

Institutional Biosafety Committee Minutes

Date: Wednesday, July 16, 2025

Time: 9:31 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE

Brown, Anthony Carroll, Ann M. Finkernagel, Scott W. Kaminsky, Stephen M. Lieggi, Christine McGuinn, Catherine Otero, Miguel Repik, Gabrielle Wagner, John A. Willis, Dianna E.

MEMBERS ABSENT

Busch, Robert H Gross, Steven S. Schnappinger, Dirk

STAFF

Gonzalez Russi, Sabrina Lejb, Katarzyna

In the absence of the Chair, the meeting was chaired by the Vice-Chair, the Biosafety Officer.

Meeting Minutes for Approval

• June 18, 2025

Changes were requested on the June 18, 2025 meeting minutes and June minutes will be reviewed /approved at the next IBC meeting.

Safety Officer Report

New Business

• Public posting of meeting minutes

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.

<u>Laboratory Safety Registrations - Initials</u>

Record Number: 23-0089 PI Name: Lauretta Lacko Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. No issues were raised. The reviewer

recommended approval at BSL-2.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorgani sm for Recombinan t work	Other microorga nism name	List strains/serot ypes for constructs	in the cell	Cell/cell type where microorganis m/vector will be propagated/pa ckaged	or in	Cell type where expressed	unregulated	Original source(s) species of DNA/RNA	Biological activity/ potential of gene modification	Manipulation types performed/plan ned	Assigned Biosafety Level(s)	Regulator y Rationale	Applicabl e NIH Guideline s
Lentivirus [Retroviridae/ Lentiviridae]		pLentiC RISPRv2, pLKO,pCS	Replication Incompeten t/Deficient ~ Self- Inactivating	HEK293T	In Vitro	Human	lineage specific for pancreatic and colon development	Human	Gene Expression Regulators ~ Marker/Report er	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

Record Number: 25-0057

PI Name: Samara Reck-Peterson

Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. The reviewer requested additional descriptions regarding the exempt work, the lentiviral work and how *Aspergillus Nidulans* is being used as a model organism. No other issues were raised. Pending administrative changes, and additional description, the reviewer recommends approval of lentiviral work at BSL-2.

Decision: Registration approval tabled

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorga nism for Recombina nt work	Other microorg anism name	List strains/ser otypes for constructs	Ability to replica te in the cell	Cell/cell type where microorganis m/vector will be propagate d/packaged		Cell type where	Gene/gene family to be inserted, dele ted, upregulated or downregulated	source(s)	Biologic al activity/pote ntial of gene modification	Manipulation types performed/plan ned	Assigned Biosafety Level(s)	Regulator y Rationale	Applicable NIH Guidelines
Lentivirus [Retrovirida e/Lentivirida e]		pLVX-Te tOne-Puro, pFUGW	Replication Incompeten t/ Deficient	HEK29 3	In Vitro	Human	LRRK2, LRRK1, Rab8, Ra b10, Rab 7	Human	Other	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-2 ~ Section III-D-2 3

Laboratory Safety Registrations - Amendments

Record Number: 19-0720 **PI Name:** David Artis

Submission Type: Amendment

Notes: The assigned IBC member reviewed the lab protocol and noted the updated administrative contact. This amendment consists of additional AAV strains and lentiviral work. No issues were raised. The reviewer recommended approval of Lentivirus

at BSL-2+ and AAV at ABSL-1/ABSL-1.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorga nism for Recombin ant work	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganis m/vector will be propagate d/packaged	In vivo or in vitro?	Cell type where expressed	upregulated	Original source(s) species of DNA/RNA	Biological activity/pote ntial of gene modification	Manipulatio n types performed/p lanned	Assigned	Regulator y Rationale	Applicable NIH Guideline
Lentivirus [Retrovirida e/Lentivirida e]	3rd generation VSV-G pseudotyped lentivirus	Replication Incompetent / Deficient	293T cells	In Vitro	In vivo ~ Human	Hcar2 (G pr109a), Mertk	Human ~ Murine	Other	Repress/ Downregulat e gene of interest ~ Transfect cells	BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III- D-3
Adeno- Associated Virus (AAV)	AAV9-hSyn-DIO-mCherry, AAV9-hSyn-DIO-hM4D(Gi) -mCherry, AAV5-hM3D(Gq)-mCherry, AAVrg-h Syn-DIO-mCherry, AAVrg-h Syn-DIO-hM3D(Gq)-mCherry, AAVrg-hSyn-DI O-hM4D(Gi)-mCherry, AAV rg-hSyn-DIO-Cre, AAV-PH-Reb-CAG-mCherry	Replication Incompetent / Deficient	239T	Both	In vivo	hM4D(Gi)-mCherry	Murine	Marker/ Reporter	Transfect cells / introduce int o in vivo model	ABSL-1 ~BSL-1	NIH Applicable	Section II I-D-4

