recused: 2
Absent: 4
Abstained: 0

Amendment/CR

6. **Review of SAMENDCR202500000026**

Title:	Amendment/CR for PROTO202400010
Investigator:	David Aggen
Submission ID	SAMENDCR202500000026

a. **Determination:** Approved

b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a phase 2, randomized, multicenter study evaluating the efficacy and safety of adjuvant treatment with autogene cevumeran plus nivolumab compared with nivolumab in patients with high-risk muscle-invasive urothelial carcinoma (MIUC). Autogene cevumeran is an individualized, neoantigen-specific immunotherapy delivered as a messenger RNA (mRNA) therapeutic vaccine. It is designed to induce antigen-specific T-cell responses against cancer neoantigens that are unique to each patient's tumor. The goal of autogene cevumeran is to expand the patient's tumor-specific T-cell repertoire, enhancing the immune system's ability to target and attack cancer cells. The primary objective is to evaluate the efficacy of adjuvant treatment with autogene cevumeran plus nivolumab compared with nivolumab. The second objective is to evaluate the safety of adjuvant treatment with autogene cevumeran plus nivolumab compared with nivolumab. 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:	0
Absent:	4
Abstained:	0

Amendment/CR

7. **Review of SAF03756**

Title:	Amendment/CR for PROTO202400013
Investigator:	Gunjan Shah
Submission ID	SAF03756

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and annual review for a phase II study This clinical trial combines pembrolizumab (a PD-1 inhibitor) with CAR T-cell therapy—axicabtagene ciloleucel (axi-cel) or lisocabtagene maraleucel—for relapsed or refractory aggressive B-cell lymphomas, including PMBCL. Pembrolizumab is administered before the CAR T-cell infusion, aiming to enhance anti-tumor immune responses.For axi-cel, the patient's T cells are genetically engineered using a retroviral vector . This vector contains the genetic sequence for a chimeric antigen receptor (CAR), which is designed to target CD19 on malignant B cells. The goal of the trial is to improve treatment efficacy and overcome resistance mechanisms

through this combined approach. 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:	12
Against:	0
Recused:	1
Absent:	4
Abstained:	0

Amendment

8. **Review of SAF03791**

Title:	Amendment for PROTO202400027
Investigator:	Christian Grommes
Submission ID	SAF03791

a. **Determination:** Approved

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

c. **Required modifications:** None

Comments: This amendment includes updates to study PI and administrative documents for a Phase I trial that evaluates the safety, tolerability, optimal dosing, and preliminary efficacy of MVR-C5252—an engineered oncolytic herpes simplex virus type 1 (HSV-1) expressing interleukin-12 (IL-12) and an anti-PD-1 antibody—for the treatment of recurrent high-grade gliomas. MVR-C5252 is designed to selectively infect and lyse tumor cells while minimizing neurotoxicity and viral spread. Additionally, expression of IL-12 and anti-PD-1 aims to modulate the tumor microenvironment by enhancing immune cell recruitment and activity against tumor cells. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the amendment.

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

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

f. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Amendment

9. **Review of SAF03748**

Title:	Amendment for PROTO202400007
Investigator:	Sridevi Rajeeve
Submission ID	SAF03748

a. **Determination:** Approved
b. **Last day of continuing review period:** 5/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment includes updates to study PI Change for a phase 1b/2, study of GC012F (AZD0120), a CD19/BCMA dual CART-cell therapy, in adult subjects with relapsed/refractory Multiple Myeloma.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:	1
Absent:	4
Abstained:	0

REVIEW OF LABORATORY SUBMISSIONS

Initial Protocol

10. **Review of LAB202500042**

Title:	Kathryn Taylor Lab
Investigator:	Kathryn Taylor
Submission ID	LAB202500042

