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|  | Institutional Biosafety CommitteeFormal Actions Taken in June 2024: HGT and rDNA |

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| **CONVENED MEETING: June 12, 2024** |

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| **ATTENDANCE** |

**Voting**

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| **Attended** | Primary Members  |  | Alternate Members |
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|  [x]  | **Chad Rappleye**, *Chair* |[x]  **Long-Sheng Chang** |
|  | Microbiology | rDNA, HGT |  | Pediatrics | rDNA, HGT |
|  |  |  |[x]  **Nathan Denlinger** |
|  |  |  |  | Hematology | Hematology |
| [ ]  | **David Puskas,** *Institutional Biosafety Officer* | [x]  | **Holly Ferris,** *Assistant Biosafety Officer* |
|  | EHS |  |  | EHS | rDNA, Bio |
|  |  |  | [x]  | **Anthony Dent,** *IBC Protocol Consultant* |
|  |  |  |  | ORRP | rDNA, Bio |
|[x]  **Monica Venere,** *vice chair* |[x]  **Adriana Forero** |
|  | Radiation Oncology | rDNA, Bio |  | Microbial Inf/Immun. | rDNA, Bio |
|[x]  **Jacob Yount** | rDNA, Bio |[x]  **Sumit Ghosh** | rDNA, Bio |
|  | Microbial Inf/Immun. |  |  | Nationwide Children’s – ext. |  |
|[x]  **Brad Youngblood** |[ ]  **Carrie Freed** |
|  | ULAR | Animal |[ ]  **Judy Hickman-Davis** |  |
|  |  |  |[ ]  **Stacey Meeker** |  |
|[x]  **Ian Davis** |[ ]  **Daniel Conway** |
|  | Veterinary Biosciences | rDNA, Clin |  | Biomedical Engineering | rDNA, Bio |
|[x]  **Christopher Taylor** |[ ]  **TBD** |
|  | Plant Pathology | Plant rDNA |  |  |  |
|[ ]  **Antoinette Marsh** |  |[x]  **Amanda Panfil** |  |
|  | Veterinary Preventive Med. | Bio |  | Veterinary Biosciences | Bio, rDNA |
|[x]  **Maera Flynn** |[ ]  **TBD** |
|  | Ohio EPA- external | Bio |  |  |  |
|[ ]  **Matthew Bolenbaugh** | Bio |  |  |  |
|  | Columbus Public Health- external |  |  |  |  |

**Non-Voting**

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| **Present:** | **Office of Responsible Research Practices (ORRP)** |
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|[x]  Linda Neidhardt, *Program Director, Office of Research Compliance* |
|[x]  Allison McMurray, *IRB Protocol Analyst II* |

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| **CALL TO ORDER** |

Dr. Rappleye called the meeting to order at 10:00 a.m. via videoconference and the meeting was adjourned at 11:00 a.m. The Committee retained quorum for the entire meeting.

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| **GENERAL DISCUSSIONS** |

* The Minutes from the June meeting were made available to the Committee in sufficient time for review. The Committee had no concerns and approved the June minutes (For: 09; Against: 00).
* The IBC program coordinator informed the committee of changes to Ohio’s Laws and Administrative Rule 3745-570-204. The new rule would require use of a fifteen per cent sodium hypochlorite solution volume per volume when treating cultures consisting of liquid culture media or of solid agar media with only surface growth. The Assistant Biological Safety Officer and EPA representative will look into the change in the law and determine if the change pertains to routine decontamination/treatment or is specific for disposal of biohazard waste. Guidance will be discussed at the July meeting.

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| **Human Clinical Trials** |

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| **2025R0020** | **A phase 3, randomized, placebo controlled, blinded trial of INO-3107 with electroporation (EP) in subjects with HPV-6 and/or HPV-11-associated recurrent respiratory papillomatosis (RRP)**Laura Matrka |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Recombinant DNA, Biohazard Clinical Trial
* NIH Guidelines: Section III C
 |
|  | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Human Source Material (Tissue, urine and blood samples) RG2 |
| **rDNA** | Host(s):* Human

Vectors: * pGX6010: Eukaryotic expression plasmid expressing two human IL-12 subunits p40 and p35.
* pGX3024: Eukaryotic expression plasmid expressing the SynCon® E6 and E7 proteins of HPV 11 and HPV 6 controlled by a synthetic human CMV promoter.

