Institutional Biosafety Committee Minutes

Date: Wednesday, October 15, 2025

Time: 9:32 AM

Location: Zoom Meeting

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

Meeting Minutes for Approval

- September 17, 2025

No issues were raised and the committee approved the minutes from September 17, 2025.

Safety Officer Report

New Business

- IBC In Vivo Pathogen Cheat Sheet

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. Schnappinger reported a conflict since his registration was being reviewed. Dr. Schnappinger left the meeting while registration was reviewed.

Laboratory Safety Registrations - Initials

Record Number: 25-0057

PI Name: Samara Reck-Peterson

Submission Type: Initial

Notes: The assigned IBC member reviewed the procedures performed in the lab. This protocol was previously reviewed, and the reviewer requested more information on the exempt work being done, and a description of how Lentivirus and Aspergillus nidulans are being used. This has been provided, and no other issues were raised. The reviewer recommended approval of Lentivirus at BSL-2 and Aspergillus nidulans at BSL-2.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	Other microorganism name	List strains/serotypes for constructs	Ability to replicate in the cell	Cell/cell type where microorganism/vector will be propagated /packaged	In vivo or in vitro?	Cell type where expressed	Gene/gene family to be inserted, deleted, upregulated or downregulated	Original source(s) species of DNA/RNA	Biological activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/ Lentiviridae]		pLVX-TetOne-Puro, pFUGW	Replication Incompetent/ Deficient	HEK293	In Vitro	Human	LRRK2, LRRK1, Rab8, Rab10, Rab7	Human	Other/ Signal transduction and membrane trafficking (basic cell biological processes)	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-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
Aspergillus [Spp.]		Nidulans (ATCC 38163)	Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	BSL-2	Not rDNA	

Laboratory Safety Registrations - 2-Year Renewals

Record Number: 19-0174

PI Name: Rohit Chandwani

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 of AAV and Lentivirus 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
Adeno-Associated Virus (AAV)		AAV-8 (UM-Vec tor Core)	Replication Incompetent/ Deficient	N/A	In Vivo	In vivo	VAV1, RAC1	Human	Oncogenic Gene Sequences ~ Other/ GTPase, RAC1 mutation	Direct inject into in vivo model	ABSL-2~ BSL-2	NIH Applicable	Section II I-D-4
Lentivirus [Retroviridae/ Lentiviridae]		pRRL.TR E3G.GFP (for both shRNA and cDNA), pTet-IRES-EG FP (pVSV-G (envelope), psPAX2 (packaging)	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Human	Foxa1, Foxa2, additional transcription factors, methionine salvage pathway genes, gastric differentiation genes	Murine	Gene Expression Regulators	Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Repress/ Downregulate gene of interest ~ Transfect cells	ABSL-2~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III- D-3 ~ Section III-D-4

Record Number: 19-0293

PI Name: Dirk Schnappinger

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted the removal of clostridium and bacteroides sp. from the registration, as well as the addition of M. abscessus in this renewal. No other issues were raised. The reviewer recommended approval with previously approved biosafety levels and the addition of M. abscessus to be handled 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	Biologic al activity/potential of gene modification	Manipulation types performed/ planned	Assigned Biosafety Level (s)	Regulatory Rationale	Applicable NIH Guidelines
Escherichia coli [K12]		DH5 alpha, Mach1, DB3.1	Replication Competent	N/A	In Vitro	Bacteria l	E. coli primarily serves as a cloning host. We clone mycobacterial genes that participate in a wide variety of bio logical functions including in transcription, RNA maturation/turnover, translation, protein transport/maturation/turnover, cell envelope synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, uptake of nutrients and other metabolites, or DNA replication. We also target genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections and express genes we expect to be toxic for mycobacteria, which includes RNases, D Nases and genes whose products can degrade the mycobacterial cell envelope. More rarely we use E. coli to purify mycobacterial proteins. Currently the only example for this work is purification of mycobacterial biotin synthase (required synthesize biotin from dethiobitin).	Bacteria ~ Bacteriophage ~ Jellyfish	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Other/Genes required for various biochemical activities. ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-1	NIH Applicable	Section II I-D-2

