IBC IUI Committee Meeting
IBC Meeting Minutes

Thursday, June 26, 2025
VIRTUAL
09:30 a.m. – 11:30 a.m.

Members Present: Charlie Dong (Chair), Ryan Relich (Vice Chair), Pat Smith, Stepen Randall, Marissa Painter, Chelsea Roberts, Dan Horan, Consuelo Davis, Lauren Kieper, Joe Yang, Stacie Seelye, Bo Zhao

Guests: Chris Fenton, Naazneen Khan, Jonathan Bardahl, Tsai-Yu Lin, Holly Moore, Emily Winters

The June IU Indianapolis IBC meeting was called to order by Dr. Charlie Dong at 9:31 a.m.

1. The committee reviewed and approved the meeting minutes from the May 15, 2025 IBC meeting.

2. News & Updates
    a. Dr. Katrina Collins (Clinical Pathology & Laboratory Medicine), Dr. Nasneen Kahn (Neurology), (Dr. Tsai-Yu Lin (Clinical Medical & Molecular Genetics), and Dr. Jonathan Bardahl (Clinical Pediatrics) are observing the June IUI IBC meeting and considering becoming members of the committee.
    b. Committee Appointment Update:
        i. Dr. Kao is leaving the committee after 22 years of service.
        ii. Dr. Ji is leaving the committee.

3. The committee reviewed the items reviewed and approved outside of full committee. There were no questions or concerns.

4. Submissions for Review:

Indiana University Genome Editing Center (IUGEC) Protocol Amendments

- None

SARS-CoV-2 Downgrade (NIH Exempt)

#836 (Robinson) *Intestinal replication of enteric viruses* (**Biosafety:** Painter)

- **This amendment does not require full committee review or approval. The committee had no questions or concerns, and the amendment review will be completed outside of FCR.** Once approved, Dr. Robinson will move his SARS-CoV-2 work to his approved BSL-2 labs.
    - Dr. Relich plans to clear out SARS-CoV-2 isolates from the BSL-3 facility -80 freezer to free up space. RSCO will contact any PIs with materials remaining in the BSL-3 facility to inform them where they can collect those samples.
- **Types of manipulations planned:** 2025 Annual Renewal
    - Personnel Amendment

- Administrative Updates
- Updating biosafety cabinet information
- SARS-CoV-2 downgrade (downgrading from BSL-3 to BSL-2)

- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Coxsackievirus B3: GP33 and GP60 Recombinant virus	prCVB3.6	Human cells, HeLa cells, E. coli	Coxsackievirus B3 Nancy Strain with LCMV GP33 and GP60 T cell epitopes	Yes Yes: Human pathogen. Causes myocarditis, pancreatitis, and hepatitis
Coxsackievirus B3	pCVB3-Nancy	E.coli, Human cells	Coxsackievirus B3 Nancy Strain infectious clone	Yes Yes: Human pathogen. Causes myocarditis, pancreatitis, and hepatitis
Coxsackievirus B3	pCVB3-H3	E. coli, Human cells	Coxsackievirus B3 H3 Strain infectious clone	Yes Yes: Human pathogen. Causes myocarditis, pancreatitis, and hepatitis
Coxsackievirus B3	pCVB3-O	E. coli, Human cells	Coxsackievirus B3 0 Strain infectious clone	Yes Yes: Human pathogen. Causes myocarditis, pancreatitis, and hepatitis
Coxsackievirus B3	pCVB3-GFP	E.coli, human cells	Coxsackievirus B3 infectious clone with GFP	Yes Yes: Human pathogen. Causes myocarditis, pancreatitis, and hepatitis
Human rhinovirus	pHRV1A	E.coli, human cells	Human Rhinovirus strain 1A infectious clone	Yes Yes: Human pathogen. Causes infections of the upper respiratory tract.
Human rhinovirus	pHRV2	E. coli, Human cells	Human Rhinovirus strain 2 infectious clone	Yes Yes: Human pathogen. Causes infections of the upper respiratory tract.
Human	pCMA3.1	E. coli, human cells	Coxsackievirus and Adenovirus Receptor (CAR)	No
Encephlomyocarditis Virus	pMC24	E. coli, Human cells	Encephlomyocarditis virus infectious clone	Yes Yes: Zoological infection mainly in rodents and pigs. pigs. Causes myocarditis in pigs. EMCV does infect humans, but with a low morbidity.
Mengovirus	pMengo	E. coli, Human cells	Mengovirus infectious clone	Yes Yes: Zoological infection mainly in rodents and pigs. pigs. Causes myocarditis in pigs. 2virus does infect humans, but with a low morbidity.
T7 Bacteriophage	pREV	E.coli, Human cells	T7 RNA polymerase	No
Ruminococcus productus	pSW321 (pCR2.1)	E.coli	Eubacterial 16S rRNA gene	No

