



Institutional Biosafety Committee Minutes

Date: Wednesday, February 18, 2026

Time: 9:30 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE

Busch, Robert H
Carroll, Ann M.
Finkernagel, Scott W.
Geri, Jacob
Kaminsky, Stephen M.
Lieggi, Christine
Otero, Miguel
Repik, Gabrielle
Schnappinger, Dirk
Wagner, John A.

MEMBERS ABSENT

McGuinn, Catherine
Ndhlovu, Lishomwa (Lish)

STAFF

Gonzalez Russi, Sabrina

Meeting Minutes for Approval

- January 21, 2026

No issues were raised and the committee approved the minutes from January 21, 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. Otero reported a Conflict of Interest with Dr. Ivashkiv and Dr. Barrat. 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/Biological Agents: Initial

HS Record Number: 25-10029493

HS PI Name: Varma, Gaurav

Record Title:

IOV-GM1-201: A Phase 1/2, open-label study of PD-1 knockout tumor-infiltrating lymphocytes (IOV-4001) in participants with unresectable or metastatic melanoma or Stage III or IV non-small-cell lung cancer

RS Record Number: 25-0101

Notes: The assigned IBC member reviewed the protocol. The reviewer noted that Phase 1 also needs to be selected on the application for the clinical trial. No other issues were raised. With this administrative change, the reviewer recommended approval at BSL-2 with standard contact precautions.

Decision: Approved with administrative changes

Laboratory Safety Registrations - Amendments

Record Number: 19-0143

PI Name: Melody Zeng

Submission Type: Amendment

Notes: The assigned IBC member reviewed the lab protocols. The amendment includes the addition of AAV in vivo model. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and the additional line of AAV at ABSL-1.

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
Adeno-Associated Virus (AAV)		AAV2-GFP, AAV2-GFP-C	Replication Competent	N/A	In Vivo	In vivo	GFP, CRE	Bacteriophage ~ Jellyfish	Marker/Reporter	Direct inject into In vivo model	ABSL-1	NIH Applicable	Section III-D-4

Record Number: 20-0026

PI Name: Lishomwa (Lish) Ndhlovu

Submission Type: Amendment

Notes: The assigned IBC member reviewed the lab protocols. The amendment added propagation of multiple patient derived HIV-1 strains obtained from BEI, to the recombinant DNA table and registration overview. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and HIV, specifically patient derived strains from BEI, 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
Human Immunodeficiency Virus (HIV) [Retroviridae/Lentiviridae Types 1 and 2]		HIV patient derived Strains from BEI: HIV-1 Ba-L, HIV-1 NL4.3, HIV-1 DH12, HIV-1 GKO, HIV-1 MN, HIV-1 CC, HIV-1 Lai, HIV-1 ADA, HIV-1 MAL, HIV-1 NH4.3 GFP, HIV-1Ba-L mCherry, HIV-1 Lai, HIV-1 CAM0002BBY, HIV-1 CAM1475MV, "HIV-1 312: PKT-0515, Clone D8", "HIV-1 317: JJS-0520, Clone G7", HIV-1 92/RW/020, "HIV-193/UG/065", HIV-1 Donor E, HIV-1 RF/41-D2, "HIV-1 MVP 5180/91", "HIV-1 93/MW/965", "HIV-1 xxHIV-1 LAI", HIV-1 A018A (H112-2), "HIV-1 91/DJ/263", HIV-1 92/TH/001, "HIV-1 92/BR/003", HIV-1 QZ4589, HIV-1 ELL, HIV-1 RTMC, HIV-1 RTME, HIV-1 RTMDR1, HIV-1 JR-FL, "HIV-1 THAI H9466", "HIV-192/US/660", "HIV-1 92/HT/593", HIV-1 SF162, HIV-1 RF, HIV-1 93/IN/101, "HIV-1 94/KE/105", HIV-1 G3, HIV-1 ME46, "HIV-1 90/SN/364 (GS015)", "HIV-1 89/SO/145 (GS 016)", "HIV-1 93/ID/12(GS 025)", "HIV-1 M124 LMU", "HIV-1 KAT 780218", HIV-1 L8-27, HIV-1 202: SK001 B1, HIV-1 BZ162 (GS 031), "HIV-1 HH8793 (GS 029)", HIV-1 Donor E, HIV-1 92/TH/006,	Replication Competent	HEK293T Cell, Activated CD4, TZM-BI	Both	In vivo~Bacterial~Human	mCherry, eGFP	Human	Marker/Reporter~Other~Virulence Factors or Enhancers	Direct inject into In vivo model~Transfect cell line~Transfect cells	BSL-2+	NIH Applicable	Section III-D-1~Section III-D-3

