Institutional Biosafety Committee Minutes

Date: Wednesday, May 20, 2026

Time: 9:30 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE	MEMBERS ABSENT	STAFF
Busch, Robert H	Kalisvaart, Anna	Gonzalez Russi, Sabrina
Carroll, Ann M.	Schnappinger, Dirk	Lejb, Katarzyna
Finkernagel, Scott W.	Wagner, John A.	
Geri, Jacob		
Kaminsky, Stephen M.		
Lieggi, Christine		
McGuinn, Catherine		
Ndhlovu, Lishomwa (Lish)		
Otero, Miguel		
Repik, Gabrielle		

Meeting Minutes for Approval:

- April 15, 2026

No issues were raised and the committee approved the minutes from April 15, 2026.

Safety Officer Report

New Business

Conflicts of Interest Disclosure:
No member of the IBC may participate in the review of any project in which the IBC member is an investigator, has a financial conflict of interest, or has any other interest which has an adverse impact on the IBC member's ability to exercise independent judgment. Under such circumstances, the IBC member shall not be present during IBC deliberations, except to provide information requested by the IBC. Each member of the IBC shall respect and preserve the confidentiality of information he/she receives as a member of the IBC, and shall use, discuss, and/or disclose such information only for purposes related to deliberations or other assigned business of the IBC.

- *Dr. Kaminsky reported a Conflict of Interest with Dr. Nociari and Dr. Grinspan. Dr. Kaminsky will abstain from voting on these registrations.*

Protocols on Agenda

The Institutional Biosafety Committee (IBC) and Biosafety staff perform pre-reviews on all protocol submissions, including consideration of: agent characteristics (e.g., virulence, pathogenicity, environmental stability, replication competence), the types of manipulations planned, the sources of nucleic sequences (species), the nature of the nucleic acid sequences (e.g., structural, enzyme, oncogene, toxin, gene regulator), the hosts and vectors to be used, whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein in the proposed system.

IBC review includes: (i) independent assessment and setting of the containment levels required by the NIH Guidelines for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research; (iii) for recombinant or synthetic nucleic acid molecule research involving human research participants assessment focused on biosafety issues (e.g., administration, shedding) (iv) set containment levels in concert with the WCM IACUC.

Prior to reviewing a registration at the IBC meeting, the Principal Investigators laboratory is inspected to confirm that facilities and biocontainment equipment (e.g., certified Class II biological safety cabinets) are available and appropriate. We also determine if all laboratory personnel are appropriately trained to adhere to institutional and federal regulations to ensure the safe and compliant conduct of research.

All protocol submissions are made available to IBC members before the meeting. During the meeting, reviewers' and members' questions are presented, discussed, and sufficiently addressed. Protocols are voted on and acted upon by the IBC, i.e., applications are either approved, rejected or returned to the applicant to request clarifying information. Protocols deemed to require changes are returned to the PI for revision before subsequent review by the IBC. Principal Investigators are then provided the results of the IBC review and official approval.

Following initial approval, IBC registration remains valid for a period of two years. During this two-year period, laboratory inspections and review of training records of lab staff are conducted annually in accordance with Weill Cornell policies.

Human Subjects Research/Human Gene Transfer: Initial

HS Record Number: 26-03029940

HS PI Name: Varma, Gaurav

Record Title:

A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicab tagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy

RS Record Number: 26-0022

Notes: The assigned IBC member reviewed the protocol. The reviewer indicated that the application does not provide a study design, purpose, nor endpoints. Additionally, there is a request to update the SOP's for accidental exposure and post exposure for consistency of reporting to the PI. Once the requested information is provided, the reviewer will review and determine for administrative approval at BSL-2 with droplet/contact precautions.

Decision: Pending administrative approval

Laboratory Safety Registrations - Amendments

Record Number: 19-0018

PI Name: Brian Zeglis

Submission Type: Amendment

Notes: The assigned IBC member reviewed the lab protocol. This amendment includes the new microorganism to be

introduced into in vivo model, Streptococcus pyogenes. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and S. pyogenes to be approved at ABSL-2/ BSL-2.
Decision: Approved

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Microbiological work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	In vivo or in vitro?	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale
Streptococcus [Pyogenes]		SF370 Strain	Replication Competent	Both	Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA

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Record Number: 19-0175
PI Name: Shuibing Chen
Submission Type: Amendment
Notes: The assigned IBC member reviewed the lab protocol. This amendment includes work with Salmonella Typhimurium to evaluate bacterial entry into organoids. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and S. typhimurium to be approved at BSL-2.
Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/ vector will be propagated/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/ planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Salmonella [Typhimurium]		Salmonella enterica serovar Typhimurium SL1344 pFPV25-mCherry (source: Creative Biogene)	Replication Competent	S. Typhimurium SL1344-mCherry; mCherry expressed via native plasmid	In Vitro	Bacterial	MCherry expressed via native plasmid	Other/reef coral	Marker/Reporter	Transfect cells	BSL-2	NIH Applicable	Section II I-D-1

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Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0688
PI Name: Michael S. Glickman
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval at previously approved biosafety levels.
Decision: Approved

Recombinant Microorganism Tracking Table:

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Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/ vector will be propagated/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines

Mycobacterium [Tuberculosis]		We create recombinant strains of M. tuberculosis that either have gene deletions or express recombinant genes. Pathways/genes include: 1) DNA repair factors 2) protein folding factors in the DnaK path way 3) signal transduction factors (Rip1, antisigma factors, PdtaS/R)	Replication Competent	N/A	Both	In vivo	DNA rep air pathways (RecA/RecF/RecO/LexA, etc) signal transduction pathways (Rip1/PdtaS/PdtaR) Biosynthetic pathways (chalkophore biosynthesis)	Bacteria	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest	ABSL-3 ~ BSL-3	NIH Applicable	Section II I-D-1 ~ Section III-D-4

