



Institutional Biosafety Committee Minutes

Date: Wednesday, July 15, 2026

Time: 9:30 AM

Location: Zoom Meeting

MEMBERS IN ATTENDANCE

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

MEMBERS ABSENT

STAFF

Gonzalez Russi, Sabrina
Lejb, Katarzyna

Meeting Minutes for Approval:

- June 17, 2026

No issues were raised and the committee approved the minutes from June 17, 2026.

Safety Officer Report

New Business

- Megan Kaylor from RARC joined as a guest

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. Crystal. Dr. Kaminsky will abstain from voting on this registration.*
- *Dr. Wagner reported a Conflict of Interest with Dr. Gudas. Dr. Wagner will abstain from voting on this registration.*

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 - 2-Year Renewals

Record Number: 19-0488

PI Name: Jacqueline Burre

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the addition of replication incompetent rabies virus experimental details. The reviewer requested to change the original source species of rabies virus to jellyfish and noted that an IACUC amendment is needed. No other issues were raised. The reviewer recommended approval at previously approved biosafety levels and replication incompetent rabies virus 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) 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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Rabies virus [Rhabdoviridae/Lyssavirus]		EnvA G-Deleted Rabies-m Cherry (Salk Institute)	Replication Incompetent/ Deficient	in vivo model brain	In Vivo	In vivo model	mCherry	Jellyfish ~ Virus	Marker/ Reporter	Direct inject into in vivo model	ABSL-2~ BSL-2	NIH Applicable	Section III-D-1~Section III-D-4
Lentivirus [Retroviridae/Lentiviridae]		pRRE, pREV, pVSVG, viral expression vector (based on FUGW)	Replication Incompetent/ Deficient	Propagated in HEK 293T. Expressed in primary in vivo model neurons and in vivo model brain.	Both	In vivo model	synuclein, syntaxin-binding protein 1, SNAP-25	Human	Other/ expressing disease linked genes	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Transfect cells	ABSL-2~ BSL-2	NIH Applicable	Section III-D-1 ~ Section III-D-3 ~ Section III-D-4
Adeno-Associated Virus (AAV)		pHelper, AAV-DJ, viral expression vector	Replication Incompetent/ Deficient	Propagated in HEK 293T. Expressed in primary in vivo model neurons and in vivo model brain.	Both	In vivo model	synuclein, syntaxin-binding protein 1, SNAP-25	Human	Other/ expressing disease linked genes	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Transfect cells	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-3 ~ Section III-D-4
Caenorhabditis [Elegans]		JP699, JP104, JP859 expression vectors	Replication Competent	C. elegans	In Vivo	In vivo model	GFP, Munc18-1b, unc18	Human ~ Jellyfish	Gene Expression Regulators ~ Marker/Reporter	Direct inject into in vivo model	ABSL-1	NIH Applicable	Section II I-D-4

Record Number: 19-0709

PI Name: Lorraine Gudas

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:

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Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/vector will be propagated/packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level (s)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/Lentiviridae]		pVSV-G (envelope plasmid), deltaR8.9 (packaging plasmid) pLKO.1 (cloning vector)	Replication Incompetent/ Deficient	HEK293T	Both	In vivo model ~ Human	Hox family, retinoic acid receptor family, nuclear receptor family, zinc finger transcription factor family, Firefly Luciferase, Oncogenes, gRNAs targeting tumor-suppressors	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences ~ Unknown	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells / introduce into in vivo model	ABSL-2~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Record Number: 19-0722