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Micro biological work	Other microorgani sm 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
Heligmosomoides [Polygrus]		Heligmosomoides polygyrus	Replication Competent	In Vivo	Culturing	ABSL-1 ~ BSL-1	Not rDNA	
Trichuris [Muris]		Trichuris muris	Replication Competent	In Vivo	Culturing	ABSL-1 ~ BSL-1	Not rDNA	
Nippostrongylus [Brasiliensis]		Nippostrongylus brasiliensis	Replication Competent	In Vivo	Culturing	ABSL-1 ~ BSL-1	Not rDNA	
Citrobacter [Rodentium]		Citrobacter rodentium	Replication Competent	Both	Culturing	ABSL-1 ~ BSL-1	Not rDNA	
Influenza Virus [Or thomyxoviridae Ty pes A, B, C]		Mouse-adapted influenza A virus strain PR8, PR8-GP 33, X31, and X31-GP33	Attenuated	Both	Culturing ~ Intro duction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Norovirus [Murine Strain]		murine norovirus strain CW3 and CR6	Replication Competent	Both	Culturing	ABSL-1 ~ BSL-2	Not rDNA	
Streptococcus [Pneumoniae]		ATCC6303, ATC C6301	Replication Competent	Both	Culturing ~ Intro duction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Trichinella [Spiralis]		Trichinella spiralis	Replication Competent	In Vivo	Culturing	ABSL-2 ~ BSL-2	Not rDNA	

<u>Laboratory Safety Registrations - 2-Year Renewals</u>

Record Number: 19-0324 **PI Name:** Giorgio Ga. Inghirami **Submission Type:** Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted the change of additional research with AAV2 and AAV6-derived vectors. No issues were raised. The reviewer recommended approval of lentivirus and retrovirus work at previously

approved biosafety levels, and AAV work conducted at BSL-2/ABSL-2.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Recombinant	icroorga	List strains/seroty pes for constructs	in the cell	type where	0	Cell type where ex pressed	Gene/gene family to be inserted, dele ted, upregulated or downregulated	Original source(s) species of DNA/RN A	Biological activity/potential of gen e modification	Manipulation types performed/planne d	Assigned Biosafety Level (s)	Regulator y Rationale	Applicable NIH Guidelines
Lentivirus [Retrovirida e/Lentivirida e]		pWl, pLentif-pGk- puro-DEST	Replicatio n Incompete nt/ Deficient	HEK, 29 3T	In Vitro	In vivo ~ Human	Stat3, My c, Jak1, N fKb2, Ro s1, Tyk2 Blimp1, NCOR2, TERT	Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/ Upregulate gene of interest ~Repress/Downreg ulate gene of interest ~ Transfect cells		NIH Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III- D-4
Retrovirus [Amphotropi c]		Pinco, Pallino, MS CV, pDEST, MSCV, pCDNA3,pG EM, pCRII	Replicatio n Incompete nt/ Deficient	293GP	Both	Human	NPM-AL K, Stat3, Bel- 2, Bl c-2, c- My c	Human ~ Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	interest		NIH Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III- D-4
Adeno- Associated Virus (AAV)		AAV2 and AAV6	Replicatio n Incompete nt/ Deficient	293T	Both	In vivo ~ Human	CD20 and CD22	Human ~ Jellyfish	Cytokine ~ Marker/Reporter	Direct inject into in vivo model ~ Transfect cell line ~ Transfect cells ~ Transfect cells / introduce into in vivo model	BSL-2	NIH Applicable	Section III- D-4