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is an initial review for the Taylor Lab. Their lab studies how neural activity influences pediatric and young adult cancers, focusing on how tumors hijack normal developmental processes. Using neuroscience tools and preclinical models, they explore how electrical signals affect cancer growth and aim to identify neuromodulator treatments for clinical use. The Reviewer's questions were addressed and recommended approval. The Committee voted to approve the lab registration.
e. **Applicable section of NIH Guidelines:** III-D-3-b; III-D-3; III-F-8 Appendix C-II; III-F-8, Appendix C-I
f. **Highest containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4

Abstained: 0

Triennial Protocol

11. **Review of LAB202500041**

Title:	Jonathan Peled Lab
Investigator:	Jonathan Peled
Submission ID	LAB202500041

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Peled lab. Their study investigates microbiota–immune interactions in cancer treatment, focusing on alloreactivity and GVHD. Research integrates mouse models, microbiome-derived metabolites, and culturomics to study anti-tumor immune responses and toxicities (e.g., CAR-T, checkpoint blockade). The lab also explores how the intestinal microbiome influences multiple myeloma progression and immune recovery post-auto-HCT, aiming to overcome therapeutic resistance through microbial modulation. 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-F, Appendix C-I
f. **Highest containment level:** BSL-2
g. **Votes:**
   For: 13
   Against: 0
   Recused: 0
   Absent: 4
   Abstained: 0

Triennial review

12. **Review of LAB202500046**

Title:	Gabriela Chiosis Lab
Investigator:	Gabriela Chiosis
Submission ID	LAB202500046

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Chiosis lab. Their laboratory aims to develop novel treatments for cancer and neurodegenerative diseases such as Alzheimer's disease. The approach is to discover and develop small molecule heat shock protein inhibitors to target signaling pathways involved in the diseases. The laboratory validates and investigates the effect of potential therapies before their translation to humans. 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, Appendix C-I; III-F-8 Appendix C-II
f. **Highest containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

13. **Review of LAB202500045**

Title:	Sarat Chandarlapaty Lab
Investigator:	Sarat Chandarlapaty
Submission ID	LAB202500045

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Chandarlapaty lab. Their goal is to understand signaling pathways in cancer. They use recombinant DNA to identify the roles of certain molecules in these pathways and this is predominantly done in cancer cell lines. 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, Appendix C-I; III-F-8 Appendix C-II; III-D-3-b
f. **Highest containment level:** BSL-2
g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

14. **Review of LAB202500050**

Title:	Alexander Rudensky Lab
Investigator:	Alexander Rudensky
Submission ID	LAB202500050

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This is the triennial review for the Rudensky lab. Their laboratory focuses on understanding the role of CD4 T-regulatory (T-reg) lymphocytes in immunity, immune diseases, tumor immunity, and the maintenance of immune

homeostasis at environmental interfaces. Major areas of interest include the molecular and cellular mechanisms leading to the differentiation and function of T-reg cells with focus in understanding the contribution of the forkhead family transcription factor Foxp3 in maintaining immune homeostasis, and in the functions and lineage stability of T-reg. The Specialist's questions were addressed. 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; III-D-3; III-F-8 Appendix C-II; III-F, Appendix C-I; III-D-1-a

f. **Highest containment level:** BSL-2+

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Triennial Protocol

15. **Review of LAB202500049**

Title:	Immunology Laboratory for Immunotherapy (Phillip Wong)
Investigator:	Phillip Wong
Submission ID	LAB202500049

a. **Determination:** Approved

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

c. **Required modifications:** None

d. **Comments:** This is the triennial review for the The Immune Monitoring Facility (IMF) provides core laboratory support for the processing, banking, and research analysis of biological samples obtained from human patients consented to various MSKCC clinical trial protocols. The primary objective is to understand better the immune response before and after treatment of cancer patients with novel immune modifying therapies and to identify possible immune correlatives of the clinical response or disease state. To this end, the IMF runs a variety of laboratory assays for analysis of human clinical samples. The Reviewer did not have any concerns and recommended approval. The Committee voted to approve the triennial review.