		HIV-1 92/TH/014, HIV-1 JR-CSF, HIV-1 TZBD9/11 (01TZ_911), HIV-1 KNH1144, HIV-1 Kvch, HIV-1 BiSi HIV-1 Mues, HIV-1 MoKw, HIV-1 SaNe, HIV-1 Zach, HIV-1 BF17, HIV-1 FaKi, HIV-1 MiMa, HIV-1 RBF125, HIV-1 YBF16, HIV-1 YBF35, HIV-2 AWY, "HIV-1 92/PR/729", "HIV-1 93/US/140", "HIV-1 Saquinavir-Resistant", HIV-1 BZ167, HIV-1 BCB93, HIV-1 YBF30, HIV-198/CN/006, "HIV-198/IN/022", "HIV-198/TZ/013", "HIV-197/ZA/003", HIV-196/ZM/651											
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Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0115

PI Name: Lionel B Ivashkiv

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols. The reviewer noted the administrative contact needs to be added to the registration form. The Lentivirus transcription factor Maf is a protooncogene, therefore the box for oncogenic gene sequences should be checked. No other issues were raised. With these administrative changes, the reviewer recommended approval at previously approved biosafety levels and the additional line of AAV at ABSL-1.

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/vee tor will be propagate d/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]		ecotropic (pMX-IRES Puro)	Replication Incompetent/Deficient ~ Self-Inactivating	HEK293 (PLATE), mouse bone marrow cells	In Vitro	In vivo ~ Human	cytokines, transcription factors (COMMD)	Human	Cytokine ~ Gene Expression Regulators	Create virions ~ Express/Uprregulate gene of interest ~ Transfect cell line	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Lentivirus [Retroviridae/Lentiviridae]		pLenti-C, pL-CRIS PR.EFS.G FP	Replication Incompetent/Deficient ~ Self-Inactivating	HEK293, mouse bone marrow and human THP-1 monocytic cells, primary monocytes, synovial fibroblasts, and IMR-90 fibroblastic cell line	In Vitro	In vivo ~ Human	cytokines, transcription factors (Maf), A20	Human	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Create virions ~ Express/Uprregulate gene of interest	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Adenovirus [Human, all types]		Ad-CMV-Null (Ad5)	Attenuated ~ Replication Incompetent/Deficient	purchased Adenoviruses (Vector Biolabs, Cell Biolabs), Primary human monocytes	In Vitro	Human	cytokines, transcription factors (Maf), GFP	Human	Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/Uprregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1

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
Staphylococcus [Aureus]		XEN36, USA 300	Replication Competent	Both	Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Mycobacterium [Bovis - BCG Vaccine Strain]		ATCC (TMC1028)	Attenuated	Both	Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0231

PI Name: Franck J. Barrat

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted this renewal includes the additional use of E. coli as a bacterial expression vector. No issues were raised. The reviewer recommended approval at previously approved biosafety levels.