Record Number: 19-0353 **PI Name:** Bishoy Morris Faltas **Submission Type:** Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted the change of additional genes. No issues were raised. The reviewer recommended approval of lentivirus and retrovirus work at previously approved biosafety levels. Since both AAV and adenovirus lead to the expression of oncogenes, the reviewer recommended to assign ABSL-2+/BSL-2+.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganis m for Recombinant work	microorga nism name	ser arms, ser oc	Ability to replicate	Cell/cell type where microorganis m/vector will be propagated/p ackaged	In vivo or in	Cell type where expressed	Gene/gene family to be inserted deleted, upregulated or downregulated		Biological activity/potenti al of gene modification	Manipulation types performed/plann ed	Assigned Biosafety Level(s)	Regulator y Rationale	e NIH
Adenovirus [Human, all types]		Adenovirus	Replicati on Incompet ent/Defici ent	293T	Both	In vivo ~ Human	APOBE C, CDKN 1A, CDK N2A, CI KN2B, M TAP PTE N, STAG 2 Cas9, FAK Luciferase, G FP RFP, FGFR-3 TACC3, BCL2, IC H J6, BAI AP2L1	Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/ Upregulate gene of interest ~ Repress/Downregu late gene of interest ~ Transfect cell line ~ Transfect cells / introduce into in vivo model		Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III-D -4

Lentivirus [Retroviridae/ Lentiviridae]	FUCR, pLenti6.3, pMIRNA1, lentiCas9 V2, pLV, pLVX	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Human	APOBE C, CDKN 1A, CDK N2A, CD KN2B, M TAP, PTE N, STAG 2 Cas9, F AK, Luciferase, G FP, RFP, FGFR-3, TACC3, BCL2, IG H J6, BAI AP2L1, TdTomato, shRNA for SOX2, gRNA exome 3.4, 4, 7 of HPR T gene, C DAC1, m Cherry, shRNA PA PR1, Cdade1, CCN D1.	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Direct inject into in vivo model ~ Express/Upregulat e gene of interest ~ Repress/Downreg ulate gene of interest ~ Transfect cell line ~ Transfect cells / introduce into in vivo model		Section II I-D-1 ~ Section III- D-3 ~ Section III-D -4
Adeno- Associated Virus (AAV)	AAVI-9, AAVm1 0	Replicatio n Incompete nt/ Deficient	293T	Both	In vivo ~ Human	APOBE C, CDKN 1A, CDK N2A, CD KN2B, M TAP, PTE N, STAG 2 Cas9, F AK, Luciferase, G FP, RFP, FGFR-3, TACC3, BCL2, IG HJ6, BAI AP2L1, I-Scel	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marke r/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Direct inject into in vivo model ~ Express/Upregulat e gene of interest ~ Repress/Downreg ulate gene of interest ~ Transfect cell line ~ Transfect cells/ introduce into in vivo model	ABSL-2 ~ BSL-2	Section II I-D-1 ~ Section III- D-3 ~ Section III-D4
Retrovirus [Amphotropic	MMLV	Replicatio n Incompete nt/ Deficient	293T	Both	In vivo ~ Human	APOBE C, CDKN 1A, CDK N2A, CD KN2B, M TAP, PTE N, STAG 2 Cas9, F AK, Luciferase, G FP, RFP, FGFR-3, TACC3, BCL2, IG H J6, BAI AP2L1	Human	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Transfect cells ~ Transfect cells / introduce into in vivo model		 Section II I-D-1 ~ Section III- D-3 ~ Section III-D -4

Record Number: 19-0379

PI Name: Teresa Sanchez Garcia Vao

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with the renewal. The reviewer requested to correct the source species of AAV. No other issues were raised. With this administrative change, the reviewer recommended approval at previously assigned biosafety levels.

