Institutional Biosafety Committee Minutes

Date: Wednesday, June 18, 2025

Time: 9:30 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE	MEMBERS ABSENT	STAFF
Brown, Anthony	Gross, Steven S.	Gonzalez Russi, Sabrina
Busch, Robert H		Lejb, Katarzyna
Carroll, Ann M.		
Finkernagel, Scott W.		
Kaminsky, Stephen M.		
Lieggi, Christine		
McGuinn, Catherine		
Otero, Miguel		
Repik, Gabrielle		
Schnappinger, Dirk		
Wagner, John A.		
Willis, Dianna E.		

Meeting Minutes for Approval

- *May 21, 2025*

No issues were raised, and the committee approved the minutes from May 21, 2025

Safety Officer Report

New Business

1. Public posting of June meeting minutes on website.

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. Grinspan, Dr. Crystal and Dr. Kaplitt.*

Human Subjects Research/Human Gene Transfer: Initial

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

Decision: Approved

Laboratory Safety Registrations - Amendments

Record Number: 21-0126

PI Name: Jonathan Zippin

Submission Type: Amendment

Notes: The assigned IBC member reviewed the work with three new genes to be manipulated with recombinant nucleic acids or shRNA. Also, an IACUC registration number is included in this amendment. No issues were raised. The reviewer recommended approval 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, 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; B RAF; shRNA against PDE8	Human ~ Jellyfish ~ Murine	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

Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0274

PI Name: Niroshana Anandasabapathy

Submission Type: Renewal

Notes: The assigned IBC member reviewed the procedures performed in the lab and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval with previously assigned 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
Vaccinia virus [Poxviridae/ Orthopoxvirus]		Recombinant WR (VACV-OVA, VACV-gp100, VACV-GFP)	Replication Competent	HeLa cells	Both	In vivo	gp100, ova protein or GFP	Human ~ Murine	Marker/ Reporter	Direct inject into in vivo model ~ Transfect cells / introduce into in vivo model	ABSL-2+~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Biological/Microbiological Microorganism Tracking Table:

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Microorganism f or 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
Vaccinia virus [Poxviridae/Orthopoxvirus]		MVA Vaccinia Western reserve, VACV-OVA, VACV-gp100, VACV SIINFEKL APL	Attenuated ~ Replication Competent	Both	Culturing ~ Introduction into in vivo model ~ Isolation DNA/RNA ~ Oth er/plaque	ABSL-2+ ~ BSL-2+	Not rDNA	
Staphylococcus [Aureus]	Staphylococcus epidermidis	epidermidis, Tü32 98	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Candida [Albicans]		ATCC MYA-2876 SC5314	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Influenza Virus [Orthomyxoviridae Types A, B, C (Vaccine Strain)]		PR8-OT1, X31	Attenuated ~ Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0296

PI Name: Nadia Dahmane
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of adding a new gene. The reviewer requested to change the description of RCAS virus to replication competent in Avian cells. No other issues were raised. With this administrative change, the reviewer recommended approval of lentivirus at BSL-2+/ABSL-2 and work with RCAS vectors at BSL-2/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/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
Avian Sarcoma Virus [Viral Vector/ In vivo retrovirus]		RCAS	Replication Competent	DF1 cell s	Both	In vivo	PDGF, Cre, H3K27 M	Human ~ Murine	Cytokine ~ Gene Expression Regulators	Repress/ Downregulate gene of interest ~ Transfect cells / introduce into in vivo model	ABSL-1~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Lentivirus [Retroviridae/Lentiviridae]		pSLS, pLentilox3. 7	Replication Incompetent/ Deficient	HEK 293 T, primary human and mouse cells	Both	In vivo ~ Human	RP58 (ZB TB18), Rp58deltaPOZ, shRP58-1, shRP58-2, EGFP, shRNA luciferase, Cas 9, LegoT2, TTi1	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ 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: 19-0299
PI Name: Nancy Du
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted no changes associated with this renewal. No issues were raised. The reviewer recommended approval with previously assigned 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]		FUW, pRRL	Replication Incompetent/ Deficient	GPG29 or 293T	Both	In vivo ~ Human	Bcl-2 family members, Py MT, RHAMM, shRNA, RhoA, TFE3, Hrg1, CYP1B1	Human	Marker/Reporter ~ Oncogenic Gene Sequences~ Unknown	Express/ Upregulate gene of interest ~ 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
Retrovirus [Amphotropic]		pQCXIP	Replication Incompetent/ Deficient	GPG29 or 293T	Both	In vivo ~ Human	Bcl-2 family members, RHAMM, shRNA	Human	Oncogenic Gene Sequences	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