Bacteriodetes	pSW324 (pCR2.1)	E. coli	Bacteroidetes 16S rRNA gene	No
Firmicutes	pSW325 (pCR2.1)	E.coli	Firmicute 16S rRNA gene	No
Segmented filamentous bacteria (SFB)	pCR4SFB	E. coli	SFB 16S rRNA gene	No
Proteobacteria	pSW322 (pCR2.1)	E. coli	Alpha-Proteobacteria 16S rRNA gene	No
Proteobacteria	pSW323 (pCR2.1)	E.coli	Gamma-Proteobacteria 16S rRNA gene	No
Actinobacteria	pSW326 (pCR2.1)	E. coli	Actinobacteria 16S rRNA gene	No
Brunello LV pooled LV library	plentiGuide-Puro	Human cells	Whole genome guide RNAs	Yes Yes, he potential generation of replication competent virus and 2) the potential for oncogenesis through insertional mutagenesis.

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
  - Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
  - Appendix C-VIII: Generation of BL1 transgenic rodents via breeding

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Non-Exempt Reviews (III-A – III-E)

<u>Major Amendments:</u>

#999 (Clinkenbeard) *Impact of chronic kidney disease factors in the development of bone and mineral disorder* (**Primary:** Gavina; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-1, pending revisions.**
- **Types of manipulations planned:**
  - Adding adenovirus
  - Adding enhancer element cloning and luciferase in vitro work.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Mouse	pCMV6-Entry	E.coli, Mouse cells	Zhx2, Kdm6b, Tead4	No
Human	pCMV6-Entry	E.coli, human cells	Zhx2, Kdm6b, Tead4	No
Rat	pCMV6-Entry	E.coli, Rat cells	Zhx2, Kdm6b, Tead4	No
S. pyogenes, A. victoria	pSpCas9-2A-GFP (PX458) with mouse guide RNA (Zhx2, Kdm6b, Tead4)	E.coli, mouse cells	Cas9, GFP	No
S. pyogenes, A. victoria	pSpCas9-2A-GFP (PX458) with human guide RNA (Zhx2, Kdm6b, Tead4)	E.coli, human cells	Cas9, GFP	No
S. pyogenes, A. victoria	pSpCas9-2A-GFP (PX458) with rat guide RNA (Zhx2, Kdm6b, Tead4)	E.coli, rat cells	Cas9, GFP	No
Mouse Lentivirus	pLenti-C-Myc-DDK-P2A-Puro (Zhx2 ORF)	Mouse cells	Zhx2, puromycin resistance gene	No
Mouse and A. victoria Lentivirus	pGFP-C-shLenti (shRNA against mouse Zhx2)	Mouse cells	4 different 29-mer against mouse Zhx2, puromycin resistance gene, GFP	No
Mouse Serpina3n	pLKO.1_U6-shRNA:hPGK--NEO-CMV-tGFP vector	Mouse cells	4 independent shRNA products against mouse Serpina3n	No
Mouse	pGL4.23	E.coli and mouse cells	Mouse Zhx2 putative enhancer element 1D, minimal promoter, firefly luciferase (luc2)	No
Mouse	pGEM-T easy	E.coli	Mouse Zhx2 putative enhancer element 1D	No
Renilla reniformis	pGL4.73	E.coli and mouse cells	Renilla luciferase under the direction of SV40 promoter	No

- **Recommended containment conditions:** BSL-2/ABSL-1
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  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
  - Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
  - Appendix C-VIII: Generation of BL1 transgenic rodents via breeding

*Dr. Dong left the meeting at approximately 9:45 a.m. during the review of his IBC amendment. He returned at 9:51 a.m. after the committee discussion.

