



Institutional Biosafety Committee Minutes

Date: Wednesday, January 21, 2026

Time: 9:30 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE

Busch, Robert H
Carroll, Ann M.
Finkernagel, Scott W.
Kaminsky, Stephen M.
Lieggi, Christine
McGuinn, Catherine
Ndhlovu, Lishomwa (Lish)
Otero, Miguel
Repik, Gabrielle
Wagner, John A.

MEMBERS ABSENT

Schnappinger, Dirk

STAFF

Gonzalez Russi, Sabrina

Meeting Minutes for Approval

- December 17, 2025

No issues were raised and the committee approved the minutes from December 17, 2025

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. Ram. Dr. Kaminsky abstained from voting on this registration.*
- *Dr. Otero reported a Conflict of Interest with Dr. Park-Min, Dr. Zhao, Dr. Barrat, and Dr. Ivashkiv. Dr. Otero abstained 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: 25-05028907

HS PI Name: Ram, Eilon

Record Title: Epicardial Delivery of XC001 Gene Therapy to promote Angiogenesis in CAD Patients undergoing Treatment with CABG (EXACT-CABG)

RS Record Number: 25-0118

Notes: The assigned IBC member reviewed the protocol. No issues were raised. The reviewer recommended approval at BSL-2 with standard contact precautions.

Decision: Approved

Laboratory Safety Registrations - Initials

Record Number: 25-0096

PI Name: Dhiman Pal

Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. No issues were raised. The reviewer recommended approval of the Lentiviral vector 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
Lentivirus [Retroviridae/Lentiviridae]		second and third generation Lentiviral plasmids	Replication Incompetent/ Deficient	HL60, RAW264.7, MDA 231, HEK293T cell lines	In Vitro	In Vivo ~ Human	lipid metabolic genes, RAS genes	Virus	Marker/Reporter ~ Oncogenic Gene Sequences ~ Unknown	Create virions ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0154

PI Name: Alessandra B. Pernis

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted minor changes, such as additional descriptive work with human samples and the removal of work with COVID-19 samples. Modifications were made to the exempt recombinant DNA section, and the recombinant microorganism table was updated. The reviewer recommended including risk language for Retroviral work and to mark oncogenic gene sequences for both Retroviral and Lentiviral work. With these administrative changes, the reviewer recommends approval of Retrovirus and Lentivirus at ABSL-2/BSL-2+.

Decision: Approved with administrative changes

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
Retrovirus [Amphotropic]		pMIG, PGCIRES	Replication Incompetent/ Deficient	HEK293, B-Cell Lines, T-Cell Lines	Both	In Vivo ~ Human	IRF4, IRF5, IRF8, IBP/DEF6, SWAP-70, ROC K1, ROC K2, Bach 2, HRI, cGAS, STING	Human ~ Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences ~ Marker/Reporter ~ Other/ Pathway regulators, signaling, molecules, enzymes.	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line ~ 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
Lentivirus [Retroviridae/Lentiviridae]		pLentiLox, pLKO.1, pHAGE, pCRISPR-LvSG02, pCW57.1, pMD2.G, pPAX2	Replication Incompetent/ Deficient	HEK293, B-Cell Lines, T-Cell Lines	Both	In Vivo ~ Human	IRF4, IRF5, IRF8, IBP/DEF6, SWAP-70, ROC K1, ROC K2, Cas9, Bach2, HRI, cGAS, STING	Human ~ Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences ~ Other/ Pathway regulators, signaling, molecules, enzymes.	Create virions ~ Direct inject into In Vivo model ~ 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