Transgene expression:* The expression of IL12A p40 subunit is driven by the human CMV promoter (hCMV promoter)
* with the SV40 poly-adenylation signal (SV40PolyA), while the expression of p35 subunit is
* driven by the simian CMV promoter (sCMV promoter) with the bovine growth hormone polyadenylation signal (bGH PolyA).
 |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Please describe the disposal procedure for the components of the CELLECTRA. Do components need to be placed in sharps containers?
2. **Descriptive Summary:** What disinfectant will be used to clean spills and what is the contact time?
3. **Descriptive Summary:** You indicated that the CELLECTRA® 5PSP device has not been approved by the FDA for sale in the US. Please discuss the risk of using this electroporation device following IM injection.
4. **Descriptive Summary:** Please explain in sections 1 and 2 what are included in the study drug INO-3107 (e.g., pGX3024, a DNA plasmid encoding a fusion protein consisting of E6 and E7 proteins from HPV types 11 and 6, and pGX6010, a DNA plasmid encoding codon-optimized human IL-12 subunit alpha (IL12A, IL-12 subunit p35) and subunit beta (IL12B, IL-12 subunit p40). Please also explain how these two plasmids could reduce the need for surgery in patients with HPV-6 and/or HPV-11-associated recurrent respiratory papillomatosis (RRP).
5. **Descriptive Summary:** Your response to the IBC Request Query #2 about human source materials is insufficient. Please also include the risks of exposure to HPV-6 and HPV-11.
6. **Exposure Assessment and PPE:** Please change the bleach concentration to 10% and the exposure time of 30 min or longer.

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0034** | **Biomarkers for an investigational new drug LH-001**Chien-Liang Lin |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Recombinant DNA, Biohazard Clinical Trial
* NIH Guidelines: None
 |
|  | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Human blood (RG2)Human cerebrospinal fluid (RG2) |
| **rDNA** | Host(s): NoneVectors: NoneTransgene expression: None |
| **Committee Review** | **Key Points**:1. **Exposure Assessment and PPE:** Please add a bit more information. What are the potential symptoms individuals might experience?

**Requirements to be completed:**NIH guideline training: Not RequiredLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0042** | **OSU-25096: Phase Ib Dose Expansion Study of NXC-201 for the Treatment of Patients with Relapsed or Refractory AL Amyloidosis**Naresh Bumma |
| **Committee** **Decision** | The Committee **APPROVED** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Recombinant DNA, Biohazard Clinical Trial
* NIH Guidelines: Section III C
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | NCX-201- (RG2)Human Source Material (Blood, Bone Marrow, Urine) – RG2 |
| **rDNA** | Host(s):* Human T cells

Vectors: * commercially produced lentiviral vector

Transgene expression:* anti-BCMA CAR retroviral vector encoding the CAR targeted to human BCMA (B-cell maturation antigen)
 |
| **Committee Review** | **Key Points**:1. No Changes need to be made

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0043** | **A PHASE 3 RANDOMIZED CONTROLLED STUDY OF RENAL AUTOLOGOUS CELL THERAPY (REACT) IN SUBJECTS WITH TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE (REGEN-006)**Isabelle Ayoub |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Biohazard Clinical Trial
* NIH Guidelines: None
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Human primary cells and cell lines (blood, urine, kidney tissue): RG2 |
| **rDNA** | Host(s): NoneVectors: NoneTransgene expression: None |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Please describe who will be responsible for isolating selected renal cells from biopsy material obtained from a participant and expanding them ex vivo to form the active biological ingredient of the REACT product? Will you be sending kidney biopsies to the sponsor for manufacturing the REACT product?
2. **Descriptive Summary:** You have described the biosafety risks associated with renal cells and blood, please also include kidney biopsies and urine in your description.
3. **Descriptive Summary:** Please correct the typo in the sentence “Potential routes of exposure associated wit the the biohazards…” in the last paragraph of Descriptive Summary.
4. **Descriptive Summary:** You indicated that REACT drug product contains renal cells selected from biopsy material from a participant and expanded ex vivo. Since “No genetic enhancement or gene editing is part of the REACT drug product”, please briefly describe how the selected renal cells are expanded ex vivo.
5. **Funding Information:** If you are sending kidney biopsies to the sponsor for manufacturing the REACT product, you should check "Yes" to the question “Is any external support other than monetary (e.g. drugs, equipment, etc.) being provided for the study”.
6. **Exposure Assessment and PPE:** Please also include kidney biopsies in your discussion of “Potential consequences of exposure”.