#1024 (Dong) *Signal transduction and gene regulation in metabolism* (**Primary:** Munoz Ramirez; **Vet:** Johnston; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
  - Adding new recombinant DNAs, AAV and adenoviral constructs, and AAV and adenoviral injections to mice.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Human, mouse, Staphylococcus aureus	AAV	E. coli, mouse cells, human cells, mice	Tumor suppressor gene (TBD) sgRNA, AMPK, ABHD5, FOXO1/3/4, SESN1/2/3, SIRT1/2/3/6/7, miR122, ATG5/7/8/14, PNPLA3, Cre, GFP, SMAD2/3/4/6/7, AMPK shRNAs, GSDMD shRNAs, MLKL shRNAs, NFkB shRNAs, FOXO1/3/4 shRNAs, SESN1/2/3 shRNAs, SIRT1/2/3/6/7 shRNAs, miR122 shRNAs, ATG5/7/8/14 shRNAs, PNPLA3 shRNAs, SMAD2/3/4/6/7 shRNAs, Kdm1a shRNAs, Kmt5a shRNAs, AAV-AIO-M11-gRNA-EFS-NMS-SadCas9, pAAV-FLEX-SaCas9-U6-sgRNA, Abhd5 sgRNAs, Gata4 sgRNAs, Nf1 sgRNAs, Sesn3 sgRNAs, control sgRNAs, Gsdmd sgRNAs, Mlkl sgRNAs, Rela sgRNAs, Kdm1a sgRNAs, Kmt5a sgRNAs	Yes AAV vectors have potential risk of infection.
Human and mouse	pcDNA3/4 and other mammalian expression vectors	E. coli, mouse cells, human cells	HDAC5, GATA4, AMPK, ABHD5, ATGL, DDIT3, FOXO1/3/4, SESN1/2/3, SIRT1/2/3/6/7, miR122, ATG5/7/8/14, PNPLA3, SMAD2/3/4/6/7, KDM1A, KDM2A, KDM4A, KMT5A, DNMT1, DNMT3A	No
Human, mouse	Adenoviral vector	E. coli, mouse cells, human cells	AMPK, ABHD5, FOXO1/3/4, SESN1/2/3, SIRT1/2/3/6/7, miR122, ATG5/7/8/14, PNPLA3, SMAD2/3/4/6/7, AMPK shRNAs, GASDMD shRNAs, MLKL shRNAs, NF-kB shRNAs, FOXO1/3/4 shRNAs, SESN1/2/3 shRNAs, SIRT1/2/3/6/7 shRNAs, miR122 shRNAs, ATG5/7/8/14 shRNAs, PNPLA3 shRNAs, SMAD2/3/4/6/7 shRNAs	Yes Adenoviral vectors have potential risk of infection.
Human, mouse	pLentiCRISPR vector	E. coli, mouse cells, human cells	HDAC5 sgRNA, SESN3 sgRNA, SMAD3 sgRNA, YAP sgRNA, WWTR1 sgRNA, ABHD5, ATGL, GASDMD, MLKL, NFkB, FOXO1/3/4, SESN1/2/3, SIRT1/2/3/6/7, miR122, ATG5/7/8/14, PNPLA3, SMAD2/3/4/6/7, KDM1A, KDM2A, KDM4A/B/C, KMT5A, DNMT1, DNMT3A	No
Human, mouse	Synthetic RNA oligos	Mouse cells, human cells	MIR122 inhibitor, KDM1A/2A/3A/4A/5A/6A/7A/PHF8 siRNAs, GATA4 siRNAs, FOXO3 siRNAs, NF1 siRNAs, PPARG siRNAs, TP53 siRNAs, TEAD1 siRNAs, WWTR1 siRNAs, YAP1 siRNAs, GASDMD siRNAs, MLKL siRNAs, NFkB siRNAs, control siRNAs	No
Adenovirus	pENTR, pShuttle, pAdEasy	E. coli, mouse cells, human cells	Empty vector	Yes Adenoviral vectors have potential risk of infection.
AAV	pAAV-BASIC	E. coli, mouse, human cells	Empty vector	Yes AAV vectors have potential risk of infection.
HIV, VSV	Lentiviral packaging plasmids:	E. coli, mouse cells,	Packaging plasmids	Yes Lentiviral vectors have

	pMD.2g, pMDLg/pRRE, pRSV-Rev	human cells		potential risk of infection.
Mouse	Lentiviral expression vector	E. coli, mouse and human cells	Gata4	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
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  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - Experiments with Transgenic Animals
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
  - III-E-3: Experiments involving transgenic rodents: involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line. Only experiments that require BL1 containment are covered under this section; experiments that require BL2 or higher containment fall under section III-D-4 above.
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
  - III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated to render them capable of penetrating cellular membranes
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
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  - Appendix C-VIII: Generation of BL1 transgenic rodents via breeding