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Microbiological work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	In vivo or in vito?	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Mycobacterium [Tuberculosis]		human samples (stool, peripheral blood cells) from TB patients	Replication Competent	Both	Culturing ~ Introduction into in vivo model ~ Isolation DNA/RNA ~ Other/aerosol	ABSL-3 ~ BSL-3	Not rDNA	
Mycobacterium [Tuberculosis]		strain Erdman	Replication Competent	Both	Culturing ~ Introduction into in vivo model ~ Isolation DNA/RNA ~ Other/aerosol	ABSL-3 ~ BSL-3	Not rDNA	

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Record Number: 19-0707

PI Name: Marshall J. Glesby

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. The reviewer requested to update the SARS-CoV-2 post exposure risk language. No other issues were raised. With this administrative change, the reviewer recommended approval at previously approved biosafety levels.

Decision: Approved with administrative changes

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Microbiological work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	In vivo or in vitro?	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Human Immunodeficiency Virus (HIV) [Retroviridae/Lentiviridae Types 1 and 2]		HIV Patient Samples	Replication Competent	In Vitro	Other/We separate, aliquot, and freeze serum and plasma and isolate/freeze PBMCs	BSL-2+	Not rDNA	
*Other	MonkeyPox	Clade II	Replication Competent	In Vitro	Other/No genetic manipulation. Collection of swaps/whole blood. No cell isolation or cell cultures.	BSL-2	Not rDNA	
*Other	Infectious SARS-CoV-2 patient samples	SARS-CoV-2	Replication Competent	In Vitro	Other/Serum and plasma separation, aliquoting and freezing for future shipment	BSL-2+	Not rDNA	

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Record Number: 21-0077

PI Name: Marcelo Mario Nociari

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. The reviewer requested to select an answer to question 2 in the eForm regarding DURC. No other issues were raised. With this administrative change, the reviewer recommended approval at previously approved biosafety levels.

Decision: Approved with administrative changes

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/vector will be propagated/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/ Lentiviridae]		We use SIGMA/ALDRICH MISSION(R) pLKO.1-puro plasmid Vector to produce the lentiviruses.	Replication Incompetent/ Deficient	293T cells	In Vitro	Human	TFEB, MCOLN1, IRE1alpha	Human	Other/Transcription factor	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Record Number: 21-0126

PI Name: Jonathan Zippin

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval at previously approved biosafety levels.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/vector will be propagated/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level (s)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/ Lentiviridae]		pLenti-6, pCW57	Replication Incompetent/ Deficient	293 and other mammalian cell lines	Both	In vivo ~ Bacterial ~ Human	Soluble Adenylyl cyclase (ADCY10); GFP and luciferase; OCA2; TPC2; TYR; DCT; YAP; TAZ; LATS; HDAC4; NRAS; BRAF; ATP6V1G1, VAMP7, OCA2, TYRP1, DCT, TYR, His-ubiquitin; shRNA against PDE8, PDE8A, PDE4D	Human ~ Jellyfish ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences ~ Other/increased cAMP signaling, melanosome activity, Hippo signaling	Create virions ~ Express/Upregulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cell line ~ Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-2 ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Microbiological work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	In vivo or in vitro?	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Escherichia Coli		DE3	Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	BSL-1	NIH-Exempt	

Record Number: 23-0040

PI Name: Yue (Cindy) Yang

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval at previously approved biosafety levels.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/vector will be propagated/ packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biologic al activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level (s)	Regulatory Rationale	Applicable NIH Guidelines
Escherichia coli [K12]		BL21, pet-28a expression vector	Attenuated ~ Replication Incompetent /Deficient	BL21	In Vitro	In vivo	COVID-19 3CL protease (synthetic gene non-identical to native).	Virus	Other/protease	Express/ Upregulate gene of interest	BSL-1	NIH Applicable	Section II I-D-2
Adenovirus [Human, all types]		Ad-GFP-U6-m-A DK-shRNA; Ad-GFP-U6-shRNA	Replication Incompetent/Deficient	HEK 293, Neu2a	Both	In vivo ~ Human	Adenosine Kinase, down regulation in model, GFP	Murine ~ Virus	Gene Expression Regulators ~ Marker/Reporter	Direct inject into in vivo model ~ Repress/Downregulate gene of interest ~ Transfect cells	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Acknowledgement of Laboratory Safety Registrations: No IBC-Applicable Work Conducted

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0690	Zev Rosenwaks	Lab Registration - Renewal

Acknowledgment of Approved Administrative Amendments

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0440	Juan R Cubillos-Ruiz	Lab Registration - Amendment

Acknowledgment of Human Subjects Research/Human Gene Transfer: Annual Report

HS Record Number: 24-12028290

HS PI Name: Grinspan, Zachary

Record Title:

n-of-1 study of an AAV9 Gene Therapy for Treatment of Severe Developmental and Epileptic Encephalopathy (DEE) due to a mutation in the Interferon Regulatory Factor 2 Binding Protein-Like (IRF2BPL) gene

RS Record Number: 24-0155

Notes:

Decision: Approved

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0026	Leandro Cerchietti

19-0428	Ari M. Melnick
23-0037	Sariah Khormaee
23-0154	Lisa Giulino Roth

The meeting adjourned at 10:04 AM.