*Other	Mycobacterium (abscessus)	ATCC19977 (L948)	Replication Competent	Bacteria will be grown in liquid media.	In Vitro	Bacteria l	We construct mutant s that have defects in a variety of biological functions including in transcription, RNA maturation/turnover, translation, protein transport/maturation/turnover, cell envelopes synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, up take of nutrients and other metabolites, or DNA replication. We also target genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections and express genes we expect to be toxic for mycobacteria, which includes RNAases, DNases and genes whose pro ducts can degrade the mycobacterial cell envelope.	Bacteria ~ Bacteriophage	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Other/The genome-wide CRISPRi library we use includes sgRNA for every gene in the genome of M. abscessus ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-2
*Other	E. coli / mycobacteria shuttle plasmids	DH5 alp ha, Mach 1, DB3.1	Replication Competent	E. coli	In Vitro	Bacteria l	These plasmids contain mycobacterial genes that participate in a wide variety of biological functions including in transcription, RNA maturation/turnover, translation, protein transport/maturation/turnover, cell envelope synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, uptake of nutrients and other metabolites, or DNA replication. We also clone genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections. We furthermore clone genes that we expect to be toxic for mycobacteria, which includes RNAases, DNases and gen es whose products can degrade the mycobacterial cell envelope.	Bacteria ~ Bacteriophage ~ Jellyfish	Antibiotic Resistance ~ Ge ne Expression Regulators ~ Marker/Reporter ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-2
Mycobacterium [Smegmatis]		mc2 155 and derivatives with specific gene deletions	Replication Competent ~ Replication Incompetent/Deficient	N/A	In Vitro	Bacteria l	We clone mycobacterial gene s that participate in a wide variety of biological functions including in transcription, RNA maturation/turnover, translation, protein transport/maturation/turnover, cell envelope synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, uptake of nutrients and other metabolites, or DNA replication. We also target genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections and express genes we expect to be toxic for mycobacteria, which includes RNases, DNases and genes whose products can degrade the mycobacterial cell env elope In so me case s, M. smegmatis will be used to test antigen expression in a fast growing, non-pathogenic mycobacterium	Bacteria ~ Bacteriophage ~ Jellyfish	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Downregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-2

Mycobacterium [Bovis - BCG Vaccine Strain]		vaccine s train	Replicatio n Competen t ~ Replicatio n Incompet ent/Defici ent	N/A	In Vitro	Bacteria l	We construct mutant s that have defects in a variety o f biologic al functions including in transcription, RNA maturation/turn over, translation, protein transport/maturation/turnover, cell envelope synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, up take of nutrients and other metabolites, or DNA replication. We also target genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections an d express genes we expect to be toxic for mycobacteria, which includes RNAases, DNases and genes whose products can degrade the mycobacterial cell envelope.	Bacteria ~ Bacteriopha ge ~ Jellyfish	Antibiotic Resistance ~ Gene Expression Regulators ~ Marke r/Reporter ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Do wnregulate gene of interest	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-2
Mycobacterium [Tuberculosis]		H37Rv, Erdman, HN878, CDC155 1, and various clinical isolates representativ e of the major lineages of Mt b, and derivatives with specific gene deletions	Replicatio n Competen t ~ Replicatio n Incompet ent/Defici ent	N/A	Both	Bacterial	We construct mutants that have defects in a variety of biological functions including in transcription, RNA maturation/turn over, translation, protein transport/maturation/turnover, cell envelopes synthesis/integrity, chromosome maintenance/integrity, central metabolism, respiration, cofactor biosynthesis, up take of nutrients and other metabolites, or DNA replication. We also target genes for mutagenesis whose function is unknown but that are essential for growth in vitro or during infections and express genes we expect to be toxic for mycobacteria, which includes RNAases, DNases and genes whose pro ducts can degrade the mycobacterial cell envelope.	Bacteria ~ Bacteriopha ge ~ Jellyfish	Antibiotic Resistance ~ Ge ne Expression Regulators ~ Marke r/Reporter ~ Unknown ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest ~ Repress/Do wnregulate gene of interest	ABSL-3 ~ BSL-3	NIH Applicable	Section II I-D-1 ~ Section III -D-4
*Other	MycoMar	Phasmid derived from the mycobacteriop hage L5; carries mariner transposon; replication competent at 30C; unable to replicate a t 37C	Replicatio n Competen t ~ Replicatio n Incompet ent/De f i c i e n t	M. smegmatis, M. bovis BCG, M. tuberculosis	In Vitro	Bacterial	mariner transposase	Other/Haem atobiairritan s (origin of the mycomartra nposon)	Other/trans position	Repress/ Downregul ate gene of interest	BSL-3	NIH Applicable	Section II I-D-1