#955 (Perrin) *Stereocilia cytoskeletal protein dynamics* (**Primary:** Gavina; **Vet:** Johnston; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:** A a lentivirus expressing a fluorescent marker to this protocol, injected into mouse tissue.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Mouse (beta-actin), Aequorea Victoria (GFP)	Transfer vector CTR4-beta-actin -GFP	E. coli	Beta-actin-GFP	No
Mouse (espin3A), Aequorea Victoria (GFP)	transfer vector CTR4 -GFP-espin3A	E. coli	GFP-espin3a	No
Aequorea Victoria	transfer vector CTR4 -GFP	E. coli	GFP	No
GFP is Aequorea Victoria and Tmod1 from mouse	transfer vector CTR4 – GFP-Tmod1	E. coli	GFP-Tmod1	No
Aequorea Victoria (GFP) and mouse (Tmod3)	transfer vector CTR4 -GFP-Tmod3	E. coli	GFP-Tmod3	No
Aequorea Victoria (GFP) and mouse (CapZ)	transfer vector CTR4 -GFP-Capz	E. coli	GFP-Capz	No
Aequorea Victoria (GFP) and mouse (Eps8)	transfer vector CTR4 – GFP-Eps8	E. coli	GFP-Eps8	No
Aequorea Victoria (GFP) and mouse (ESPNL)	pcDNA3.1 and pAdenoX-CMV	E. coli, Human cells	EGFP-ESPNL	No
Aequorea Victoria (GFP) and mouse (PDZD7)	pcDNA3.1 and pAdenoX-CMV	E. coli, human cells	EGFP-PDZD7	No
Aequorea Victoria (GFP) and mouse (Myo3a)	pcDNA3.1 and pAdenoX-CMV	E. coli, human cells	EGFP-MYO3A	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.

- III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
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#1112 (Vidal) *Animal Models of Neurodegenerative Diseases* (**Primary:** Gavina; **Vet:** Seelye; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
  - 2025 annual renewal
  - Personnel Amendment
  - Administrative Updates
  - Adding additional AAVs and lentiviral vectors
  - Adding Discosoma spp. as a new rDNA source species
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Aequorea victoria	AAV-CMV-GFP	whole mouse (brain injection)	GFP	No
Human	AAV- CMV-APP	whole mouse (brain injection)	APP	No
Human	AAV- CMV-tau	whole mouse (brain injection)	tau	No
Human	AAV- CMV-BRI2	whole mouse (brain injection)	BRI2	No
Human	AAV- CMV-TREM2	whole mouse (brain injection)	TREM2	No
Human, Aequorea victoria, Discosoma spp	For cell transfection: pCR3.1; pcDNA3.1: pcDNA3.1 directional topo: pcDNA-GFP, pcMyc (all from Invitrogen), for general cloning: pCR2. I, pUC18, pUC 19, for recombinant expression: pGEX, pET18; pET19; pET28 (Novagen). Additional plasmids: AAVS1, CYBL, PB, pZT, pUCM	Human cells, mouse cells, E. coli	APP, tau, BRI2, TYROBP, TREM2, GFP. Others: IRF5, hNGN2, L1, R1, TALEN, mCherry, EGFP.	No
Human, Aequorea victoria	For lentiviral work (FuGW, LentiCRIPSR v2 puro)	Human cells, mouse cells, E. coli, mice	APP, tau, BRI2, TYROBP, TREM2, PSEN1, APOE, GFP, MAPT	No
HIV, VSV	psPAX2, pMD2.G	E. coli and human cells	HIV gag/pol, VSV envelope glycoprotein	No
Human	AAVS1-MAFB-IRF8-CEBPA (Addgene)	Human cells	CCAAT/enhancer-binding protein alpha (CEBPA), IRF8, also known as ICSBP	Yes tumor suppressor and transcription factor found to be recurrently altered by mutation in acute myeloid leukemia. Mutations in IRF8 can lead to

				immunodeficiency and susceptibility to certain infections.
Human	PB-TO-NFIA.1-SOX9 (bi-directional promoter) (Addgene)	Human cells	Sox9, also known as SRY-Box Transcription Factor 9, NFIA (Nuclear Factor I A)	Yes SOX9 encodes a putative tumor suppressor and transcription factor involved in organ and skeletal development. This gene is frequently mutated in colorectal cancer.