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	Applicable NIH Guidelines
Influenza Virus [Orthomyxoviridae Types A, B, C]		H1N1, strain A/P R/8/34 (inactivated)	Attenuated Replication Competent	~ In Vitro	Culturing	BSL-2	Not rDNA	
*Other	House Dust Mite	Dermatophagoides pteronyssinus	Replication Incompetent/Deficient	In Vivo	Introduction into In vivo model	ABSL-1 ~ BSL-2	Not rDNA	
Herpes Simplex Virus [Herpesviridae/Alpha-herpesviridae types 1, 2]		KOS (inactivated)	Attenuated Replication Competent	~ In Vitro	Culturing	BSL-2	Not rDNA	
*Other	Coronavirus (SARS CoV-2)	Inactivated SARS-CoV-2, Isolate U SA-WA1/2020 (BEI-NR52287, NR52286)	Replication Incompetent/Deficient	In Vitro	Culturing ~ Other/co-culturing inactivated SARS CoV-2 with cells from blood	BSL-2	Not rDNA	

Record Number: 19-0244

PI Name: Frederick R. Maxfield

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 Lentivirus at BSL-2+ and Retrovirus 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]		pMD2.G, psPAX2, FUWOK SM, pH R, pDHS, pCMV8.91, LT3R EPIR	Replication Incompetent/Deficient ~ Self-Inactivating	mouse J774 immortalized cell line	In Vitro	In vivo	Myc, Sox2, Oct4, Klf4, HSP1A1A, HSPA1B	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences ~ Other/We transfected cultured mouse macrophages (J774) to examine effects on lipid metabolism.	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

Retrovirus [Amphotropic]		pBABEpur GFP-LC3, pBABE-puro mCherry-EGFP-LC3B, pBABE GFP	Replication Incompetent/Deficient	mouse immortalized macrophages (J774)	In Vitro	In vivo	regulators of membrane traffic - endocytosis and exocytosis	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Other/ looking for changes in lipid transport and metabolism	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
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Record Number: 19-0294

PI Name: Heidi Stuhlmann

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
Lentivirus [Retroviridae/Lentiviridae]	Lentiviral and retroviral vectors	pLKO, FG12, pCCL2	Replication Incompetent/ Deficient	293, HUVEC, mESC, mTSC, mEC	Both	In vivo ~ Human	Egfl7: mouse and human angiogenic factor; pre-miR-126; various mouse Notch receptors and ligands, other interacting or downstream genes; eGFP: green fluorescent protein from A.victoria; MAP and ERK signaling pathway members	Human ~ Jellyfish ~ Murine	Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	ABSL-2~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4
Lentivirus [Retroviridae/Lentiviridae]		CRISPR/Cas9 "Smart Nucleases" lentivirus vectors (SBI)	Replication Incompetent/ Deficient	HEK293	Both	In vivo ~ Human	Cas9 nuclease, single guide RNA	Bacteriophage ~ Murine	Unknown	Direct inject into In vivo model ~ Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells	ABSL-2 ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Record Number: 19-0571

PI Name: Hugh C Hemmings

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
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Adeno-Associated Virus (AAV)		AAV1.Syn.GCaM P6s.WPRE.SV40, AAV-hSyn-Cre-GFP, P.AAV-hSyn-EGFP; serotype1; pAAV.hSynapsin.SF-iGluSnFR.S72 A; pAAV.hSynapsin.SF-iGluSnFR.A184S; pAAV.CAG.SF-iGluSnFR.S72A; pAAV.CAG.SF-iGluSnFR.A184S; AAVDJ-hSyn-DO-GCaMP6m; AAVDJ-E F1a-DIO-RCaMP2	Replication Incompetent/Deficient	cultured mouse hippocampus, in vivo hippocampus	Both	In vivo	mDlx-eGFP, GCaMP6-Ca2 + indicator, Cre recombinase tagged with GFP, and eGFP under the synapsin promoter	Fungi ~ Jellyfish ~ Murine ~ Other/Synthetic	Gene Expression ~ Regulators ~ Marker/Reporter	Direct inject into In vivo model ~ Transfect cells ~ Transfect cells / introduce into In vivo model	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-1 ~ Section III-D-4
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Record Number: 19-0579

PI Name: Heather Winona Stout-Delgado

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

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
Streptococcus [Pneumoniae]		ATCC 6303, serotype 3, ATCC 700669, serotype 27 F	Replication Competent	Both	Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Staphylococcus [Aureus]		ATCC 12600, serotype 3	Replication Competent	Both	Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Influenza Virus [Orthomyxoviridae Types A, B, C]		(H1N1) A/PR/8/34, HKx31	Attenuated Replication Competent	~ Both	Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0583