Decision: Approved with administrative changes

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorg anism for Recombi nant work	Other microor ganism name	List strains/sero types for constructs	Ability to replicate in the cell	Cell/cell type where microorganis m/vector 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/potent ial of gene modification	Manipulation types performed/pla nned	Assigned Biosafety Level(s)	Regulator y Rationale	Applicabl e NIH Guidelin es
Adeno- Associated Virus (AAV)		AAV2-B R1		The AAV 2-BR1 will not be grown in our lab.	In Vivo	In vivo	non-specific scramble oligonucleotide , eGFP reporter 2 shRNA sequences to knock down the long non-coding RNA H19, o mCherry reporter, Cre recombinase	Bacteriophage ~ Jellyfish ~ Murine	Unknown		ABSL-1~ BSL-1	NIH Applicable	Section II I-D-4
Adenoviru s [Huma n, all type s]		pAdEasy		HEK-293, primary neuron s, glial cells, human umbilical vein endothelial cells, HU VEC	In Vitro	In vivo ~ Human	sphingosine-1- phsophate receptor 1 (S1 P1R), sphingosine-1- phsophate receptor 2 (S1P2R), sphingosine- kinase 1 (S K1), PTEN wild type, dominant negative Rho, dominant negative Rac, b- galactosidase	Human ~ Murine	Gene Expression Regulators ~ Marker/Report er ~ Ot her	Create virions ~ Transfect cell line	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III- D-3

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Record Number: 23-0001 PI Name: Elisa ten Hacken Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with the renewal. No issues were

raised. The reviewer recommended approval at previously assigned biosafety levels.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorga nism for Recombina nt work	Other microorg anism name	List strains/ser otypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganis m/vector 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	Biologic al activity/pote ntial of gene modification	Manipulation types performed/plan ned	Assigned Biosafety Level(s)	y	Applicable NIH Guidelines
Lentivirus [Retrovirida e/Lentivirida e]		2nd gene ration, Pseudotype d VSVG lentiviral vectors	Replication Incompetent/ Deficient	293T	Both	In vivo	sgRNAs against Spen, Cdk n2a/b, Ezh2, Ep30 0, Dnmt3 a, Setd2, Kmt2e, Kmt2e, mCherry	Murine ~ Other	Regulators ~	Express/ Upregulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cells ~ Transfect cells / introduce into in vivo model	~ BSL-2+	Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III- D- 4

Record Number: 23-0024 PI Name: Despina Siolas Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with the renewal. The reviewer requested clarification if they plan to use only mouse derived xenograft models. No other issues were raised. The reviewer recommended approval at previously assigned biosafety levels with the addition of ABSL-1.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorg anism for Recombin ant work	microorg	List strains/seroty pes for constructs	Ability to replicate in the cell	Cell/cell type where microorganis m/vector will be propagate d/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to inserted, ted, upregulated downregula	dele l or	source(s)	Biological activity/potent ial of gene modification	Manipulation types performed/pa nned	Assigned Biosafety Level (s)	Regulato ry Rational e	Applicabl e NIH Guidelin es
Lentivirus [Retrovirid ae/Lentivir idae]		Addgene (pCF806-reci, #186711; pCF806- shRen.713, #186712; pCF806-shAB C1, #186713; pCF806-shA BC2, #186714)	Attenuated ~ Replication Incompetent /Deficient	HEK 293T	Both	In vivo ~ Human	Kras, TP SMA D4, F A		Human ~ Murine	Oncogenic Gene Sequences	Repress/ Downregulate gene of interest ~ Transfect cell line ~ Transfect cells ~ Transfect cells / introduce into in vivo model	BSL-2+	Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III-D -4

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

Record Number		Laboratory Safety Registration Submission Type
20-0167	Tan Ince	Lab Registration - Renewal
22-0073	Rajshri Hirpara	Lab Registration - Renewal

25-0048	Radda Rusinova	Lab Registration - Initial

Laboratory Safety Registrations: Exempt

Record Number	IPI Name	Laboratory Safety Registration Submission Type	
22-0007	Laura Beth J McIntire	Lab Registration - Renewal	

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

HS Record Number: 24-0071 HS PI Name: Sarva, Harini

Record Title: Long-term Follow-up of Glutamic Acid Decarboxylase Gene Transfer to the Subthalamic Nuclei

in Participants with Parkinson's Disease

RS Record Number: 24-0069

Notes:

Decision: Approved

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name		
19-0608	Olaf Sparre Andersen		
19-0664	Glen Prusky		
24-0019	Teresa Evering		

The meeting adjourned at 10:24 AM.