Record Number: 19-0286

PI Name: Kyung-Hyun Park-Min

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols 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
Retrovirus [Amphotropic]		pMX-IR ES puromycin	Replication Incompetent/ Deficient	293T cells	In Vitro	In Vivo ~ Human	MYC,NF ATC1, ES RRA, MI CD, MTO R, TSC 1, TSC2, N RF2, SRE BF1, SRE BF2, BAT F, MAF, MAFF, F ASN, Schurri-3, sclerostin, cathepsin K, and Rank	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Lentivirus [Retroviral/Lentiviral]		pLenti C MYC-D DK	Replication Incompetent/ Deficient	293T cells	In Vitro	In Vivo ~ Human	c-Fms, mutant c-Fms, MIC D, TACE, Enhancer RNAs, Schnurri-3, sclerostin, cathepsin K, and Rank	Human ~ Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences ~ Other/Regulates Osteoclasts and osteoblasts	Create virions ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Adenovirus [Human, all types]		type5(dE1-E3)	Replication Incompetent/ Deficient	HEK293	In Vitro	In Vivo ~ Human	TACE, S REBP-2, GFP (as a control), PPARgamma, BAT F, MAF, IRF7, IRF 3, TLR4, TLR3, E GFR	Human	Antibiotic Resistance ~ Gene Expression Regulators ~ Oncogenic Gene Sequences ~ Other/Regulates Osteoclasts and osteoblasts	Transfect cell line	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Adeno-Associated Virus (AAV)		AAV2, AAV6, and AAV9 (from Dr. Jae-Hyuck Shim at UMass Medical Center, AAV Manufacturing facility core center)	Replication Incompetent/ Deficient	293 T cells	In Vitro	Human	c-Fms, mutant c-Fms, MIC D, TACE, Enhancer RNAs, Schnurri-3, sclerostin, cathepsin K, and Rank	Human ~ Murine	Cytokine ~ Marker/Reporter	Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3

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
Listeria [Monocytogenes]		Listeria Monocytogenes 1043S	Replication Competent	In Vivo	Conduct Multiplicity of infection (MOI) studies ~ Culturing ~ Introduction into In Vivo model	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0600

PI Name: Gang Lin

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols 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) of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Escherichia coli [K12]		DH5alpha, BL2(D E3), Rosetta, Mac h1, Stb13	Replication Competent	E. Coli	In Vitro	Bacterial	prcBA, (M.tb), UBR5 (Human), E1 (Mouse)	Bacteria ~ Human ~ Murine	Gene Expression Regulators	Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-1	NIH Applicable	Section II 1-D-2

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
Plasmodium [Falciparum]		3D7	Replication Competent	In Vitro	Other	BSL-2	Not rDNA	

Record Number: 25-0008

PI Name: Abid Hussaini

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval of AAV at ABSL-1/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) of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)
Adeno-Associated Virus (AAV)		AAV8-E F1a-DIO -hChr2 (H134R) AAV8-h Syn-DIO -EGFP A AV-TH- Cre virus AAV-DI O-eNPh R2 AAV-CaMKII a-ChRmine-oScar let-Kv2.1-WPRE AAV-Efl a-DIO C hRmine-oScarlet-Kv2.1-W PRE AA V-CaMK IIa-hChr 2(H134 R)-mCherry AAV 5- CaMK IIa-hM4 Di-mCherry AAV 5- CaMK IIa-hM3 Dq-mCherry AA V8-hSyn -DIO-H A-hM4D (Gi)-IRE S-mCitrine AAV8 -hSyn-DI O-HA-h M3D(G q)-IRES- mCitrine AAV_Bi PVe3_Ch R2_mCherry AA V_BiSS Te10_Ch R2_mCherry AAV -PolyA-Reelin i Cre min CMV (T RE3G) Odz WP RE AAV- PolyA-C alb/WFS 1 iCre mi nCMV (TRE3G) Odz WP RE	Replication Incompetent/Deficient	AAV vectors are produced in HEK 293 cells	Both	In Vivo	Channelrhodopsin-2 (ChR2) gene, Tyrosine Hydroxylase, Human M4 muscarinic DR EADD (hM4Di) gene, Human M3 muscarinic DREAD D (hM3D (Gq)) gene, Enhanced Natronomonas pharaonis halorhodopsin 2 gene upregulated in targeted neurons upon Cre-mediated recombination and used for downregulation of neuronal activity upregulated in CamKIIa-expressing (excitatory) neurons, upregulated or downregulated in PV+ inhibitory neurons, SST: upregulated or downregulated in SST+ inhibitory neurons, Reelin: upregulated or downregulated in Reelin, upregulated or downregulated in Calbindin or WFS1+ neurons	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter	Direct inject into In Vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells introduce into In Vivo model	ABSL-1 ~ BSL-2

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0643	Jason McCormick	Lab Registration - Renewal
19-0645	Baohong Zhao	Lab Registration - Renewal
25-0108	Qiuying Chen	Lab Registration - Initial

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
22-0087	Edwin Carl Fluck	Lab Registration - Renewal
25-0099	Zhen Zhao	Lab Registration - Initial

Approved Extension of Expiration Date to February 18, 2026

Record Number	PI Name
19-0231	Franck Barrat
19-0115	Lionel Ivashkiv

The meeting adjourned at 9:52 AM.