PI Name: Hasina Outtz Reed

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

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
Influenza Virus [Orthomyxoviridae Types A, B, C]		A/Puerto Rico/8/1934, 12.5 PFU	Attenuated Replication Competent	~ Both	Conduct Multiplicity of infection (MOI) studies ~ Culturing ~ Introduction into In vivo model	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0657

PI Name: Todd R. Evans

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 with the following changes to biosafety levels: Work with Gateway Cloning Vectors approved at BSL-2/ABSL-2 due to oncogenic sequences. Work with AAV done under BSL-1/ABSL-1 protocols, and work with lentivirus for in vivo/in vitro experiments approved at BSL-2+/ABSL-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, upregulated, downregulated, deleted, or	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]		eg. PrecisionXTM Gene Tagging HR Targeting Vector (T2A-GFP-pA-LoxP-EF1a-RF P-T2A-Puro-pA-LoxP-MCS), LGR5 Lentiviral Vector (Human) (CMV) (pLenti-GIII-CMV-GFP-2A-Puro), Empty control vector for pReceiver-Lv225, etc.	Replication Incompetent/ Deficient ~ Self-Inactivating	293T, to reprogram differentiated cells to a pluripotent state (embryonic stem cells)	In Vitro	In vivo ~ Human	Reprogramming factors, AI D, TET proteins, GFP and other FPs, GATA factors, variety of shRNA constructs	Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter ~ Oncogenic Gene Sequences	Create viruses ~ Express/Up regulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cell line	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3
*Other	Sandai Virus	N/A (purchased for use)	Replication Incompetent/ Deficient	N/A	In Vitro	In vivo ~ Human	Reprogramming factors (Myc, So2, Oct4, Klf4), Fluorescent proteins	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/Upregulate gene of interest	BSL-2+	NIH Applicable	Section II I-D-1
*Other	Plasmid cloning and expression vectors	pCS2, pCDNA3, pBluescript, pGEM, and derivatives	Replication Competent	E. coli	Both	In vivo ~ Human	GATA factors, Smads, SIP signaling components, many other transcriptional regulators and signaling molecules eg. for WNT, TGF-β and other developmental pathways. Fluorescent proteins (such as GFP).	Human ~ Murine ~ Zebrafish	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter	Direct inject into In vivo model ~ Express/Up regulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-I ~ Section III-D-4
*Other	Plasmid targeting vectors	pLoxP, pICE	Replication Competent	E. coli, mouse or human embryonic stem cells	Both	In vivo ~ Human	GATA factors, Smads, chimeric or mutant variants, Cre recombinase	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Direct inject into In vivo model ~ Express/Up regulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-I ~ Section III-D-4
*Other	Gateway cloning vectors	5' entry, middle entry, 3' entry, destination vectors	Replication Competent	E. coli	Both	In vivo ~ Human	Large variety of promoters, cDNAs and reporter genes (such as GFP, RFP). TALENs and CRISPR-guide RNAs, transposases and Cas9 RNA.	Human ~ Murine ~ Zebrafish	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Direct inject into In vivo model ~ Express/Up regulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Appendix C-I ~ Section III-D-4
Adeno-Associated Virus (AAV)		pseudotyped AAV9 (AAV2 core)	Replication Incompetent/ Deficient	N/A (obtained commercially)	In Vivo	In vivo	sgRNAs targeting mouse genes listed above or growth factors listed above plus dTomato	Murine	Cytokine ~ Marker/Reporter	Direct inject into In vivo model	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4