PI Name: Margaret Elizabeth Ross

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the changes of removing the admin contact and including protein expression in question 1.1 of the exempt recombinant DNA section. The reviewer requested to include oncogenic gene sequences for sendai virus and to mark both in vivo and in vitro for AAV. No other issues were raised. The reviewer recommended approval at previously approved biosafety levels, AAV at BSL-2/ABSL-1 and sendai virus 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
Retroviral Vectors		Cre with nuclear localization signal {nls} and Ds RED {nls Cre-T2A-DsRed-Express} or EGFP	Replication Incompetent/Deficient	murine neurons	In Vivo	In vivo model	Lis1	Murine	Gene Expression Regulators	Express/Upregulate gene of interest	ABSL-2	NIH Applicable	Section II I-D-4
Lentivirus [Retroviridae/Lentiviridae]		1. pCMV-R8:pMD2g 2. hairpin(Lis1)-pLKO.1	Replication Incompetent/Deficient	293T	In Vitro	In vivo model ~ Human	1. lentiviral vector with conditional packaging system for use with replication defective vector 2. shRNAs for knock down of selected genes; replication defective	Human ~ Murine	Gene Expression Regulators	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3
*Other	CytoTuc Sendai Virus Kit (thermofisher)	SeV	Replication Incompetent/Deficient	N/A (Purchased from thermofisher catalog #'s A16517, A16518) used to infect human fibroblasts	In Vitro	In vivo model	Myc, Sox2, Oct4, Klf4 (Commercial Kit for)	Murine	Gene Expression Regulators ~ Oncogenic Gene Sequences	Express/Upregulate gene of interest ~ Transfect cells	BSL-2+	NIH Applicable	Section II I-D-1
Rabies virus [Rhabdoviridae/Lyssavirus]		SAD-deltaG-mCherry	Attenuated ~ Replication Incompetent/Deficient	BHK-B19G	Both	In vivo model	mCherry (rabies for stereotactic injections)	Jellyfish	Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Adeno-Associated Virus (AAV)		AAV1.hSyn.ChR2 (H134R)-eYFP.WPRE.hGH	Replication Incompetent/Deficient	293T	Both	In vivo model ~ Human	Channel rhodopsin, eYFP (AAVs for stereotactic injections)	Jellyfish	Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4
Adeno-Associated Virus (AAV)		rAAV2-retro, AAV 1-pCAG-FLEX-tdTomato-WPRE	Attenuated ~ Replication Competent	murine neurons	Both	In vivo model	Cre recombinase	Bacteriophage	Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
Adeno-Associated Virus (AAV)		AAV2.Io xP.hM3Dq-mCherry	Attenuated ~ Replication Competent	murine neurons	Both	In vivo model	hM3Dq	Murine	Gene Expression Regulators	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
*Other	Plasmid cDNA	a dicistronic plasmid	Replication Competent	murine neurons	In Vivo	In vivo model	cD1, cD2	Murine	Gene Expression Regulators	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1	NIH Applicable	Section II I-D-4

Record Number: 19-0725

PI Name: Dilek Colak

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and suggested that we inquire with the PI on a change from the previous submission, to provide context on the use and/or Introduction of siRNA, shRNA, mRNA, miRNA. No other issues were raised. The reviewer recommended the renewal be tabled and re-reviewed after more detailed description is provided.

Decision: **Registration approval tabled**

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)		AAV5, pAAV-CaMKIIa-EGFP	Replication Incompetent/Deficient	N/A	Both	In vivo model	enhanced GFP	Murine	Marker/Reporter	Direct inject into in vivo model ~ Express/Upr regulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4 ~ Section III-E-1

Record Number: 19-0726

PI Name: Natalia De Marco Garcia

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
Adeno-Associated Virus (AAV)		AAV1.hSyn.ChR2(H134R)-eYFP.WPRE.hGH.AAV_Flex_EF1aGFPAAV_Flex_EF1a_GT_B, AAV-DIO-GCaMP6S, AAV-E2-tdTom, AAV-fDIO-Cre, AAV-hsynjRGECO1	Replication Incompetent/Deficient ~ Self-Inactivating	293T	Both	In vivo model	Channel rhodopsin, eYFP (AAVs for stereotactic injections), GCaMP, GFP, tdTomato, RECO	Jellyfish	Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upr regulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
Rabies virus [Rhabdoviridae/Lyssavirus]		SAD-deltaG-mCherry, SAD-deltaG-mCherry(EnvA)	Attenuated ~ Replication Incompetent/Deficient	BHK-B19G	Both	In vivo model	mCherry (rabies for stereotactic injections)	Jellyfish	Marker/Reporter	Direct inject into in vivo model ~ Express/Upr regulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