Avian Leukosis Virus [Viral Vector/In vivo retrovirus]		RCASBP, RCAN	Replication Incompetent/ Deficient	DF1 chicken fibroblast	Both	In vivo ~ Human	RHAMM	Human	Unknown	Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-2~ BSL-2	NIH Applicable	Section II I-D-4

Record Number: 19-0301
PI Name: Howard Alan Fine
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of removing the administrative contact and indicated the use of transgenic in vivo models. Also, new biological activity has been included in the recombinant table and new gene family details have been added. The reviewer requested to correct the source of DNA for Retrovirus. No other issues were raised. With this administrative change, the reviewer recommended approval with previously assigned 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**
Adenovirus [Human, all types]		Ad-5	Replication Incompetent/ Deficient	293T	Both	Human	Red Fluorescent Protein (RFP), Green Fluorescent Protein (GFP), FOSL1, DLX5, DOCK6, CSF1R	Human	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	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
*Other	Sendai Virus	SeV- CytoTune Sendai Virus Reprogramming Kit (Invitrogen)	Replication Incompetent/ Deficient	Not propagated. Commercial Kit.	In Vitro	Human	Myc, Sox 2, Oct4, Klf4 (Commercial Kit for Reprogramming)	Human	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/Upregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1
Lentivirus [Retroviridae/Lentiviridae]		pLKO.1	Replication Incompetent/ Deficient	293T	Both	Human	Histone3, Syncidin 1 and 2	Human	Antibiotic Resistance ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Repress/ Downregulate gene of interest ~ 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
Retrovirus [Amphotropic]		MMLV	Replication Incompetent/ Deficient	293T	Both	Human	Green Fluorescent Protein (GFP)	Jellyfish	Marker/Reporter	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: 19-0304
PI Name: Jeffrey P. Greenfield
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of adding 2 extensions of a gene and the removal of in vivo experiments with lentivirus constructs. The reviewer requested to have RCAS vectors listed as replication competent. No other issues were raised. With this administrative change, the reviewer recommended approval of RCAS at ABSL-1/BSL-2 and Lentivirus at BSL-2+.
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
Avian Sarcoma Virus [Viral Vector/ In vivo retrovirus]		RCAS	Replication Competent	DF1 cells	Both	In vivo	PDGF, Cre, Igsf3	Human ~ Murine	Cytokine ~ Gene Expression Regulators	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-1~ BSL-2	NIH Applicable	Section II I-D-4
Lentivirus [Retroviridae/ Lentivirid ae]		pSLS, pLentilox3. 7	Replication Incompetent/ Deficient	HEK 293T, primary human and mouse cells	In Vitro	In vivo ~ Human	mirIGSF3, shRNA IGSF3, sgRNAI GSF3-E GFP, Fire fly Lucif erase, LegoT2, CAS9,sgRNA-EGFP, TTI1, TONSL	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cells ~ Transfect cells / introduce into in vivo model	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Record Number: 19-0306
PI Name: Michael G. Kaplitt
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of sample source. Additionally, changes to the sources of DNA/RNA and the inclusion of CRISPR/Cas9 technology. No issues were raised. The reviewer recommended approval with previously assigned 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/panned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines

Adeno-Associated Virus (AAV)		serotypes 1-2	Replication Incompetent/ Deficient	293 cell s	Both	In vivo	pten, pten siRNA, p11 (s10 0A10), tyrosine hydroxylase, channelrhodopsin, halorhopsin, GFP/RFP, Cre, DR EADD, GCaMP	Virus	Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Other/ Pathology	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-1 ~ BSL-2	NIH Applicable	Section II I-D-3 ~ Section III-D-4
Adeno-Associated Virus (AAV)		AAV 1an d 2 AAV Serotypes 5,8,9, RG 10 AAV a - synuclein.U6U 6, AAV1/2. DIO.hM3 Dq.mCherry Retro AAV2.Cr e.GFP, RetroAAV 2.GFP	Replication Incompetent/ Deficient	293 cell s	Both	In vivo ~ Bacteria l	p11 (s100A10), pt en, tyrosine, hydroxylase, channelrhodopsin, halorhopsin, GFP/ RFP, Cre	Human ~ Virus	Marker/Reporter ~ Other/ Creating Pathology	Direct inject into in vivo model ~ Repress/Downregulate gene of interest	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4
Lentivirus [Retroviridae/Lentiviridae]		serotypes 1 and 2, p BOB	Replication Incompetent/ Deficient	293 cell s	Both	In vivo	Magneto genetics cell channels	Virus	Gene Expression Regulators ~ Other/ Pathology	Transfect cells	ABSL-2 ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Herpes Simplex Virus [Herpesviridae/ Alpha-herpesviridae types 1, 2]		serotype 1-oncoly	Replication Inco	Vero cell s	Both	In vivo	Red Fluorescent Protein (RFP)	Other	Marker/Reporter	Direct inject into in vivo model	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4

Record Number: 19-0312
PI Name: Mark M. Souweidane
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of adding a mutant variant to the list of gene sequences and CRE. The reviewer requested that the RCAS vector is listed as replication competent. No other issues were raised. The reviewer recommended approval of RCAS at ABSL-1/BSL-2 and Lentivirus 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) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)
Avian Leukosis Virus [Viral Vector/In vivo retrovirus]		RCAS	Replication Competent	DF-1 chicken cells, e.coli	Both	In vivo ~ Bacterial	PDGF-B, H3K27M, CRE,	Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Hormone ~ Oncogenic Gene Sequences	Direct inject into in vivo model ~ Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-1 ~ BSL-2
Lentivirus [Retroviridae/Lentiviridae]		CAG-Luci-GFP & RFP Puro (Gene Traget INC. Cat #LVP570 & LVP572)	Replication Incompetent/ Deficient	Procured directly from Gene Target Inc- Virus will not be generated in the lab. Transfected into mammalian cells, xenografted in-vivo.	Both	In vivo	CAG-Luciferase (firefly), GFP/RFP-Puro)	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Transfect cell line ~ Transfect cells ~ Transfect cells / introduce in to in vivo model	ABSL-2 ~ BSL-2

Record Number: 19-0326
PI Name: Dawid Nowak
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of updating the administrative contact. Besides this, there is an addition of hormone and transfect cell lines under the Lentivirus biological activity section. No issues were raised. The reviewer recommended approval with previously assigned biosafety levels and updated AAV to ABSL-1/BSL-1 and adenovirus to BSL2+.
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)		pEFS-Rluc-2A-Cre	Replication Incompetent / Deficient	N/A, purchased from U. Iowa	Both	In vivo ~ Human	Cre/loxP, Luc	Bacteriophage ~ Jellyfish	Marker/ Reporter	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cells ~ Transfect cells / introduce into in vivo model	ABSL-1~ BSL-1	NIH Applicable	Section II I-D-4
Retrovirus [Amphotropic]		LPE-sh, pMSCV	Replication Incompetent / Deficient	Phoenix (ecotrophic, amphotropic)	In Vitro	In vivo ~ Human	gene knockdown	Human ~ Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences	Express/ Upregulate gene of interest ~ Transfect cell line	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III - D-3
Adenovirus [Human, all types]		AdCre, Ad CreGFP	Replication Incompetent / Deficient	HEK293 FT	In Vitro	In vivo ~ Human	1) markers (eGFP) functional enzymes/systems (e.g., Cre)	Bacteriophage ~ Jellyfish	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	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	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III - D-3