**Requirements to be completed:**NIH guideline training: Not RequiredLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **Recombinant DNA Protocols** |

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| **2020R0059-R1** | **Study SARS-CoV-2 and common cold human coronaviruses (Renewal 1)**Qiuhong Wang |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocoland REASSESSMENT BY REVIEWERS |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2 and ABSL-2
* Type of Research: Biohazard rDNA, Animal
* NIH Guidelines: Section III D (1), (2), (4); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Coronaviruses (SARS-CoV-2, recombinant SARS-CoV-2, HKU1, 229E, NL63, and OC43) – RG2Human and Animal Cell lines (Caco-2, IPECJ2, A549, Calu-3, HULEC-5a, Vero) – RG2Hamsters – RG1*E. Coli* – RG1Human and animal clinical samples for virus isolation (blood borne pathogens) – RG2 and potentially RG3 for isolation of samples from animals |
| **rDNA** | host(s):* *E. Coli*
* Mammalian cells (HEK293T cells, BHK cells, Vero cells)

vectors: * pET23b, pET30 – prokaryotic expression vectors
* pUC19 – For the construction of infectious clones
* pSELECT-CHis-blasti, pCAGGS – transfect HEK293T or BHK cells for protein expression.
* pCR2.1, pCR4-TOPO, and pCR-XL –will be used for cloning and sequencing small and large DNA fragment

transgene expression: (none in infectious virus for gain of function)* expression of non-glycosylated viral proteins (e.g., nucleocapsid protein)
* expression of viral proteins (e.g., pET23b, pET30)
* expression of partial or full glycosylated viral proteins (e.g., spike (S) protein, the receptor binding domain (RBD) of S protein)
 |
| **Committee Review** | **Key Points**: Return to Reviewers prior to approval to assess whether BSL-3 will be required for potential isolation of coronavirus from animals1. **Descriptive Summary:** Please be more specific about what animal clinical samples you expect to be isolating viruses from.
2. **Descriptive Summary:** Please add that working hamsters in general presents a risks of bites/scratches and possible development of allergies. This should be mitigated by proper training in animal handling and wearing PPE, including masks.
3. **Descriptive Summary:** Please define PO vaccination
4. **Descriptive Summary:** You indicated that REACT drug product contains renal cells selected from biopsy material from a participant and expanded ex vivo. Since “No genetic enhancement or gene editing is part of the REACT drug product”, please briefly describe how the selected renal cells are expanded ex vivo.
5. **Descriptive Summary:** Please mention what specific type of disinfectants will be tested by the lab in the proposed studies (e.g. Quaternary based etc.)
6. **Descriptive Summary:** Please outline how samples are transported from the animal facility to the lab areas.
7. **Descriptive Summary:** Please clarify for what specific work BSL1 practices will be utilized.
8. **Descriptive Summary:** Please outline what safer sharps practices will be utilized for animal work.
9. **Exposure Assessment and PPE:** If there is a loss of containment, please outline any possible environmental consequences.

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2022R0095** | **Effect of infections on airway epithelial and immune cells**Estelle Cormet-Boyaka |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocoland REASSESSMENT BY REVIEWERS |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Biohazard Clinical Trial
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | MRSA, MSSA – (RG2)Human epithelial cells (CFBE cells, F508del, Calu-3 cells, 16HBE cells) – (RG2)primary human airway cells – (RG2)*E. Coli* BL21 – (RG1)Lentiviral vector 3rd gen – (RG2) |
| **rDNA** | host(s):* *E. Coli* BL21
* Primary human airway cells.
* Cell lines CFBE, 16HBE, and Calu-3.

vectors: * pLV[CRISPR]-hCas9:T2A:Puro-U6 lentivirus vector will be used to knock-down the cannabinoid receptors 1 and 2 (CNR1 and CNR2).
* pRP[Exp]-CMV vector will be used to express Intelectin-1 and intelectin-2.
* pCDNA3 vector will be used to express CFTR and CFTR mutants.