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

f. **Highest containment level:** BSL-2

g. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4
Abstained:	0

Continuing Review

16. **Review of SAF03784**

Title:	Continuing Review for LAB202200082
Investigator:	Robert Benezra
Submission ID	SAF03784

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for the Benezra Lab. Their study uses mouse models of cancer to elucidate mechanisms of tumor initiation and progression. Using mouse models to elucidate mechanisms i) of mammalian development ii) underlying adult stem cell self-renewal and differentiation. 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-3-b; III-F-8 Appendix C-II; III-F, Appendix C-I; III-D-1; III-D-1-a
f. **Highest containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Continuing Review

17. **Review of SAF03761**

Title:	Continuing Review for LAB202400010
Investigator:	Mark Klang
Submission ID	SAF03761

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/31/2026
c. **Required modifications:** None
d. **Comments:** This annual review is for The Pharmaceutical Product Facility, a member of the Research Pharmacy (RP) Core. The Pharmaceutical Product Facility is for drug formulation/stability and compatibility issues The PPF provides consultation, bulk product analysis and purification, formulation, vialing, labeling, stability/sterility testing, and dispensing. The PPF works hand-in-hand with the Investigational Products Core to prepare the Chemistry, Manufacturing, and Control (CMC) Section for each of MSK's IND's. Through the PPF, MSK can advance internal ideas into early human testing. Owing to the infrastructure of the RP, MSK has been able to bring multiple distinct types of pharmacologic agents into early clinical trials. The PPF prepares and develops formulations for topical, injectable and oral administration. 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. **Highest containment level:** BSL-1
g. **Votes:**

For: 12
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Continuing review with amendment
18. **Review of SAF03762**

Title:	Amendment/CR for LAB202400013
Investigator:	Joachim Silber
Submission ID	SAF03762

a. **Determination:** Approved
b. **Last day of continuing review period:** 8/31/2026
c. **Required modifications:** None
d. **Comments:** This is the amendment and the annual review for the MSK Biobank: Biofluids Division of the MSK Biobank processes and stores biologic specimens under IRB-approved protocols for future research. Samples are handled using BSL-2 precautions, and data is accessible to investigators via a DARWIN-based intranet database. The Biofluids Division is supported by the Centralized MSK Biobanking Initiative. 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:** N/A
f. **Highest containment level:** BSL-2
g. **Votes:**
For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Continuing review with amendment
19. **Review of SAF03773**

Title:	Amendment/CR for LAB202300051
Investigator:	Tuomas Tammela
Submission ID	SAF03773

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 Tuomas Tammela Lab. Their study is interested in understanding the remarkable phenotypic heterogeneity of cancer cells within tumors. They approach this question using a combination of sophisticated genetically engineered mouse models, single cell transcriptomics, tracing and ablation of distinct tumor cell lineages, CRISPR-

mediated gene regulation, and advanced imaging techniques. They utilize the exceptional resources developed by their MSK collaborators, such as organoids and xenografts, for the translation of their findings into new treatments for human cancer. Their goal is to discover pathways that drive distinct cellular phenotypes and to develop new therapeutic concepts aimed at reducing cellular heterogeneity in tumors. No accidents or loss of containment were reported. The purpose of the amendment was to add plasmids, a new transgenic mouse, and update funding and personnel. 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:** III-F-8, Appendix C-I; III-D-3-b; III-D-3; III-F-8 Appendix C-II; III-F, Appendix C-IF

f. **Highest containment level:** BSL-2

g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Continuing review with amendment

20. **Review of SAF03766**

Title:	Amendment/CR for LAB202300049
Investigator:	Andrew Intlekofer
Submission ID	SAF03766