Record Number: 19-0351
PI Name: Ronald G Crystal
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of new transgenes and CRISPR/Cas9 technology used. No issues were raised. The reviewer recommended approval with previously assigned 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/vectr 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)		Human derived Adeno-associated virus vectors. Serotypes/variants: serotypes 1,2,5, 6, 7m8, 8, 9, 11, PHP.eB, and CAP-B10. The vector is replication competent in the packaging cell line but is replication incompetent in other cells.	Replication Competent ~ Replication Incompetent/Deficient	293, 293 T	Both	In vivo ~ Bacterial ~ Human ~ Insect	Luciferase, Beta Galactosida se (lacZ), mCherry, cytokines, antibodies (anti-s iglec, anti-IgE, anti-Tau), transcription factors (Mef2c, GATA4, Tbx5,Tbx 18), Vascular Endothelial Growth Factor (VEG F), GFP, RFP, lysosomal proteins (CLN2, CLN3, IDUA, SGSH, SUMF1, ARSB, AR SA), Alpha1-antitrypsin, apolipoproteins (ApoE4, ApoE2), differentiation f actors (Notch, delt alike1, J AG, VEGF), C1 est erase inhibitor (C1- Inh), Frataxin (FX N), Sodium Iodide symporter, RNA Helicase (UPF1), Glucocerebrosidase 1 (GBA1), Catalase, Superoxide Dismutase (S OD3), Connective Tissue Growth Factor (CTG F), AAV Receptor (AAVR), Glial Fibrillary Acidic Protein (GFAP), Troponin (TNN I3), cytochrome P4 50 family 2 subfamily U mem ber 1 (CY P2U1), phospholipase A2 group VI (P LA2G6), adaptor related protein complex 4 sub unit beta 1 (AP4B1), histone deacetylase 8 (H DAC8), Murine IL5, murine Eotaxin, Urocortin-2, Chronos-GFP Fusion, erythropoietin (EP O), CRISPR-associated protein 9 (Cas 9), thrombopoietin (THPO), and angiopoietin-1 (Ang1).	Bacteria ~ Human ~ Jellyfish ~ Murine ~ Virus	Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter ~ Other/Gene expression ~	Create virions ~ Direct inject into in vivo model ~ Express/Up regulate gene of interest ~ Repress/ Downregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-4
Adenovirus [Human, all types]	Adeno viruses	NHP serotypes Ad C5, AdC6, AdC7, AdC8, AdC9, sAd35; The vector is replication competent in the packaging cell line but is replication incompetent in other cells	Replication Competent ~ Replication Incompetent/Deficient	293, 293T embryonic kidney, 293O RF6	Both	In vivo ~ Human	Luciferase, lacZ, G FP, lysosomal proteins, cytokines, antibodies, catalase, superoxide dismutase, VEGF	Human ~ Jellyfish ~ Murine Other/DNA sequences are primarily derived from human material, with some material from other sources.	Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter Other/Gene expression	Create virions ~ Direct inject into in vivo model ~ Express/Up regulate gene of interest ~ Repress/ Downregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-4
Lentivirus [Retroviridae/Lentviridae]		Lentivirus constructs	Attenuated	239T	In Vitro	Human	AAVR, A TX5, GP R108, R NF121, T M9SF2, TROAP, UBA2, R AD50, C HAF1A, UBE21, SFP638, FKBP4	Bacteria ~ Human	Gene Expression Regulators	Repress/ Downregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-3
Adeno-Associated Virus (AAV)	Adeno-associated viruses	NHP serotypes 7, 8, 9, rh.10, and 32. 33	Replication Incompetent/ Deficient	HEK 293, HEK 293T, 293 Orf6	Both	In vivo ~ Bacterial ~ Human Insect	Luciferase, Beta Galactosidase (lacZ), mCherry, cytokines, antibodies (anti-siglec, anti-IgE, anti-Tau), transcription factors (Mef2c, GATA4, Tbx5,Tbx 18), Vascular Endothelial Growth Fact or (VEG F), GFP, RFP, lysosomal proteins (CL N2, CLN 3, IDUA, SGSH, SUMF1, A RSB, AR SA), Alpha1-antitrypsin, apolipoproteins (Apo E4, ApoE2), differentiation factors (Notch, delt alike1, J AG, VEGF), C1 esterase inhibitor (C1- Inh), Frataxin (FX N), Sodium Iodide symporter, RNA Helicase (UPF1), Glucocerebrosidase 1 (GBA1), Catala se, Super oxide Dismutase (S OD3), Connective Tissue Growth Factor (CTGF), AAV Receptor (AAVR), Glial Fibrillary Acidic Protein (GFA P), Troponin (TNN I3), cytochrome P4 50 family 2 subfamily U member 1 (CY P2U1), phospholipase A2 group VI (P LA2G6), adaptor related protein comp lex 4 sub unit beta 1 (AP4B1), histone deacetylase 8 (H DAC8), Murine I L5, murine Eotaxin, Urocortin-2, Chronos-GF P Fusion, erythropoietin (EP O), CRISPR-associated protein 9 (Cas9), thrombopoietin (THPO), and angiopoietin-1 (Ang1). Genes cloned into AAV with modified capsids include luciferase, lacZ, mCherry, VE GF, and APOE.	Human ~ Murine ~ Other/DNA sequences are primarily derived from human material, with some material from other sources.	Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter Other/Gene expression	Create virions ~ Direct inject into in vivo model ~ Express/Up regulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cell line	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-2 ~ Section III-D-3 ~ Section III-D-4
Adenovirus [Human, all types]		Ad5	Replication Competent ~ Replication Incompetent/Deficient	293, 293 AD, 293 T	Both	In vivo ~ Human	Luciferase, lacZ, GFP, mCherry, lysosomal proteins, cytokines, antibodies, catalase, superoxide dismutase, VEGF, CTGF, Potassium Channel (KCNH 2), CRIS PR-associated protein 9 (Cas9)	Human ~ Jellyfish ~ Murine Other ~ Virus	Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/ Reporter Other/Gene	Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Other ~	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-3 ~ Section III-D-4