- **Recommended containment conditions:** BSL-2/ABSL-2
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  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
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  - III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
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<u>5-year Renewals:</u>

#1217 (Liang) *Genetic determination for brain and liver disease* (**Primary:** Dong; **Vet:** Seelye; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-1, pending revisions.**
- **Types of manipulations planned:**

    - Administrative Updates; No changes to approved work
- Transgenic animals: Mouse
- Recombinant DNA:

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Mice	pGL3	Human cells	Luciferase, Fkbp5	No
Rodent DNA	pGL3	Human cells	Luciferase, genes related to mitochondria function and liver disease. For example Park2 gene	No
Firefly	pGL3	Human cells	Luciferase	No
Mice	PGL3	E. coli	Fkbp5	No
HIV and VSV	Packaging plasmid (psPAX2), env plasmid (pMD2.G)	E. coli; human cells	Tat, Gag.Pol and Env	No
S. pyogenes	pX333	E. coli; mouse cells	CAS9, gRNA	No
S. pyogenes, HIV, mouse	pLentiCas9-Fkbp5	E. coli; human cells; mouse cells	Fkpb5 guided-RNA	No

- Recommended containment conditions: BSL-2/ABSL-1
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#1256 (Linnemann) *Prostaglandin E2 Actions and Enhanced Susceptibility to Skin Infection in Diabetic Mice* (**Primary:** Dong; **Vet:** Seelye; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
    - Administrative Updates
    - Updating route of administration and minimum containment for Heat killed MRSA (S. auereus) to match IACUC protocol
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Human/Aquorea victoria	AKAR4	Mouse Skin	Proteinkinase A substrate/ contains a cerulean fluorescent protein and a venus fluorescent protein	No
Human	Ad5-AKAR4	Mouse	Protein Kinase A substrate	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
    - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
    - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
    - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
    - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
    - III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated to render them capable of penetrating cellular membranes
    - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
    - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
    - Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1

#1251 (Prosperi) *Wnt-independent functions of APC in breast cancer* (**Primary:** Kim; **Vet:** Johnston; **Biosafety:** Painter; **Secondary Biosafety:** Rayadurg)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
    - Administrative Updates
    - No changes to approved protocol.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
TCF – human luciferase – firefly	pTOP-flash	human cells; mouse cells; E. coli	Firefly luciferase	No
TCF – human luciferase – firefly	pFOP-flash	human cells; mouse cells; E. coli	Firefly luciferase	No
Renilla reniformis	pRL-TK	human cells; mouse cells; E. coli	Luciferase (renilla reformis)	No
AP1 – human luciferase – firefly	pAP1-luciferase	human cells; mouse cells; E. coli	Firefly luciferase	No
Human	pEGFP-APC	human cells; mouse cells; E. coli	APC	No
Human and mouse	pLKO.1	human cells; mouse cells; E. coli	shRNA for APC	No
Human and S. pyogenes	lentiCRISPR v2	human cells; E. coli	Cas9 expression gRNA	No
HIV	psPAX2	human cells; E. coli	Lentiviral packaging plasmid	No
VSV	pMD2	human cells; E. coli	VSV-G envelope protein	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
  - Appendix C-VIII: Generation of BL1 transgenic rodents via breeding