transgene expression:* Human Intelectin-1 and intelectin-2
* Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) and CFTR mutants which lack activity
 |
| **Committee****Review** | **Key Points**:1. **Descriptive Summary:** Please address if you will be using an ussing chamber and how it will be decontaminated.
2. **Descriptive Summary:** It is mentioned that - BSL2 facility will be used for all the experiments. Please clarify what specific practices will be used for the proposed work at BSL2.
3. **Descriptive Summary:** Please spell out CB1 and CB2 receptors or provide information about these receptors. What are the biosafety risks associated with the use of lentiviral vector systems in the proposed studies?
4. **Descriptive Summary:** Under PPE practices, please clarify "eyewear". Will safety glasses or goggles be used for the proposed studies?
5. **Procedures, Locations & Inspections:** DNA/RNA extraction, Tissue culture and growing bacterial cultures all need to be addressed in the descriptive summary.
6. **Safety Equipment:** Please include the model number, serial number and manufacturer of the BSC.
7. **Exposure Assessment and PPE:** Please include the risks associated with working with lentiviral vectors and recombinant DNA. Some of the previous comments are still not addressed.
8. **NIH Section Designation:** Please also select E and E.1

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0016** | **Novel Mechanism of Nuclear HDAC4 in Early life Stress-Induced Alcohol Consumption, Preference and Tolerance in Offspring**Erbo Dong |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2 and ABSL-2
* Type of Research: Biohazard Clinical Trial
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Lentivirus 3rd gen (RG2)AAV2 (RG1) |
| **rDNA** | host(s):* Mice

vectors: * Lentiviral vectors (pLL3)
* AAV2

transgene expression:* shRNA delivery – Targets: Fluc, Pp1a, Hdac4
 |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Please clarify in the instances in which the lentiviral work would need to be done outside of containment.
2. **Descriptive Summary:** Under Personal Protective Equipment, please indicate what research activities can be performed outside of the Biological Safety Cabinet.
3. **Locations (continued):** Please include an inspection date. This will need to be provided before the work starts.
4. **Exposure Assessment and PPE:** What is the appropriate PPE to be used with lentiviral vectors?
5. **Exposure Assessment and PPE:** Also include exposure risk information provided in the descriptive summary in this section

**Requirements to be completed:**NIH guideline training: [REDACTED]Lentiviral Training: [REDACTED]Occupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0037** | **Highly Pathogenic Avian Influenza Viruses**Cody Warren |
| **Committee** **Decision** | The Committee **DEFERRED** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2 and ABSL-2
* Type of Research: Biohazard Clinical Trial
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Avian Influenza Viruses (RG3)recombinant Vesicular Stomatitis Virus (RG2) expressing HA/NA from HPAI.Human cell lines: 293, A549 (RG2)Primary human cells (RG2)Bovine fluids (milk, blood, nasal/oral swabs, fecal slurry, etc.) |
| **rDNA** | host(s):* *E. Coli* such as NEB 5-alpha
* Human cell lines: A549 human lung epithelial cells, human embryonic kidney epithelial cells (HEK 293T)
* Primary human cells: bronchial epithelial cells, nasal epithelial cells, precision cut lung slices, lung explants
* Non-human cell lines: Madin-Darby canine kidney cells (MDCK), Vero cells (grivet monkey)
* Non-huma primary cells: bronchial epithelial cell cultures (swine/bovine), nasal epithelial cell cultures (swine/bovine), precision cut tissue (lung/mammary/teat) slices (swine/bovine),

vectors: * pHH21 vector - For reverse genetics
* the pCDNA3.1-eGFP vector will be used for HA/NA cloning

transgene expression:* Expression of individual viral genes in cells
 |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Please provide information as to what changes you plan to introduce into the HPAIV via reverse genetics so that safety can be evaluated.
2. **Descriptive Summary:** Please include approved virus handling protocols.
3. **Descriptive Summary:** Add Turkey as species in the Summary section.
4. **Descriptive Summary:** Please add a brief description of animal infection procedures described in IACUC protocol in this protocol.
5. **Descriptive Summary:** Please clarify what is used for surface decontamination of sample tubes.
6. **Locations (continued):** Provide updated inspection date for Veterinary Medicine Academic Building 345/347 (last inspection 5/21/2024)