Record Number: 19-0727

PI Name: Conor Liston

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the change of removing reporters of neuronal activity for Lentivirus. 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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Lentivirus [Retroviridae/Lentiviridae]		psPAX2, pMD2.G	Replication Incompetent/Deficient	Human Primary Neural Cell and Organotypic Slice/Tissue, ReNCell VM Established Neural Cell Line, ReN Cell CX	In Vitro	Human	GCAMPS, Voltage Imaging GEVIs	Human ~Murine	Marker/Reporter	Transfect cell line ~ Transfect cells	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3
Adeno-Associated Virus (AAV)		Serotypes 2, 5	Replication Incompetent/Deficient	N/A	In Vivo	In vivo model	Channel rhodopsin2, GCAMPS	Murine	Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
Rabies virus [Rhabdoviridae/Lyssaviruses]		SAD-deltaG-mCherry, SAD-deltaG-mCherry (EnvA)	Attenuated ~ Replication Incompetent/Deficient	BHK-B19 G	In Vivo	In vivo model	mCherry rabies for stereotactic injections	Jellyfish	Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Canine Adenovirus [CAV-1, CAV-2]		CAV-1, CAV-2	Attenuated ~ Replication Incompetent/Deficient	N/A	In Vivo	In vivo model	channel rhodopsin2, GCAMPS	Virus	Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Adeno-Associated Virus (AAV)		pAAV-double floxed-EYFP-WPREpA	Replication Incompetent/Deficient	N/A	In Vivo	In vivo model	Enhanced green fluorescent protein, TVA, rabies B19 glycoprotein	Murine	Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4

Record Number: 19-0728

PI Name: Anna G Orr

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 and AAV in human cells should be approved at BSL-2/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
Lentivirus [Retroviridae/Lentiviridae]		PL-SIN-PGK	Replication Incompetent/Deficient ~ Self-Inactivating	293T	Both	In vivo model	Recombinant G-protein coupled receptor genes, fluorescent reporters/proteins, FTD and AD-related genes		Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Virulence Factors or Enhancers	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate 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-3 ~ Section III-D-4
Adeno-Associated Virus (AAV)		AAV1-9, PHP.cB	Replication Incompetent/Deficient	vectors will be obtained from Addgene, Franklin Bio Labs, Vector Bio Labs, GeneWiz, or viral vector core facilities at academic institutions (e.g. University of Iowa). AAV particles will be applied onto primary in vivo model cells	Both	In vivo model	Recombinant GP CRs, fluorescent reporters/proteins, FTD and AD-related genes	Human ~ Jellyfish ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Marker/Reporter ~ Virulence Factors or Enhancers	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4

Herpes Simplex Virus [Herpesviridae/Alpha-herpesviridae types 1, 2]		Strains such as H129 HSV2772, 17+/- OK12, KOS, Mckr ae. These viruses will be obtained from academic labs that have validated the strains, including Matt Tayl or at Montana State and Patrick Card at the University of Pittsburgh. For further information, please see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5977213/ ; http://pubmed.ncbi.nlm.nih.gov/24585022/	Replication Competent	Vero cell line is used to propagate and titer HSV-1	Both	In vivo model	eGFP, mCherry, or similar fluorescent tags may be inserted to facilitate detection.	Jellyfish	Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Transfect cell line ~ Transfect cells	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4
Adenovirus [Human, all types]		serotype5, obtained from the University of Iowa Viral Vector Core Facility	Replication Incompetent/Deficient	Vero cell line	In Vitro	In vivo model	eGFP, mCherry, or similar fluorescent tags may be inserted to facilitate detection.	Jellyfish	Marker/Reporter ~ Other	Create virions ~ Direct inject into in vivo model ~ Transfect cell line ~ Transfect cells	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4
*Other	Vesicular Stomatitis Virus	VSV-deltaG-Luciferase - Kerafast, number EH1007 (Note: infectivity of rVSV-deltaG is restricted to a single round of replication)	Replication Incompetent/Deficient	Vero cells	In Vitro	In vivo model	eGFP, mCherry, or similar tags may be inserted to facilitate detection.	Jellyfish	Marker/Reporter	Create virions ~ Transfect cell line ~ Transfect cells	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism for Biological/Microbiological work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	In vivo or in vitro?	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Herpes Simplex Virus [Herpesviridae/Alpha-herpesviridae types 1, 2]		Strains such as H 129 HSV2772, 17+, KOS, Mckrae.	Replication Competent	Both	Conduct Multiplicity of infection (MOI) studies ~ Culturing ~ Introduction into in vivo model~ Isolation DNA/RNA	ABSL-2 ~ BSL-2	Not rDNA	