									expression	Repress/ Downregulate gene of interest			
Escherichia coli [K 12]		Dh5alpha, XL10-Gold, TOP10, and Stbl2	Attenuated ~ Replication Competent	HEK293, HEK293 T	In Vitro	In vivo	Luciferase, Beta Ga lactosidase (lacZ), mCherry, cytokines, antibodies (anti-siglec, anti-IgE, anti-Tau), transcription factors (Mef2c, GATA4, Tbx5,Tbx 18), Vascular Endothelial Growth Fact or (VEG F), GFP, RFP, lysosomal proteins (CL N2, CLN 3, IDUA, SGSH, S UMF1, A RSB, AR SA), Alpha1-antitrypsin, apolipoproteins (Apo E4, ApoE2), differentiation factors (Notch, delt alike1, J AG, VEGF), C1 esterase inhibitor (C1-Inh), Frataxin (FX N), Sodium Iodide symporter, RNA Helicase (UPF1), Glucocerebrosidase 1 (GBA1), Catalase, Superoxide Dismutase (SOD3), Connective Tissue Growth Factor (CTGF), AAV Receptor (AAVR), Glial Fibrillary Acidic Protein (GFAP), Troponin (TNN I3), cytochrome P450 family 2 subfamily U member 1 (CY P2U1), phospholipase A2 group VI (P LA2G6), adaptor related protein complex 4 sub unit beta 1 (AP4B1), histone deacetylase 8 (HDAC8), Murine I L5, murine Eotaxin, Urocortin-2, Chronos-GF P Fusion, erythropoietin (EPO), CRISPR-associated protein 9 (Cas9), thrombopoietin (THPO) and angiopoietin-1 (Ang1).	Human ~ Jellyfish ~ Murine Other ~ Virus	Antibiotic Resistance ~ Gene Expression Regulators ~ Hormone ~ Marker/Reporter ~ Other ~ Virulence Factors or Enhancers	Create virions ~ Express/Upregulate gene of interest ~ Repress/ Downregulate gene of interest	BSL-1	NIH Applicable	Section II I-D-2 ~ Section III -F-6

