Institutional Biosafety Committee Minutes

Date: Wednesday, November 19, 2025

Time: 9:32 AM

Location: Zoom Meeting

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

Meeting Minutes for Approval

- October 15, 2025

No issues were raised and the committee approved the minutes from October 15, 2025.

Safety Officer Report

New Business

- Creation of a blurb for our IBC 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.

- None reported

Laboratory Safety Registrations - Initials

Record Number: 25-0075

PI Name: Nicole Mercer Lindsay

Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. The reviewer requested to add in vitro work for both AAV and Rabies virus. No other issues were raised. With this administrative change, the reviewer recommended approval of AAV at ABSL-1/BSL-1 and Rabies virus at ABSL-2/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
Adeno-Associated Virus (AAV)		AAV2, AAV2 retro, AAV2. 5, AAVDJ	Replication Incompetent/ Deficient	Neurons	Both	In vivo	GFP, synaptophysin-mRuby, RFP, mCherry, ChR2, Chrmine, GCaMP, hM4Di, TVA, Rabies G	Human ~ Jellyfish ~ Murine ~ Other/GCaMP is a mix of GFP (jellyfish), calmodulin (rat), M13 peptide (chicken) ~ Virus	Marker/Reporter ~ Other/neural modulation via optogenetic or chemogenetic actuators	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-F-6
Rabies virus [Rhabdoviridae/Lyssavirus]		G-deleted N2C	Replication Incompetent/ Deficient	Neural	Both	In vivo	GFP or mCherry	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

Record Number: 25-0094

PI Name: Kareem Rashid Rumah

Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. No issues were raised. The reviewer recommended approval of E. Coli expressing etxD at ABSL2/BSL2 with BSL-3 practices and clostridium perfringens 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
Escherichia Coli		pET28::h-pETX-D	Attenuated ~ Replication Competent	E. coli str. DH5-Alp ha, E. coli str. BL21-AI	In Vitro	Bacterial	etxD	Bacteria	Toxin	Express/ Upregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-B-1 ~ Section III-D-2

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

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
Clostridium perfringens		Patient derived perfringens strains	Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	ABSL-2 ~ BSL-2	Not rDNA	

Laboratory Safety Registrations - Amendments

Record Number: 19-0493
PI Name: John Blenis
Submission Type: Amendment
Notes: The assigned IBC member reviewed the lab protocol. This amendment consists of a description of melanoma model-mouse xenotransplantation assay, mammalian and lenti expression vectors. No issues were raised. The reviewer recommended approval at previously assigned biosafety levels and of 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)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/ Lentiviridae]		e.g. pLKO1, pTRIPZ, pLT, pSLIK, pLenti, pL X, pLIX, pCW57.1, pHAGE TREX, FU-tetO-Gateway, LentiCRI SPR v2, pKLV, pLV, pCWH, pCW, LentiCas9, LentiGuide, FUGW, pLoc, miR-E backbones, pLentiV, pMSCV, pLTGME, pSIN	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Human	protein kinases, lipid kinases, metabolic enzymes, transcription factors, cytokines, GTPases, chromatin modifiers, scaffolding proteins, tRFP, dsRed, GFP, Luciferase	Bacteria ~ Human ~ Jellyfish ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ Hormone ~ Marker/Reporter ~ Oncogenic Gene Sequences	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 III-D-1 ~ Section III-D-3 ~ Section III-D-4

Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0504
PI Name: Rajiv R. Ratan
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol 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
Adenovirus [Human, all types]		VQAd, AD5, AD5	Replication Incompetent/ Deficient	packaged at Viraquest in Iowa, Vector Biolabs, PA, and Viral Vector Core, University of Iowa	Both	In vivo ~ Human	Cat, Cat-GFP, MnSOD, Gpx1, PGC-1a, Keap1, Nrf2, rgDAAO, rgDAAO-GFP, ARE-Luciferase mutant, ARE-Luciferase, Myc, ATF4WT, ddATF4, ATF 4delta RK, ATF4 P/A, gox, ddgpx4, ddgpx1, ddcat,, HDAC3, LMN A, progerin, Prdx3, AMPK-D. N., Ad-Prdx3, Ad-MnSOD, Ad-GPX1, Ad-dd GPX4, Ad-GRX1, Ad-OGA, Ad-OGT, Ad-Kdm4C	Human ~ Murine	Antibiotic Resistance ~ Marker/Reporter ~ Oncogenic Gene Sequences	Direct inject into in vivo model ~ Transfect cells	ABSL-2 ~ BSL-2+	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Lentivirus [Retroviridae/ Lentiviridae]		pLKO.1, pLVX	Self-Inactivating	293T	Both	In vivo ~ Human	siPUMA, Cre, Trans glutaminase2 family, PHD family, HD AC family, GFP, HIF2, siSP1 family, GSX1	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Down regulate gene of interest ~ 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)		AAV8-Cre-GFP, AAV8-GFP, AAV8-ATF4-Luciferase, AAV8-drkATF4, AAV8-GPX4, AAV8-GSX1, AAV8-SGLT4, AAV8-Glut2	Replication Incompetent/ Deficient	HEK 293 cells	Both	In vivo ~ Human	Glut1, Glut3, MCT 2, OGA, OGT, G6PD, CRE B S40A, and PFK1 over-expression and shRNA AAV, Neh2 Luc PHD1, 2, 3 and HDAC family, ATF4, GPX4, GSX1, S GLT4, Glut2	Human ~ Murine	Gene Expression Regulators ~ Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/Down regulate gene of interest ~ Transfect cells / introduce into in vivo model	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4