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#1245 (Spandau) *Epidermal photocarcinogenesis and wound healing* (**Primary:** Zhao; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2, pending revisions.**
- **Types of manipulations planned:**
  - Administrative Updates
  - Removed VA affiliation
  - No changes to approved protocol
- **Transgenic animals:** n/a
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Human	Gene expression using plasmid pcDNA3.1 and related commercial vectors; pCMV5, pSCMV, pCITE, pGEX, pLP, pTRC, pROEX, pCA-IB, pBioD-HA, pMYC-BioID	Cultured cells, NTERT, primary keratinocytes, primary fibroblasts, E. coli	These genes will be expressed or depleted in these cell lines: EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF4, CHOP, GADD34, GCN1, NOS2, ARG1	No
Photinus pyralis	Luciferase-pcDNA3	Cultured cells, NTERT, primary keratinocytes, primary fibroblasts, E. coli	GFP	No
Human	pLKO.1 lentiviral vector, pVSV, pRSV, pRRE (production of lentiviral particles)	HEK293T, E. coli, NTERT, primary human keratinocytes, primary human fibroblasts	shRNA to EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF4, CHOP, GADD34, GCN1, NOS2, ARG1	No
Human	pCLXSN retroviral vector, pCL-Ampho (for production of retroviral particles)	HEK293T, E. coli, NTERT, primary human keratinocytes, primary human fibroblasts	EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF4, CHOP, GADD34, GCN1, NOS2, ARG1	No
Aequorea victoria	pcDNA3-EGFP	Cultured cells, NTERT, primary keratinocytes, primary fibroblasts, E. coli	GFP	No

- **Recommended containment conditions:** BSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*

#1258 (Wek) *Regulation and Function of Integrated Stress Response* (**Primary:** Dong; **Vet:** Johnston; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
  - Administrative Updates
  - Animals, modified human cells: Updating route of administration response to match IACUC 24022.
  - Subcutaneous (SQ) injection of cell lines modified with shRNA or CRISPR-Cas 9 generated knock-outs. Alternatively, targeted gene expression is carried out in these injected cells using lentivirus or pcDNA3.1.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Mouse	Gene expression using plasmid pcDNA3.1 and related commercial vectors. Enhanced gene expression or knockdown using lentivirus, e.g. PLKO.1, and derived siRNAs.	E. coli; human cells	ISR genes will be expressed or depleted in these cell lines, such as EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF3, ATF4, ATF5, ATF6, CHOP, GADD34, IBTK, IRAK2, and XBP1.	Yes Enhancing the levels of select components of the eIF2 kinase pathway have been implicated in the progression and treatment of cancers. See PMID: 29959193.
Human	Gene expression using plasmid pcDNA3.1 and related commercial vectors. Enhanced gene expression or knockdown using lentivirus, e.g. PLKO.1, and derived siRNAs.	E. coli; human cells	ISR genes will be expressed or depleted in these cell lines, including EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF3, ATF4, ATF5, ATF6, CHOP, GADD34, and XBP1.	Yes Enhancing the levels of some components of the eIF2 kinase pathway have been implicated in the progression and treatment of cancers. See PMID: 29959193.
Budding yeast Saccharomyces cerevisiae	pRS series of yeast vectors derived from those cited in PMID: 2659436, all based on pBLUESCRIPT	S. cerevisiae and E. coli	GCN2 and GCN4	No
Mouse and human	PLKO.1-targeted knockdowns: packaging plasmids pCMV-JR8.91 and VSV-G. Expression of target genes using pLenti, pLenti6.3, pLVX, pLPCX, and 7TGC:	E. coli; mouse cells; human cells	Expression or knockdown of ISR genes, including EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF3, ATF4, ATF5, ATF6, CHOP, GADD34, and XBP1.	Yes Enhancing the levels of some components of the eIF2 kinase pathway have been implicated in the progression and treatment of cancers. See PMID: 29959193.
HIV and VSV	Lentiviral packaging plasmids PMDLg/pRRE, pRSV/REV,	E. coli; human cells	Gag, pol rev and env	No

	and pVSV-G pCMV-JR8.91 and VSV-G			
Mouse and human	pCL (or pLPCX) transfer vector and pCL-Ampho packaging plasmid	E. coli; human cells	Expression or knockdown of ISR genes, including EIF2AK1, EIF2AK2, EIF2AK3, EIF2AK4, ATF3, ATF4, ATF5, ATF6, CHOP, GADD34 and XBP1	Yes Enhancing the levels of some components of the eIF2 kinase pathway have been implicated in the progression and treatment of cancers. See PMID: 29959193
Mouse and human	pCAS9-guide, pLenti-CRISPRv2/puro, pTRIPZ/puro	E.coli; human cells; mouse cells	Knock-out or knock-down of EIF2AK1, EIF2AK2, EIF2AK3,vEIF2AK4, ATF4	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)
  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
  - Experiments with Transgenic Animals
  - Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
  - III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated to render them capable of penetrating cellular membranes
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)

- Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture
- Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
- Appendix C-III: Saccharomyces Host-Vector Systems*
- Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1

New Protocols:

#27368 (Moutinho) *Investigating the biology underlying Alzheimer's disease and related dementias* (**Primary:** Randall; **Vet:** Seelye; **Biosafety:** Painter; **Secondary Biosafety:** Rayadurg)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-1, pending revisions.**
- **Types of manipulations planned:** Our studies aim to further our understanding on the biological mechanisms underlying Alzheimer's disease and related dementias (ADRD). We are specifically focused on the role of brain-resident immune cells, microglia, in disease. Microglia represent a heterogeneous cell population that can acquire a plethora of phenotypes throughout disease progression, thus, their role in ADRD is highly complex and remains somewhat contentious. We aim to leverage this phenotypic plasticity of microglia to identify and modulate particular microglial functions that can lead to beneficial outcomes in disease. The overarching goal is to understand the mechanisms underlying microglia actions in ADRD that can guide the development of novel therapeutics as well as the identification of new biomarkers. To achieve this we will analyze different cellular and mouse models of disease.
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Human	pcDNA3.1	E.Coli, Human cells, Mouse cells	human TREM2 isoform 1	No
Human	pcDNA3.1	E. coli, Human cells, Mouse cells	Human TREM2 isoform 2	No
Human	pcDNA3.1	E. coli, Human cells, Mouse cells	Human TREM2 isoform 3	No
Synthetic	FANA antisense oligonucleotides (ASO) for HCAR2	Human cells, Mouse cells	antisense oligonucleotide	No
Human and Aequeorea Victoria	pAAV9-CMV>eGFP:P2A:hTau(2N4R)P301L	Mouse brain cells	eGFP (A. Vicotria) hTau(2N4R)P301L (Human)	No
E. coli	pcDNA3.0	E. coli	It is the plasmid backbone only - it contains an ampicillin resistant protein for selection.	No
E. coli	pcDNA3.0	E.coli	pncA enzyme and the HA tag	No
E.coli	n/a	E. coli	pncA gene was deleted and replaced with a kanamycin resistanca cassette	No
Mouse	pcDNA3.1	E.coli, Human cells, Mouse cells	Mouse TREM2 isoform 1	No
Mouse	pcDNA3.1	E.coli, Human cells, Mouse cells	Mouse TREM2 isoform 2	No

Aequorea victoria	pcDNA3.1	E.coli, Human cells, Mouse cells	GFP	No

- **Recommended containment conditions:** BSL-2/ABSL-1
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
  - III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
  - III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
  - III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
  - III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
  - Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
  - Appendix C-VIII: Generation of BL1 transgenic rodents via breeding
  - Appendix C-II: Escherichia coli K-12 Host-Vector Systems*

Non-Exempt Veteran's Affairs Reviews (III-A – III-E)

<u>Major Amendments:</u>

#1531 (Liangpunsakul) *Mechanism of alcohol-induced liver injury* (**Primary:** Horan; **Vet:** Seelye; **Biosafety:** Painter)

- **This submission was unanimously provisionally approved at BSL-2/ABSL-2, pending revisions.**
- **Types of manipulations planned:**
  - Adding experiments involving murine extracellular vesicles (EVs)
- **Transgenic animals:** Mouse
- **Recombinant DNA:**

SOURCE SPECIES	PLASMID AND/OR VECTOR	HOST TO BE USED	GENE OR TRANSCRIPTION PRODUCT	KNOWN HARM
Photinus pyralis, Rat, mouse, and human DNA	pGL3	McR RH7777 rat hepatoma, E. coli K12	ADH promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	H4IIEC3 rat hepatoma, E. coli K12	PPAR alpha and gamma, promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	HeLa cells, E. coli K12	AMPK promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	AML12 mouse hepatoma, E. coli K12	ChREBP promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	HuH7 human hepatoma cell, E. coli K12	Foxo1/3/4 promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	HepG2 human hepatoma cells, E. coli K12	Sestrins promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	HepG2 human hepatoma cells, E. coli K12	FKBP-5 promoter for expression of luciferase	No