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
*Other	blood and lung samples from HIV+ individuals	HIV	Replication Competent	In Vitro	Isolation DNA/RNA ~ Other	BSL-2	Not rDNA	

Record Number: 19-0378
PI Name: Li Gan
Submission Type: Renewal
Notes: The assigned IBC member reviewed the procedures performed in the lab and noted the change of adding lentivirus strain and adding electroporation in the lab. No issues were raised. The reviewer recommended approval with previously assigned biosafety levels and lentivirus to be updated to 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) 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]		p156RRLsin, pMK1334, pXPR_003, pLKO.1, pLVX, pFUGW	Replication Incompetent/Deficient ~ Self-Inactivating	293T	Both	In vivo ~ Human	MAPT, TREM2, Progranulin, ApoE, VP535	Human	Other	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 ~ Section III-D-4
Adeno-Associated Virus (AAV)		AAVrh.10, AAVrh.9, AAV rh.4, AAVrh.5, AAVrh.2, AAVrh.3	Replication Incompetent/Deficient	293T	Both	In vivo ~ Human	MAPT, TREM2, Progranulin, ApoE	Human	Other	Create virions ~ Direct inject into in vivo model ~ Transfect cells / introduce into in vivo model	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4 ~ Section III-F-6

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

HS Record Number: 22-08025192

HS PI Name: Pearse, Roger N

Record Title:
68284528MMY3004: A Phase 3 Randomized Study Comparing Bortezomib, Lenalidomide and Dexamethas one (VRd) followed by Ciltacabtagene Autoleucel, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Di rected Against BCMA versus Bortezomib, Lenalidomide, and Dexamethasone (VRd) followed by Lenalido mide and Dexamethasone (Rd) Therapy in Participants with Newly Diagnosed Multiple Myeloma for Whom Hematopoietic Stem Cell Transplant is Not Planned as Initial Therapy (CARTITUDE-5)

RS Record Number: 22-0109

Notes:

Decision: Approved

Acknowledgment of Human Subjects Research/Human Gene Transfer: Administrative Amendment

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 Encephalopat hy (DEE) due to a mutation in the Interferon Regulatory Factor 2 Binding Protein-Like (IRF2BPL) gene

RS Record Number: 24-0155

Notes:

Decision: Approved

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0313	Bobak Mosadegh	Lab Registration - Renewal
22-0125	Zhuhao Wu	Lab Registration - Renewal

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0316	Jessica Tyler	Lab Registration - Renewal

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0245	Margaret Elizabeth Ross
19-0275	Babacar Cisse
19-0320	Hanna Rennert
19-0496	Douglas Thomas Fearon

Approved Extension of Expiration Date to July 16, 2025

Record Number	PI Name
19-0276	Simon Dunham
19-0297	Ethel Cesarman
19-0324	Giogio Inghirami
20-0167	Tan Ince

The meeting adjourned at 10:44 AM.