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0039** | **Development of targeted therapies for NSCLC and brain metastases**Timothy Burns  |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2 and ABSL-2
* Type of Research: Biohazard, rDNA, Animal
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Lentivirus (RG2)*E. Coli* (RG1)lung cancer cell lines (RG2)Patient cancer blood samples (RG2)Patient cancer tumor samples (RG2)HEK 293T cells (RG2) |
| **rDNA** | Host(s):* *E. Coli* K-12 DH5alpha and Stbl3
* Human lung cancer cell lines: A549. H460, H23, H727, H358, H838, H1666, SW1573, H226, Calu1, H1993, H596, H1838, Calu6, HCC827, H1793, H1734, H1435, H2122, H3255, H1975, H1648, H1650, PC-9, 11-18, HCC4006, HCC4011, H1437
* HEK 293T for packaging lentivirus
* Mouse immortalized fibroblast cells: NIH 3T3
* Mouse lung cancer cell lines: FVBW-17, FVB-HGF

Vectors: * General cloning (pDONR 221, pENTR 221, pcDNAV5DEST)
* GFP fusion proteins (pEGFPN1)
* Lentivral packaging system including VSVg envelope (pLPVSVG, pLP2, pLP1)
* Lentiviral vector for shRNA expression and tet-induced expression (pLKO.1 neo/hygro/puro, pLKO-TET-ON, pLVTHM)
* Lentiviral vector for expression of Tet transactivator protein and transgene (pLVX-TET3G, pLVX-TRE3G-IRES)
* Lentiviral vector for expression of luciferase and GFP (pLL-CMV-fLuc-T2A-GFP-mPGK)
* Lentiviral vector for transgene expression (pLENTI-CMV, pLENTI-CMV to NEODEST, pLenti6V5)
* Mammalian expression vector (pcDNAV5DEST)
* Luciferase transcriptional reporter fusions (pGL2-Basic, pGL4.15)
* Luciferase expression (pRL-TK)
* Mammalian expression vector for Tet transactivator (pTet-On Advanced, pTRE-Tight)

Transgene expression:* Tumor Suppressors and cell cycle regulators: CDKN1A, CDKN1B, TP53, CDC25A,B,C,
* Oncogenes and tumor promoting genes: KRAS, NRAS, ERK2, RSK1-4, E7, E6, HGF, MET, SKP2
* EMT transcription factors and potential regulators: TWIST1, TWIST2, SNAl1, SNAI2, ZEB1, ZEB2, E12, E47, TRIB3
* Proteins involved in Apoptosis regulation: FLIP, BCL-2, BID, BIK, BIM, DRS, DR4, PUMA,
* Proteins involved in metabolism: HK2 – Hexokinase 2, key regulator of glycolysis
* EGFP - Enhanced Green Fluorescent Protein
* LUC – luciferase for in vitro and in vivo imaging, also for reporter assays
 |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Please clarify what safer sharps practices will be utilized by the lab staff during animal experiments.
2. **Descriptive Summary:** It is mentioned that - We can then do in vitro and in vivo experiments with these cells. Please mention how these cells will be injected into animals.
3. **Descriptive Summary:** Please spell out NSCLC in the protocol.
4. **Descriptive Summary:** State the source of the human blood and patient-derived tumor samples and list any associated IBC protocols.
5. **Descriptive Summary:** Address risk of mutagenesis for CRISPR/Cas9 gene editing approaches and mitigation strategies in the approach used, if relevant (i.e., recombinant Cas9, electroporation, etc.).
6. **Descriptive Summary:** The Exposure Assessment and PPE section indicates “Eyewear” will be worn by the staff. If this is the case, please mention it in the Descriptive Summary section below.
7. **Descriptive Summary:** Directly state in this section that some of the genes to be investigated are oncogenes or disrupt tumor suppressors.