Photinus pyralis, Rat, mouse, and human DNA	pGL3	PLC (human hepatoma cells), E. coli K12	Pyruvate dehydrogenase 4 promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	RAW264.7 (rat Kupffer cell line), E. coli K12	Pyruvate dehydrogenase 4 promoter for expression of luciferase	No
Photinus pyralis, Rat, mouse, and human DNA	pGL3	HEK 293A cells, E. coli K12	Pyruvate dehydrogenase 4 promoter for expression of luciferase	No
Mouse	Adenovirus generated by using pAdEasy system (Agilent)	HepG2 human hepatoma cells	Sestrin3 and fkbp5	No
Mouse and human	pAAV-Fkbp5	Human cells; mouse cells	Fkbp5	No
Mouse and human	pAAV-FAF2	Human cells; mouse cells	Faf2	No
Mouse	pAAV-CD63	Human cells	Cd63	No
Mouse and human	pAAV-shFAF2	Human cells; mouse cells	Faf2	No
Mouse and human	pAAV-Sens3	Human cells; mouse cells	Sens3	No
Adenovirus	pAdEasy for Sesn3	Human cells; mouse cells	Sesn3	No
Adenovirus	pAdEasy for fkbp5	Human cells; mouse cells	Fkbp5	No
Mouse	pAdV-shSesn3	Human cells; mouse cells	Sesn3	No
Mouse	pAdV-Atg14	Mouse cells	Atg14	No
Jellyfish Aequorea victoria	pAdV-GFP	Human cells; mouse cells	GFP	No
Mouse	pAdV-Atg14-shRNA	Mouse cells	Atg14	No
Mouse	pAdV-GFP-CD63	Mouse cells	CD63	No
Mouse	pAdV-shRNA	Mouse cells	synthetic gRNAs	No
Adenovirus	pAAV-Helper	Mouse cells	Adeno E2A, and E4	No
AAV	pAAV-RC	Mouse cells	rep and cap for co-transfection with the ITR-containing vectors	No
AAV	pAAV-AK128	Mouse cells; E. coli	AK128	No
AAV	pAAV-ASMT	Mouse cells; E. coli	ASMT	No
Mouse	pAAV-Ncf1	Mouse cells; E. coli	Ncf1	No
Mouse	pAAV-p38	Mouse cells; E. coli	p38	No
Mouse, VSV	psPAX2; pMD2.G	Mouse cells, AML12	Whole genome library	No
bacteria, S.pyogenes; synthetic	pFUGW	Mouse cells, AML12	Cas9	No

- **Recommended containment conditions:** BSL-2/ABSL-2
- **Section of the NIH guidelines selected by the investigator:**
  - III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)

- III-D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
- III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid Molecules
- Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
- III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required.
- III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.
- III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight.
- III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)
- Appendix C-II: Escherichia coli K-12 Host-Vector Systems*
- Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
- Appendix C-VIII: Generation of BL1 transgenic rodents via breeding

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<u>5-year Renewals:</u>

- None

<u>New Protocols:</u>

- None

Non-Compliance and Reportable Events

<u>Non-Compliance:</u>

- Pattabiraman lab: Non-response to revisions for 5-year renewal of IBC 1175
    - The PI responded to the initial reminder for 5-year renewal, due in January 2025, and the protocol was provisionally approved, pending revisions, at the February 2025 IBC meeting.
    - The PI was initially responsive to reminders, but never returned the requested revisions, causing the protocol to become non-compliant.
    - RSCO emailed the PI a final time on 6/18/2025, requiring immediate action, informing the PI that their protocol would be terminated if revisions were not returned by 06/20/2025, and that their other compliance approvals may also be affected.
    - The PI responded that day, and the protocol has since been revised and approved. The PI is now compliant with all IBC requirements.

Reportable Events:

NIH Reportable

- None

Non-NIH Reportable

- None

Other Business

Other Business:

- New Clinical Trials Guidance Website: https://research.iu.edu/compliance/biosafety/submissions/clinical-trials.html
- New IBC Meeting Minutes Website: https://research.iu.edu/compliance/biosafety/ibc-meeting-minutes.html

Next Meeting

Thursday, July 17, 2025, 9:30 – 11:30 a.m., Virtual Meeting

The meeting adjourned at approximately 10:41 a.m.