Record Number: 19-0543

PI Name: Vibhu Sahni

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol 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

Retroviral Vectors		pBABE,pMX, pWZL, pLXSN, pCMV	Replication Incompetent/ Deficient	PhoenixA, 293T	Both	In vivo	Klhl14, Crim1, IGFs, IGFBPs, Ryk, WNTs, Lumican, Nrf3, Cbl n1, PTEN, Cre , Cas9, dCas9, Mafs, FlpO, GFP, tdTomato, m-cherry, d s-red, CF P, YFP, RFP, lacZ, ion channels, transcription factors-fusion proteins	Bacteria ~ Bacteriophage ~ Human ~ Jellyfish ~ Murine ~ Other	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate 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
Rabies virus [Rhabdoviridae/Lyssavirus]		EnvA-pseudotyped	Attenuated ~ Replication Incompetent/Deficient	BHK	Both	In vivo	Cre recombinase, tdTomato, mcherry, GFP, FlpO recombinase	Bacteriophage ~ Jellyfish	Gene Expression Regulators ~ Marker/Reporter	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Transfect cell line	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Lentivirus [Retroviridae/Lentiviridae]		plKO3.1, pCDH1	Replication Incompetent/ Deficient ~ Self-Inactivating	HEK293T	Both	In vivo	Klhl14, Crim1, IGFs, IGFBPs, Ryk, WNTs, Lumican, Nrf3, Cbl n1, PTEN, Cre , Cas9, dCas9, Maf s, FlpO, GFP, tdTomato, m-cherry, ds-red, CF P, YFP, RFP, lacZ, ion channels, transcription factors-fusion proteins	Bacteria ~ Bacteriophage ~ Human ~ Jellyfish ~ Murine ~ Other	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate 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)		pHpa-trs-KS, pSubMam	Replication Incompetent/ Deficient	HEK293T	Both	In vivo	Klhl14, Crim1, IGFs, IGFBPs, Ryk, WNTs, Lumican, Nrf3, Cbln1, PTEN, Cre , Cas9, dCas9, Mafs, FlpO, GFP, tdTomato, m-cherry, ds-red, CF P, YFP, RFP, lacZ, ion channels, transcription factors-fusion proteins	Bacteria ~ Bacteriophage ~ Human ~ Jellyfish ~ Murine Other	Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Transfect cell line	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-3 ~ Section III-D-4

- - - - - - - - - - - - - -

Record Number: 20-0017
PI Name: Mary Teruel
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol and noted the addition of AAV work. The reviewer suggested to change the use of AVV from in vivo to in vivo and in vitro. 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]		Human Adenovirus Type 5 (dE1/E3)	Replication Incompetent/ Deficient	293A	In Vitro	In vivo	GCaMP6f	Human	Marker/Reporter	Create virions ~ Express/Upregulate 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

Adeno-Associated Virus (AAV)		AAV8-T BG-iCre, AAV8-T BG-lacZ	Replication Incompetent / Deficient	HEK293	Both	In vivo	Cre recombinase or LacZ gene	Bacteria ~ Bacteriophage	Gene Expression Regulators	Direct inject into in vivo model	BSL-2	NIH Applicable	Section II I-D-4
Lentivirus [Retroviridae/Lentiviridae]		CSII-EF-MCS (pMDLg/pRRE, pR SV-Rev, pMD2.G) pLenti CMV/TO Puro Dest (pMDLg/pRRE, pRSV- Rev, pMD2.G)	Replication Incompetent / Deficient ~ Self-In activating	293FT	In Vitro	In vivo ~ Human	hGeminin-FP, hCdt1-FP, HDHB-FP, H2B-FPFLNA, FABP4, CEBPZ	Human ~ Murine	Marker/Reporter ~ Other/ Expression of fluorescently-tagged proteins in the cells	Create virions ~ Transfect cell line ~ Transfect cells	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3