Biological/Microbiological Microorganism Tracking Table:

Biological/Microbiological Microorganism Tracking Table:

Microorganism f or Biological/Microbiolo gical work	Other microorganis m 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	Mycobacterium (abscessus)	ATCC19977 (L948)	Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	BSL-2	Not rDNA	
Mycobacterium [Tuberculosis]		H37Rv, Erdman, HN878, CDC155 1, and various clinical isolates	Replication Competent ~ Replication Incompetent/Deficient	Both	Culturing ~ Introduction into in vivo model ~ Isolation DNA/RNA	ABSL-3 ~ BSL-3	Not rDNA	
Mycobacterium [Smegmatis]		mc2 155 and derivatives with specific gene deletions	Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	BSL-2	Not rDNA	
Mycobacterium [Bovis - BCG Vaccine Strain]		Pasteur	Attenuated ~ Replication Competent	In Vitro	Culturing ~ Isolation DNA/RNA	BSL-2	Not rDNA	

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Record Number: 19-0354

PI Name: Ding Cheng Gao

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 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 Ratio nale	Applicable NIH Guidelines
Adenovirus [Human, all types]		Ad5-CC10-Cre, Ad5-CMV-Cre, and Ad5-SPC-Cre	Replication Incompetent /Deficient	293T Cell	In Vivo	In vivo	Cre Recombinase	Virus	Gene Expression Regulators	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
Lentivirus [Retroviridae/Lentiviridae]		pCDH, pWPT	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Human	GFP, RFP, CRE, LCN2, MMP8, LTF, NGP, CXCL7, Versican, Prosaposin, VEGFR2, TspI, miR708, miR27a/b, PD1, Z-Cadherin, K14, ATX, Interleukin IR6	Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Create virions ~ Express/Upregulate 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
Retrovirus [Amphotropic]		MSCV	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Human	GFP, RFP, CRE LCN2, MMP8, LTF, NGP, CXCL7, Versican, Prosaposin, VEGFR2, TspI, miR708, miR27a/ b, PD1, Z-Cadherin, K14, ATX, Interleukin IR6	Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Create virions ~ 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: 19-0358

PI Name: Vivek Mittal

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 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
*Other	LNP-XAGE-1b RNA Vaccines	LNP-XAGE-1B, LNP-Kras G12D, LNP-Kras G12C, LNP-EGF R	Unknown	No Packaging: Non-viral delivery systems are lipid nano particles (LNP's) which are received already packaged from a collaborator in Ithica.	In Vivo	In vivo	Xage, KrasG12D, KrasG12C,EGFR	Other/ It is a sequence of nucleotides packaged into a lipid nanoparticle.	Cytokine	Direct inject into in vivo model	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4

Lentivirus [Retroviridae/Lentiviridae]		pCDH, pWPT	Replication Incompetent/ Deficient ~ Self-Inactivating	293T cells	Both	In vivo ~ Human	LCN2, MMP8, LTF, NGP, CXCL7, Versican, Prosaposin, VEGF R2, TspI, miR708, miR27a/ b	Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Create virions ~ 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)		AAV1-9	Replication Incompetent/ Deficient ~ Self-Inactivating	Packaged offsite	In Vivo	In vivo	CRISPR oligonucleotide (gRNA) for inducing the EML-ALK translocation	Bacteria ~ Other/Virus (Adeno Associated Virus)	Gene Expression Regulators	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
Adenovirus [Human, all types]		Ad-CMV-iCre	Replication Incompetent/ Deficient ~ Self-Inactivating	Packaged offsite	In Vivo	In vivo	Cre recombinase	Bacteriophage ~ Virus	Gene Expression Regulators	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
Retrovirus [Amphotropic]		MSCV	Replication Incompetent/ Deficient ~ Self-Inactivating	293T	Both	In vivo ~ Human	LCN2, MMP8, LTF, NGP, CXCL7, Versican, Prosaposin, VEGFR2, TspI, miR708,miR27a/ b	Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Create virions ~ 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

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Record Number: 19-0440

PI Name: Juan R Cubillos-Ruiz

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 approved biosafety levels.