Record Number: 19-0729

PI Name: Manu Sharma

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocols and noted the addition of a cloning vector. No issues were raised. The reviewer recommended approval at previously approved biosafety levels and AAV work at BSL-2/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
Lentivirus [Retroviridae/Lentiviridae]		pRRE, pREV, pVSVG, viral expression vector (based on FUW/FUW)	Replication Incompetent/Deficient	HEK293 T cells; Expressed in : in vivo model primary neuron cultures and in vivo model brain regions	Both	In vivo model ~ Human	Alpha-Synuclein, SNAP-25, Cysteine String Protein-alpha, Tau, APP, Presenilin, Valosin Containing Protein, Hsp70, Hsp104, CHIP, SGT	Human ~ Murine	Other/expressing disease linked genes	Create virions ~ Direct inject into in vivo model ~ 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
Adeno-Associated Virus (AAV)		pHelper, viral expression vector (AAV-DJ)	Replication Incompetent/Deficient	HEK293 T cells; Expressed in :in vivo model primary neuron cultures and in vivo model brain regions	Both	In vivo model ~ Human	Alpha-Synuclein, SNAP-25, Cysteine String Protein-alpha, Tau, APP, Presenilin, Valosin Containing Protein, Hsp70, Hsp104, CHIP, SGT	Human ~ Murine	Other/expressing disease linked genes	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4

Record Number: 19-0731

PI Name: Jochen Buck

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]		pLent-6, pCW57	Replication Incompetent/Deficient	293, and other mammalian cell lines	In Vitro	In vivo model ~ Human	Soluble Adenylyl cyclase (ADCY10); GFP and luciferase	Human ~ Murine	Marker/Reporter ~ Other/Enzyme Making cAMP	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0730	Hagen Tilgner	Lab Registration - Renewal
26-0003	Dena Almeida	Lab Registration - Initial

Human Subjects Research/Human Gene Transfer: Annual Report

HS Record Number: 24-06027591

HS PI Name: Crystal, Ronald G

Record Title: Gene Therapy for Alpha 1 Antitrypsin Deficiency

RS Record Number: 25-0019

Notes:

Decision: Approved

HS Record Number: 25-02028504

HS PI Name: Khatri, Jaikirshan

Record Title:

Endocardial Delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment: A 26-Week (with 26 Week Extension) Phase 2b Randomized, Multi-Center, Double-Blind, Sham Controlled Study to Evaluate Efficacy and Safety (EXACT 2)

RS Record Number: 25-0012

Notes:

Decision: Approved

HS Record Number: 25-02028575

HS PI Name: Gribbin, Caitlin K

Record Title:

A Phase 2, Multicenter, Open-Label Study Of CC-97540 (BMS-986353), CD19-Targeted NEXT CAR T Cell s, in Participants with Active SLE (Including Lupus Nephritis) with Inadequate Response to Glucocorticoids and at Least 2 Immunosuppressants (Breakfree-SLE)

RS Record Number: 25-0029

Notes:

Decision: Approved

Human Subjects Research/Human Gene Transfer: Closure

HS Record Number: 23-05026022

HS PI Name: Sternberg, Cora

Record Title:

PCA001: A Phase 1/Phase 2 Trial to Evaluate Safety, Immunogenicity and PSA Response of VTP-850 Prostate Cancer Immunotherapeutic in Men with Biochemical Recurrence after Definitive Local Therapy for Prostate Cancer

RS Record Number: 23-0133

Notes:

Decision: Closed/Completed

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0614	Lawrence G. Palmer
19-0645	Baohong Zhao

Request for Extension of Expiration Date to August 19, 2026

Record Number	PI Name
19-0152	Christopher Mason
19-0732	Lonny R. Levin

The meeting adjourned at 10:06 AM.