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 Andrew Intlekofer Lab. Their research explores the role of altered metabolic pathways in cancer progression and examines the potential of targeting metabolic enzymes for cancer therapy. The team utilizes advanced metabolic assays, genetically engineered mouse models, and patient biospecimens to study how specific metabolites impact chromatin modifications, gene expression, and cell differentiation. Their goal is to modulate cellular metabolism to enhance stem cell function, strengthen immune responses, or inhibit cancer cell proliferation. No incidents or loss of containment have occurred. The purpose of the amendment is to update personnel and incorporate work with human blood, patient-derived tumor specimens, and two additional microorganisms: Citrobacter rodentium and Fusobacterium nucleatum (invasive).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:** III-D-3-b;III-F-8 Appendix C-II; III-F, Appendix C-I

f. **Highest containment level:** BSL-2

g. **Votes:**

For: 13

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

Amendment

21. **Review of SAF03771**

Title:	Amendment for LAB202200043
Investigator:	Kojo Elenitoba-Johnson
Submission ID	SAF03771

a. **Determination:** Approved
b. **Last day of continuing review period:** 9/30/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for adding personnel and Complete Freund's Adjuvant (CFA) as hazardous biologics. 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. **Highest containment level:** BSL-1
g. **Votes:**
For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

22. **Review of SAF03735**

Title:	Amendment for LAB202200126
Investigator:	Jan Grimm
Submission ID	SAF03735

a. **Determination:** Approved
b. **Last day of continuing review period:** 12/31/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for adding expression and purification of the Prostate Specific Mature antigen (PSMA) protein from Sf9 and High Five cells (insect 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-E
f. **Highest containment level:** BSL-1
g. **Votes:**
For: 13
Against: 0
Recused: 0
Absent: 4

Abstained: 0

Amendment

23. **Review of SAF03755**

Title:	Amendment for LAB202200009
Investigator:	Jonathan Coleman
Submission ID	SAF03755

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/28/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for adding urine collection, plasma for IMPACT and whole genome sequencing. The Reviewer concerns were addressed and recommended approval. The Committee voted to approve the amendment.
e. **Applicable section of NIH Guidelines:** N/A
f. **Highest containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

24. **Review of SAF03728**

Title:	Amendment for LAB202400017
Investigator:	Chrysothemis Brown
Submission ID	SAF03728

a. **Determination:** Approved
b. **Last day of continuing review period:** 12/31/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for adding three new strains of bacteria (two Lactobacillus species and Salmonella typhi), Adeno Associated Virus (AAV) vectors and update to personnel. 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. **Highest Highest containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

25. **Review of SAF03597**

Title:	Amendment for LAB202500005
Investigator:	Esther Babady
Submission ID	SAF03597

a. **Determination:** Approved
b. **Last day of continuing review period:** 1/31/2026
a. **Required modifications:** None
c. **Comments:** This amendment is for updating funding sources and updating tissues. The Reviewer concerns were addressed and recommended approval. The Committee voted to approve the amendment.
b. **Applicable section of NIH Guidelines:** N/A
c. **Highest containment level:** BSL-2
d. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

26. **Review of SAF03752**

Title:	Amendment for LAB202200058
Investigator:	Prasad Adusumilli
Submission ID	SAF03752

a. **Determination:** Approved
b. **Last day of continuing review period:** 7/28/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for adding personnel, updated cell lines and lentiviral vector. 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. **Highest containment level:** BSL-2
g. **Votes:**

For: 12
Against: 0
Recused: 1
Absent: 4
Abstained: 0

Amendment

27. **Review of SAF03747**

Title:	Amendment for LAB202300066
Investigator:	Luis Diaz
Submission ID	SAF03747

a. **Determination:** Approved
b. **Last day of continuing review period:** 10/31/2025
c. **Required modifications:** None
d. **Comments:** This amendment is for adding select agent (Staphylococcal enterotoxin B) in exempt quantity and updates to personnel. 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:** N/A
f. **Highest containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0

Amendment

28. **Review of SAMEND202500000003**

Title:	Amendment for LAB202300034
Investigator:	Vinod Balachandran
Submission ID	SAMEND202500000003

a. **Determination:** Approved
b. **Last day of continuing review period:** 5/31/2026
c. **Required modifications:** None
d. **Comments:** This amendment is for adding mRNA vaccine and updating personnel and 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:** III-C-1
f. **Highest containment level:** BSL-2
g. **Votes:**

For: 13
Against: 0
Recused: 0
Absent: 4
Abstained: 0