Decision: Approved

Recombinant Microorganism Tracking Table:

Recombinant Microorganism Tracking Table:

Microorganism for Recombinant work	**Other microorganism name**	**List strains/serotypes for constructs**	**Ability to replicate in the cell**	**Cell/cell type where microorganism/ vector will be propagated/ packaged**	**In vivo or in vitro?**	**Cell type where expressed**	**Gene/gene family to be inserted, deleted, upregulated or downregulated**	**Original source(s) species of DNA/RNA**	**Biological activity/potential of gene modification**	**Manipulation types performed/planned**	**Assigned Biosafety Level(s)**	**Regulatory Rationale**	**Applicable NIH Guidelines**
Retrovirus [Amphotropic]		pMSCV, pMLV, GFP-RV, hCD4-RV, pCCMP-IRESeGFP, MSCV-EGFP	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Bacterial ~ Human	LP-BM5, Schnurri-3, WWPI, MLK3, MAP4K2, Twist2, GSK3beta, XBP-1	Human ~ Murine	Gene Expression Regulators ~ Virulence Factors or Enhancers	Express/ Upregulate 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
Lentivirus [Retroviridae/Lentiviridae]		pLKO.1, pHAGE, pLenti, pLVET-tTR-KRAB, pLVHM, LT3Gepir	Replication Incompetent/ Deficient	293T, E. Coli K12, HeLa	Both	In vivo ~ Bacterial ~ Human	Schnurri-3, WWPI, MLK3, MAP4K2, Twist2, GSK3beta, XBP-1, shRNA, GFP, Puromycin, rtTA	Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Virulence Factors or Enhancers	Create virions ~ Express/Upregulate gene of interest ~ Repress/ Downregulate 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
Adenovirus [Human, all types]		pAdTrack-CMV, pAdEasy-1	Replication Incompetent/ Deficient	293T	In Vitro	In vivo ~ Bacterial ~ Human	CREB-H, XBP-1	Human ~ Murine	Gene Expression Regulators ~ Virulence Factors or Enhancers	Express/ Upregulate gene of interest	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
Candida [Albicans]		Candida albicans SC5314	Replication Competent	In Vivo	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Enterococcus [Faecium]		MMH594, V583, OG1RF	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2~BSL-2	Not rDNA	

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Record Number: 19-0495

PI Name: Lukas Edward Dow

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted no changes associated with this renewal. The reviewer recommends that oncogenic sequences be marked for Lentivirus, given that b-catenin is a potential oncogene. No other issues were raised. The reviewer recommended approval with 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)		AAV5-td Tomato	Replication Incompetent/ Deficient	purchased	In Vivo	In vivo	express a small guide RNA for CRISPR editing, tdTomato fluorescent reporter	Jellyfish ~ Murine	Marker/Reporter	Direct inject into in vivo model ~ Repress/Downregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4 ~ Section III-F-6
Adenovirus [Human, all types]		Ad5	Replication Incompetent/ Deficient ~ Self-Inactivating	Purchased	Both	In vivo	Cre recombinase	Bacteriophage	Gene Expression Regulators	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-4
Lentivirus [Retroviridae/Lentiviridae]		VSV-G pseudotyped	Replication Incompetent/ Deficient~ Self-Inactivating	293T	Both	In vivo ~ Human	Cas9, Base editor enzymes, Cre, GFP, iRFP, mScarletI, RFP, mKate2, beta-catenin, shRNAs, miRNAs	Bacteriophage ~ Human ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter	Express/ Upregulate gene of interest ~ 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]		MSCV	Replication Incompetent/ Deficient ~ Self-Inactivating	PlatE	Both	In vivo	Cas9, Cre, GFP, RFP, mKate, Myc, Kras, YAP, beta-catenin	Bacteriophage ~ Murine	Antibiotic Resistance ~ Gene Expression Regulators ~ Marker/Reporter ~ Oncogenic Gene Sequences	Express/ Upregulate gene of interest ~ 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

