



Institutional Biosafety Committee Minutes

Date: Wednesday, April 15, 2026

Time: 9:31 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE

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

MEMBERS ABSENT

Carroll, Ann M.
Geri, Jacob
Schnappinger, Dirk

STAFF

Gonzalez Russi, Sabrina
Lejb, Katarzyna

Meeting Minutes for Approval:

- March 18, 2026

No issues were raised and the committee approved the minutes from March 18, 2026.

Safety Officer Report

New Business

- **Introduction of new IBC member resource: Vector Biosafety Guide**

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.

- *No Conflicts of Interest reported.*

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.

Laboratory Safety Registrations - Amendments

Record Number: 20-0142

PI Name: Karin Hochrainer

Submission Type: Amendment

Notes: The assigned IBC member reviewed the lab protocols. This amendment includes the addition of AAV delivery into in vivo models and the addition of Nedd4-1 to be manipulated in vitro and in vivo by Lenti or AAV mediated delivery. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and Lentivirus 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
Lentivirus [Retroviridae/Lentiviridae]		derived from pLV (gene of interest), pMD2.G (VSV-G envelope), and pCMVdeltaR8.91 (gag-pol) plasmids second generation	Replication Incompetent/Deficient	HEK293T cell line	In Vitro	In vivo ~ Human	GFP, MAPT, deubiquitinases (DUBs), palmitoyl transferases, Nedd4-1	Human ~ Murine ~ Other/synthetic	Marker/Reporter ~ Other/ Tau protein overexpression and mislocalization; ubiquitination and palmitoyltransferase activities	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
Adeno-Associated Virus (AAV)		AAV(PH P.eB) (SignaGen)	Replication Incompetent/Deficient	AAV-HT packaging cell line (Signa Gen)	Both	In vivo	GFP, mCherry, CaMKIIa, palmitoyltransferases, Nedd4-1	Human ~ Murine ~ Other/synthetic	Marker/Reporter ~ Other/kinase activity; ubiquitination and palmitoyltransferase activities	Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells / introduce into in vivo model	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-4

Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0010

PI Name: Sandra Demaria

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the addition of a series of genes, the use of PCR, and RT-PCR in 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]		Stbl3, pTRIPZshRNA vector, pMD2G (envelope plasmid), PsPAX2 (packaging plasmid, pCDNA3)	Replication Incompetent/Deficient ~ Self-Inactivating	HEK293 FT, GP293, PlatA, PlatE	Both	In vivo ~ Human	Mb21d1, Tmem173, CD73, RNaseH1, cd47, RNaseH2, zbp1, TP53, Trex1	Bacteria ~ Human ~ Murine	Cytokine ~ Marker/Reporter ~ Other/ DNA and RNA Sensor, nuclease (RNase H1)	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate 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

Record Number: 19-0155

PI Name: Claire I Vanpouille-Box

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the change of the route of administration in 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]		Stbl3, T RIPZ	Replication Incompetent/Deficient ~ Self-Inactivating	HEK293 FT	Both	In vivo ~ Human	Inhba, TGFb, Trex	Murine	Cytokine ~ Other/DNA exonuclease, TGFb superfamily members	Repress/Downregulate gene of interest ~ Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-2 ~ Section III-D-3 ~ Section III-D-4

Record Number: 19-0161

PI Name: Xiaojing Ma

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the addition of new genes under Retrovirus work in 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]		pMSCV (VectorBuilder)	Replication Incompetent/ Deficient	Platinum-E	In Vitro	In vivo	SMAD2, SMAD3, GranzymeB, shRNA UBR5, shRNACDK9, cmyc, rpl11	Murine	Gene Expression Regulators	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

Record Number: 19-0458

PI Name: Neal F Lue

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
Ustilago [Maydis]		FB1, UC M350	Replication Competent	none	In Vitro	Fungal	telomere-related genes	Fungi	Gene Expression Regulators	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-1	NIH Applicable	Section II I-F-4

Candida		glabrata (BG2, BG14), parapsilosis CLIB214 derivatives	Replication Competent	N/A	In Vitro	Fungal	telomere regulation: Cdc13, Stn1, Ten1, Pri1, Pri2, Pol12, Pol1	Fungi	Gene Expression Regulators	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1
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Record Number: 19-0473

PI Name: Laura Santambrogio

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted no changes associated with this renewal. The reviewer requested to check for indication of work with human cells. No other issues were raised. The reviewer recommended approval at previously approved biosafety levels and Lentivirus to be approved at ABSL-2/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)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/Lentiviridae]		Lentiviral vector containing GFP and TFEB under the control of the mCD11c promoter (mCD11c promoter-GFP-TFEB-lentiviral vector).	Replication Incompetent/ Deficient ~ Self-Inactivating	DCs TFEB	Both	In vivo	CD34 positive hematopoietic stem cells from model	Murine	Gene Expression Regulators	Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-2 ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Mammalian Expression Vector		pVAX-FIT3L	Replication Incompetent/ Deficient	NA	In Vivo	In vivo	vaccine construct, as a means to stimulate dendritic cell (DC) proliferation. DNA vaccines harboring mFlt3L (model Fms-like tyrosine kinase 3 ligand)	Murine	Gene Expression Regulators	Direct inject into in vivo model	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-1 ~ Section III-D-4

Record Number: 19-0692

PI Name: Beate Schwer

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
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Escherichia coli [K12]		pET16, pUC18	Replication Competent	E. Coli (B L21(DE3) and Dg98)	In Vitro	Bacterial	Kinases and phosphatases involved in transcription regulation (e.g. Cdk9, Csk1, Fcp1, Ssu72, Dis2); components of the cleavage/polyadenylation and termination machinery (e.g. Ctf1, Ppn1, Swd22, Rhn1); Rpb1; genes involved in inositolpyrophosphate metabolism and sensing (e.g. Asp1, Spx1)	Fungi	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells	BSL-1	NIH Applicable	Section II I-D-2
Saccharomyces [Cerevisiae]		Expression vectors: PRS415, PRS316, pRE, P41x, pDS472	Replication Competent	Saccharomyces cerevisiae, Schizosaccharomyces pombe	In Vitro	Fungal	Kinases and phosphatases involved in transcription regulation (e.g. Cdk9, Csk1, Fcp1, Ssu72, Dis2); components of the cleavage/polyadenylation and termination machinery (e.g. Ctf1, Ppn1, Swd22, Rhn1); Rpb1; genes involved in inositolpyrophosphate metabolism and sensing (e.g. Asp1, Spx1)	Bacteria ~ Fungi	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells	BSL-1	NIH Applicable	Section II I-D-2

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0633	Mary E. Choi	Lab Registration - Renewal
25-0071	Rie Nygaard	Lab Registration - Renewal

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
23-0127	Silvia Chiara Formenti	Lab Registration - Renewal
24-0035	Lan Zhou	Lab Registration - Renewal

Human Subjects Research/Human Gene Transfer: Closure

HS Record Number: 25-04028729

HS PI Name: Grinspan, Zachary

Record Title:

A Phase 1/2a, Open-Label, Multi-Center, Dose-Escalation Trial to Assess Safety, Tolerability, and Efficacy of a Single Dose of CAP-002 Gene Therapy Administered to Pediatric Patients with Syntaxin-Binding Protein 1 (STXBP1) Encephalopathy

RS Record Number: 25-0038

Notes:

Decision: Closed/Completed

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0164	Bjorn F Kafsack
19-0739	Steven Lipkin

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0633	Mary E Choi	Lab Registration - Renewal
25-0071	Rie Nygaard	Lab Registration - Renewal

The meeting adjourned at 9:49 AM.