Record Number: 22-0057
PI Name: Tobias Meyer
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol and noted the addition of Murine to original species to DNA/RNA. 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
Adenovirus [Human, all types]		Human Adenovirus Type 5 (dE1/E3)	Replication Incompetent/ Deficient	293A	In Vitro	In vivo	GCaMP6f	Human ~ Murine	Marker/Reporter	Create virions ~ Express/Upregulate 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
Lentivirus [Retroviridae/Lentiviridae]		CSII-EF-MCS (pMDLg/pRRE, pRSV-Rev,pMD2.G) pLenti CMV/TO Puro Dest (pMDLg/pRR E, pRSV- Rev, pMD2.G)	Replication Incompetent / Deficient ~ Self-Inactivating	293T	In Vitro	Human	hGeminin-FP, hCdt1-FP, HDH B-FP, H2B-FP, hCDC6-FP, MAPPER-FP, MPAct-FP, iRFP-SEC61b,PTP1B-FP, CLIMP63-FP, RTN4-FP, CAAX-FP, EGFR, E-Cadherin, TSC2, E2F, CyclinF, YAP1, NF2, CD H2, ERBB2, MET, LATS1, LATS2, WWTR1, AXL, CTNNB1, CTNNA1, EZR, AKT, PI3K, MEK, MAPK1, RAC1, APC, Cdh1, Emi1,Geminin, CDK 2/4/6, E2F, Cyclin A/B/D/E, DBF4, Cdc7, Cdt1,CDK 4/6, CDK2, CDK1, Rb, E2F, CDC6, Myc, cyclinD, cyclinE, cyclinA, p53, p21, p27, CDC25, EGFR, E1A	Human ~ Murine	Marker/Reporter ~ Oncogenic Gene Sequences ~ Other/ mostly markers	Create virions ~ Express/Upregulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-2

Record Number: 23-0094
PI Name: James (Jim) Marshel
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol 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
Adeno-Associated Virus (AAV)		AAV8, AAVdj, AAV1, AAV 5	Replication Incompetent/ Deficient	murine neuronal or HEK cells	Both	In vivo ~ Human	neural activity reporters such as genetically encoded calcium indicators, and neural activity manipulators such as light-sensitive opsin channels (optogenetics)	Human ~ Murine	Other/ neural reporter opsins	Direct inject into in vivo model ~ Transfect cells	ABSL-1 ~ BSL-2	NIH Applicable	Section II I-D-4

Record Number: 23-0127
PI Name: Silvia Chiara Formenti
Submission Type: Renewal
Notes: The assigned IBC member reviewed the lab protocol and noted the addition of 2 PI's research under this registration. The reviewer requested clarification and additional details on the lentiviral work being done. No other issues were raised. The reviewer recommended the renewal be tabled and re-reviewed after a 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
Lentivirus [Retroviride/ Lentiviride]		Pax2, VSVG	Replication Competent	293FT, phoenix cells	Both	In vivo, Human	CRISPR	Jellyfish, Murine	Antibiotic Resistance, Cytokine, Marker/Reporter	Transfect cell line, Transfect cells, Transfect cells / introduce into in vivo model	TBD	NIH Applicable	Section II I-D-1, Section II I-D-3, Section II I-D-4

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

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0527	Alicia Alonso	Lab Registration - Renewal
19-0737	Jorge Gandara	Lab Registration - Renewal
21-0037	Sharmaine Griffith-Baker	Lab Registration - Renewal

Acknowledgment of Closed Laboratory Safety Registrations

Record Number	PI Name
19-0008	Mande Holford

19-0295	Steven S. Gross
19-0547	Yutaka Yoshida

Human Subjects Research/Human Gene Transfer: Closure

HS Record Number: 21-02023276

HS PI Name: Shah, Manish A

Record Title:

KISIMA-01: An Open-Label, Multicenter, Non-Randomized, Dose-Confirmation and Cohort-Expansion Phase 1b Study to Evaluate the Safety, Tolerability, and Anti-Tumor Activity of ATP128, VSV-GP128 and BI 754091, in Patients with Stage IV Colorectal Cancer

RS Record Number: 22-0010

Notes:

Decision: Closed/Completed

The meeting adjourned at 10:32 AM.