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Record Number: 19-0498

PI Name: Steven Zvi Josefowicz

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted the addition of two new microbiological agents in this renewal. The reviewer recommends that M. Bovis BCG use in vivo is changed to both in vivo and in vitro. Additionally, the reviewer recommends that E. Coli DH5 alpha should be marked as both replication incompetent and replication competent. With these administrative changes, the reviewer recommended approval with previously approved biosafety levels and the new microbiological agents, Listeria monocytogenes and Influenza virus both approved at BSL-2/ABSL-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
Lentivirus [Retroviridae/Lentivirida e]		pCDH-EF1	Replication Incompetent/ Deficient	293T	Both	In vivo ~ Bacterial	H3f3a, H 3f3b	Murine	Gene Expression Regulators	Create virions ~ 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	ABSL-2+ ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III-D-4

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
Mycobacterium [Bovis - BCG Vaccine Strain]		M. bovis bacillus Calmette-Guérin (BCG) vaccine, BCG-TetON-DL	Attenuated ~ Replication Competent	Both	Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
*Other	Sheep red blood cells infected with Plasmodium Chabauidi	Plasmodium Chabauidi	Replication Competent	Both	Introduction into in vivo model	ABSL-2 ~ BSL-1	Not rDNA	
Escherichia Coli		(K12, strain DH5a - thymidine auxotrophs (thyA-))	Attenuated ~ Replication Competent ~ Replication Incompetent/Deficient	Both	Introduction into in vivo model ~ Isolation DNA/RNA	ABSL-2 ~ BSL-1	Not rDNA	
Listeria [Monocytogenes]		10403s(Obtained from Lab of Joseph Sun at MSKCC)	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Influenza Virus [Orthomyxoviridae Types A, B, C]		PR8	Attenuated ~ Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Staphylococcus [Aureus]		S. aureus strain X EN36 (obtained from Dr Ivashkiv (H SS))	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
Citrobacter [Rodentium]		DBS100 (obtained from Dr Rudensky) or purchased from ATCC	Replication Competent	Both	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-1	Not rDNA	
Trichuris [Muris]		intestinal parasitic nematode (David Artis Laboratory)	Unknown	In Vivo	Introduction into in vivo model	ABSL-2 ~ BSL-1	Not rDNA	

Record Number: 19-0499

PI Name: Edmund Hollis

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 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]		pCDH1 (3rd generation lenti)	Replication Incompetent/ Deficient	HEK293	Both	In vivo	Fluorescent reporters (ie. eGFP, tdTomato, mCherry), Recombinases (Cre, Flp)	Bacteriophage ~ 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-3 ~ Section III-D-4
Adeno-Associated Virus (AAV)		pHpa-trs-KS, pSub Mam	Replication Incompetent/ Deficient	293T AAV Pro	In Vivo	In vivo	Fluorescent reporters (ie. eGFP, tdTomato, mCherry), Recombinases (Cre, Flp), Optogenetic constructs (ie. channelrhodopsin, iC++, C1V1, GCaMPs, etc.), Chemogenetic constructs (h M4Di, h M3G), TVA (avian EnvA receptor)	Bacteriophage ~ Jellyfish ~ Murine	Marker/Reporter	Direct inject into in vivo model	ABSL-1~ BSL-2	NIH Applicable	Section II I-D-4
Rabies virus [Rhabdoviridae/Lyssavirus]		EnvA-pseudotyped	Replication Incompetent/ Deficient	BHK	In Vivo	In vivo	Cre recombinase, tdTomato, mCherry, eGFP	Bacteriophage ~ Jellyfish	Gene Expression Regulators ~ Marker/Reporter	Direct inject into in vivo model	ABSL-2~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4