Lentivirus [Retroviridae /Lentiviridae]		pCCL4, GFP.Cre empty, pVLX-Tight-Puro, VLX-Puro, pLVX-Tet-Off Advanced, pLVX-Tet-On Advanced, pLVX-V, pLenti-CRISPR	Replication Incompetent/Deficient	293T	Both	In vivo ~ Human	RET, EPHB2, DYRK1A, CHD8, SKI, CUL3, ELAVL4, POGZ, FGF2, FGF10, GDNF, CSF1, ETV5, UTF1, GPR125, E4ORF1, IKB1, KISS, p65, Cdh1, EPCAM, βcatenin, Oct4, Sox2, CKIT, NANOG, AKT, Klf4, P53, C-KIT, CCND2, CCND1, RARα,β,γ, RXRα,β,γ, P21, pRb, CDK2/4, CCNE1, CDK1/2/4, Lin28, CDKN1A, CDKN2A, Hif1a, cMyc, nMyc, DX4, Dazl, FGF22, FGF9, HRAS, KRAS, ITGA6, Laminin, PTN11, FGFR1-4, His-tag, TBX3FLAG tag, GFP, RFP, mCherry, tet transactivator, reverse tet transactivator, Bcl6, Spry family, Dusp family, Lztr1, antibiotic resistance genes, LacZ, DPPA4, BCN1; Variants of genes above including gain and loss-of function mutations and corresponding shRNAs; CRISPR/Cas9	Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells / introduce into In vivo model	BSL-2+ ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-2 ~ Section III-D-3
Retrovirus [Amphotropic]		pMIG class of replication defective vectors	Replication Incompetent/Deficient	293T	In Vitro	In vivo ~ Human	AID, TET proteins, GFP, various shRNA constructs	Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Record Number: 21-0074

PI Name: Michael Podolsky

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
Adenovirus [Human, all types]		Ad-5 (E1A deletion)	Replication Incompetent/Deficient	293A	In Vitro	In vivo ~ Human	Cre Recombinase, Rac1, RhoA, Sel11, Mzf1, Mrc2, Ebf1, Tfap4	Bacteriophage ~ Human	Other/ Hypothesized to have an effect on collagen turnover genes	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 ~ Section III-F-6

Lentivirus [Retroviridae/Lentiviridae]	pSicoR, pHIV, pLKO.1, pLenti, pCW57.1	Replication Incompetent/Deficient ~ Self-Inactivating	HEK293T	Both	In vivo ~ Human ~ Insect	shRNA or overexpression sequences: COP9, COP9/alien, dCAS9, Mrc2, Sel11, Flotillin, Mrc1, Sec61 b, Mzf1, Cdc7, Cbx5, Tram 2, Col1a1, Col1a2, Col5a1, Col5a2, Col5a3, Gapdh shRNA, sgRNA, dsRNA, GFP, mCherry, Cre, TERT, TERC, Ebfl, Tfap4	Bacteria ~ Bacteriophage ~ Human ~ Jellyfish ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences ~ Other/ Hypothesized to regulate downstream collagen synthesis or collagen degradation genes	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 ~ Section III-F-6
Murine leukemia virus [Viral vector/In vivo retrovirus]	pBABE (MMLV)	Replication Incompetent/Deficient	HEK293 T	In Vitro	Human	Signaling Protein genes, TERT, TERC	Human ~ Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences ~ Other/ Hypothesized to have effect on collagen turnover genes.	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 ~ Section III-F-6

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
24-0090	Romulo Hurtado	Lab Registration - Renewal

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0382	Renat Shaykhiev
19-0668	Suzanne Adele Maher
19-0695	Lee Cohen-Gould
24-0024	Michael Corley

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0003	Alessio Accardi	Lab Registration - Renewal
19-0014	Crina Nimigeian	Lab Registration - Renewal
19-0435	Olga Boudker	Lab Registration - Renewal
19-0655	Simon Scheuring	Lab Registration - Renewal
19-0656	Yuan-Shan Zhu	Lab Registration - Renewal
23-0035	Lisa Newman	Lab Registration - Renewal

Human Subjects Research/Human Gene Transfer: Annual Report

HS Record Number: 23-09026471

HS PI Name: Gribbin, Caitlin K

Record Title:

KT-US-484-0136:An Adaptive Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of Axicabtagene Ciloleucel versus Standard of Care Therapy as First-Line Therapy in Subjects with High-Risk Large B-Cell Lymphoma (ZUMA-23)

RS Record Number: 23-0136

Notes:

Decision: Approved

Request for Extension of Expiration Date to March 18, 2026

Record Number	PI Name
19-0633	Mary E. Choi

The meeting adjourned at 10:13 AM.