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Record Number: 19-0501

PI Name: Barbara L. Hempstead

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted changes including protein expression of experiments using E. coli and an addition of several murine/human B7-1 gene variants. Besides this, this renewal includes an introduction of siRNA, shRNA and mRNA, and breeding/crossbreeding transgenic murine work. No other issues were raised. The reviewer recommended approval with 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)		AAV2/1-hyperfolding GFP(mGreenLantern)	Replication Incompetent/ Deficient	Not Applicable	Both	In vivo	Enhanced Green fluorescent protein	Jellyfish	Marker/ Reporter	Transfect cells / introduce into in vivo model	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4

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Record Number: 19-0505

PI Name: Joseph M Scandura

Submission Type: Renewal

Notes: The assigned IBC member reviewed the lab protocol and noted changes including updating administrative contact and adding human as an organism from which genetic material is derived in this renewal. No issues were raised. The reviewer recommended approval with 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	Biologic al activity/potential of gene modification	Manipulation types performed/planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Lentivirus [Retroviridae/Lentiviridae]		pLKO, p Lenti, pLVX-TRE 3G	Replication Incompetent/Deficient ~ Self-Inactivating	293T	Both	In vivo ~ Bacterial ~ Human	shRNA to SDF1, R GS1, CX CR4, CD KN1C, S MAD2, E NG, CRI PTO, TP OR, SMA D2-RFP, SMAD4-GFP, NS L-GFP, H 2B-RFP, Cas9, GA RP, SPI1, RUNX1, GFI1, FO SB, LAM C1, FAN CA, RIP K3, CAL R, MPL, MGMT	Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ 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 II I-D-1 ~ Section III- D-3 ~ Section III-D-4
Retrovirus [Amphotropic]		MIGR1	Replication Incompetent/Deficient	293T	Both	In vivo ~ Human	NUP-Jari d1, MLL- ENL, AM L1-ETO, E4ORF1	Bacteria ~ Human ~ Murine	Antibiotic Resistance ~ Cytokine ~ Gene Expression Regulators ~ 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 II I-D-1 ~ Section III- D-3 ~ Section III-D-4

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Record Number: 23-0020

PI Name: Taha Merghoub

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 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

Enterococcus [Spp.]		Enterococcus faecalis (SagA OVA, faecalis SagA, faecalis-OVA) E. faecium (OVA) (Howard Hang of Scripps Institute)	Replication Competent	N/A	In Vivo	In vivo ~ Bacterial	E. faecalis SagA OVA, The plasmids will contain the Sag A and OVA genes from E. faecalis which can de grade bacterial peptidoglycan and prime host innate immune responses through the Nod2receptor, and fragments of the OVA protein and/or other neo antigens from the injected tumor model, which may initiate tumor antigen-specificCD8 T cells.	Bacteria	Other/ model antigen and elicit an immune response in the murine	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
Lactococcus [Lactis]		lactis sub sp. lactis – OVA (Howard Hang of Scripps Institute)	Replication Competent	N/A	In Vivo	In vivo ~ Bacterial	a. L. lactis subsp. lactis OVA, The plasmids will contain the OVA genes fro m L. lactis subsp. lactis and fragments of the OV A protein and/or other neoantigens from the inject ed tumor model, which may initiate tumor antigen-specific CD8 T cells.	Bacteria	Other/ model antigen will elicit an immune	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
*Other	Lactobacillus	L. plantarum-OVA (Howard Hang of Scripps Institute)	Replication Competent	N/A	In Vivo	In vivo ~ Bacterial	a. L. plant arum OVA, The plasmids will contain the OVA genes from L. plantarum and fragments of the OVA protein and/or other neoantigens from the inject ed tumor model, which may initiate tumor antigen-specific CD8 T cells.	Bacteria	Other/ model antigen and will elicit an immune response in the murine	Direct inject into in vivo model ~ Express/Upregulate gene of interest	ABSL-1 ~ BSL-1	NIH Applicable	Section II I-D-4
*Other	Newcastle Disease Viral Vector	(NDV-cGAS-NLS (parent strain is the nonpathogenic ND V-LaSota strain), NDV-cGAS (parent strain is the nonpathogenic NDV-LaSota strain), NDV- IL-12 (non-pathogenic NDV-LaSota strain), LaSota, Hitchner B1)	Attenuated ~ Replication Competent	Vaccine strain in Embryonated hen eggs, A549, Vero	Both	In vivo ~ Human ~ Other/ NDV, HPV	NDV-cGAS-NLS, NDV-cG AS, NDV-IL-12, I COSL, 4-1 BBL, C D40L, GI TRL, OX 40, anti-C D28 scFv antibody, cytokines, HPV 16 and HPV 18 E6 and E7	Fungi ~ Virus	Other/ Tumor lysis, immune activating, cyclic GMP-AMP, synthase (cGAS), nuclear-localizing signal NLS	Create virions ~ Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Other/ viability assays, flow cytometry of infected fixed cells	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-4
Lentivirus [Retroviridae/ Lentiviridae]		2nd/3rd generation Lenti-Cre (Cre-recombinase), Lenti-OVA (ovalbumin), Lenti-GFP-Luciferase (GFP and luciferase)	Replication Incompetent/ Deficient	HEK 293 T	Both	In vivo ~ Human	cDNA of murine, chicken ova albumin, insect (firefly), cnidaria (jelly fish) or P1bacterio phage. Lenti-Cre (Cre-recombinase), Lenti-OVA (ovalbumin), Lenti-GFP-Luciferase (GFP and luciferase)	Bacteriophage ~ Jellyfish ~ Murine ~ Other	Marker/ Reporter ~ Other/ immunogen	Direct inject into in vivo model ~ 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
Adenovirus [Human, all types]		commercial-cre-recombinase	Replication Incompetent/ Deficient	N/A	In Vivo	In vivo	Cre recombinase gene - P1 Bacteriophage cDNA	Bacteriophage	Marker/ Reporter	Express/ Upregulate gene of interest	ABSL-2 ~ BSL-2	NIH Applicable	Section II I-D-1 ~ Section III-D-3 ~ Section III- D-4
Retroviral Vectors		Mig-R1, ecotropic (murine cell in	Replication Incompetent/ Deficient	293T, Phoenix	Both	In vivo	insect (firefly), cnidaria (jelly fish), murine CD1 9 CARs (m19dz.GFP, m19z. GFP, and m1928z. GFP).	Jellyfish ~ Murine	Gene Expression Regulators ~ Marker/Reporter	Direct inject into in vivo model ~ Express/Upregulate gene of interest ~ Transfect cell line	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-I ~ Section III-D-4

Retroviral Vectors		RCAS vector RCA SBP (RC AS-LV (L TR) w/Splice acceptor	Replication Incompetent/ Deficient	DF-1	In Vitro	In vivo	Murine oncogenic gene (Kras, bref) sequences. Melanoma differentiation antigens.	Murine	Oncogenic Gene Sequences	Express/ Upregulate gene of interest ~ Transfect cells	ABSL-1 ~ BSL-1	NIH Applicable	Appendix C-I ~ Section III-D-4
*Other	Venezuelan Encephalitis Virus	Togaviridae-Alpha vax; Harr is Vaccine	Attenuated ~ Replication Competent	N/A	In Vitro	In vivo ~ Human	Murine or human cDNA of melanocyte differentiation antigen	Human ~ Murine	Gene Expression Regulators	Create virions ~ Express/Upregulate gene of interest ~ Transfect cell line ~ Transfect cells	BSL-2	NIH Applicable	Section II I-D-1 ~ Section III -D-4

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
Lactococcus [Lac tis]		lactis subsp. lactis (Howard Hang of Scripps Institute)	Replication Competent	In Vivo	Culturing ~ Introduction into in vivo model	ABSL-1 ~ BSL-1	Not rDNA	
Enterococcus [Spp.]		faecalis, faecium (Howard Hang of Scripps Institute)	Replication Competent	In Vivo	Culturing ~ Introduction into in vivo model	ABSL-2 ~ BSL-2	Not rDNA	
*Other	Lactobacillus	L. plantarum (Howard Hang of Scripps Institute)	Replication Competent	In Vivo	Culturing ~ Introduction into in vivo model	ABSL-1 ~ BSL-1	Not rDNA	

Record Number: 23-0075

PI Name: Michelle S. Bradbury

Submission Type: Renewal

Notes: The assigned IBC member reviewed the procedures performed in the lab. This protocol was previously reviewed, and the reviewer requested clarification on vectors used and enhanced descriptions for model plans. This has been provided, and no other issues were raised. The reviewer recommended approval with previously approved biosafety levels and Lentivirus at 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	Biologic al activity/potential of gene modification	Manipulation types performed/ planned	Assigned Biosafety Level(s)	Regulatory Rationale	Applicable NIH Guidelines
Avian Leukosis Virus [Viral Vector/In vivo retrovirus]		RCAS-P DGF-HA ("transfection of D F1 cells with RC AS-PDG F-HA vec tor" - are generated by Dr. Eri c Hollan d's lab (previously MSK)	Replication Incompetent/ Deficient ~ Self-In activating	murine D F-1 cells generated by Dr. Eric Hollan d's lab (previously MSK)	In Vivo	In vivo	PDGF-HA	Human ~ Murine	Cytokine ~ Gene Expression Regulators	Transfect cells / introduce into in vivo model	ABSL-1	NIH Applicable	Section II I-D-4

Lentivirus [Retroviridae/ Lentivirid ae]		pCCLsin.PPT. hPG K.GFP	Replication Incompetent/ Deficient ~ Self-In activating	luc-transfected triple-negative breast cancer (T NBC) cel ls (4T1-L uc2)" we re genera ted by Dr Adrienne Boire (Neurology, MSK)	In Vivo	In vivo	luciferase	Other/firefl y	Marker/Report er	Transfect cells / introduce into in vivo model	ABSL-1	NIH Applicable	Section II I-D-4
Murine leukemia virus [Viral vector/In vivo retrovirus]		MMLV retroviral vector SF G (MUC 16-transfected cell s are gene rated by Dr. Dmitriy Zamari n (MS K))	Replication Incompetent/ Deficient ~ Self-In activating	murine I D8 cells (MUC16 -transfect ed cells a re genera ted by D r. Dmitri y Zamari n (MS K))	In Vivo	In vivo ~ Human	muc-16	Human ~ Murine	Cytokine ~ Gene Expression Regulators ~ Oncogenic Gene Sequences	Transfect cells / introduce into in vivo model	ABSL-1	NIH Applicable	Section II I-D-4

Laboratory Safety Registrations: Exempt

Record Number	PI Name	Laboratory Safety Registration Submission Type
22-0035	Massimo Cristofanilli	Lab Registration - Renewal

Acknowledgment of Approved Administrative Amendments

Record Number	PI Name	Laboratory Safety Registration Submission Type
19-0726	Natalia De Marco Garcia	Lab Registration - Amendment

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

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

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

HS Record Number: 19-04020122

HS PI Name: Milsom, Jeffrey W

Record Title:
An Open-Label, Single-Center, Investigator Initiated Phase 1B Trial of E-CEL UVEC as a Novel Experiment al Treatment of Anal Fistulas

RS Record Number: 23-0156

Notes:

Decision: Approved

Acknowledgement of Human Subjects Research/Human Gene Transfer: Closure

HS Record Number: 1609017585

HS PI Name: Roboz, Gail J

Record Title:
Phase I, open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence a nd clinical activity of UCART123 (allogeneic engineered T-cells expressing anti-CD123 chimeric antigen rec eptor), administered in patients with Relapsed/Refractory Acute Myeloid Leukemia

RS Record Number: 19-0585

Notes:

Decision: Closed/Completed

Decision: Approved

HS Record Number: 22-10025232

HS PI Name: Nguyen, Alana

Record Title:
P-VCNA-003: A Phase IIb, Open-label, Randomized Study of Nab-Paclitaxel and Gemcitabine plus/minus VCN-01 in Patients with Metastatic Pancreatic Cancer

RS Record Number: 23-0047

Notes:

Decision: Closed/Completed

The meeting adjourned at 10:37 AM.