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0046** | **Study on the role of the Dihydroxyacetonephosphate Shunt in Extraintestinal Pathogenic *E. Coli***Justin North |
| **Committee** **Decision** | The Committee **REQUIRES MODIFICATION to** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Biohazard, rDNA
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | *E. Coli* (K12 BW25113, ATCC 25922, Stellar) – RG1*E. Coli* (JJ1886, JJ1887, CFT073) – RG2 |
| **rDNA** | Host(s):* EPEC strains (JJ1886, JJ1887, CFT073): RG2 - ingestion and injection hazard
* non-EPEC *E. Coli* (ATCC25922, BW25113): RG1

Vectors: * DHAP gene knockouts (via phage recombinase system)
* overexpression of DHAP genes: pTETTET expression vector for Tet-inducible expression
* transcriptional reporters: promoter-lacZ fusions
* introduction of transgenes via electroporation or phage transduction

Transgene expression:* genes involved in part of the DHAP shunt or closely associated with the DHAP shunt (mtnN, mtnK, DR76\_RS12415, yjhU, crp-cAMP receptor protein)
* genes involved in synthesis of *E. Coli* cell wall (rfaP, waaO, DR76\_RS04505, DR76\_RS04495, DR76\_RS04485)
* genes involved in central carbon metabolism (lacI, lacZ, fuc regulon fucPIK fucAO, Fbp, glpX, talab, tpiA, pykFA
* promoter regions for mtnN, mtnK/mtnA/ald2, mtnR, crp, cyaA, any promoter or transporter gene for DHAP shunt substrate
 |
| **Committee Review** | **Key Points**: 1. **Exposure Assessment and PPE:** Address change in potential virulence of *E. Coli* upon introduction of DHAP genes.
2. **NIH Section Designation:** E and E1 should be checked since vectors do not contain viral components

**Requirements to be completed:**NIH guideline training: CompletedLentiviral Training: Not RequiredOccupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **2025R0049** | **In vitro investigation of molecular drivers of endometrial cancer cell malignancy and immune cell reprogramming.**Casey Cosgrove |
| **Committee** **Decision** | The Committee **DEFERRED** the biosafety protocol |
| **Biosafety****Risk****Assessment** | * Biosafety Level: BSL-2
* Type of Research: Biohazard, rDNA
* NIH Guidelines: Section III D (1); E (1)
 |
| **Vote** | Total Votes: 09 For: 09 Against: 00 Abstained: 00 |
| **Biohazards** | Human cell lines (endometrial cancer lines HEC-1A, -1B, KLE, AN3CA, ISHIKAWA, RL95-2): RG2Human cell lines (stromal cells T-HESC, HEK293T): RG2Lentivirus: RG2AAV: RG1 |
| **rDNA** | Host(s):* Human endometrial cancer cell lines (HEC-1A, HEC-1B, KLE, AN3CA, ISHIKAWA, RL95-2, human normal endometrial T-HESC cell line
* Human embryonic kidney HEK293 cell line.

Vectors: * AAVS1 Transgene knockin via CRISPR
* Human DKK1 (NM\_012242) AAV Particle
* DKK1 Human shRNA Lentiviral Particle (Locus ID 22943)
* Lenti-vpak packaging kit

Transgene expression:* DNA mismatch repair (MSH, MSh6, MLH1, PMS2)
* DNA replication (POLE)
* Tumor Suppressor (TP53)
* cGAS/Sting inflammatory pathway genes
* WNT pathway for cell proliferation genes
 |
| **Committee Review** | **Key Points**:1. **Descriptive Summary:** Delineate which genes are to be silenced (shRNA), mutated (CRISPR/Cas), overexpressed and which systems will be used (Lentivirus, AAV, transfection)?
2. **Descriptive Summary:** Remove "The procedures for DNA and RNA extraction require the use of small volumes of organic solvents (e.g., ethanol and beta-mercaptoethanol). These experiments are performed in designated lab areas, such as chemical fume hoods, with lab members wearing lab coats, gloves, and protective eyewear, to prevent or minimize direct exposure to tissues and chemical agents." as this is chemical hazard for the Chem Hygiene Plan, not biohazards
3. **Descriptive Summary:** Remove chemical hazard description "Similarly, immunofluorescence involves the use of organic solvents such as xylene, histochoice, and ethanol. The experiments are conducted in designated lab areas (fume hoods), lab members perform these procedures wearing lab coats, gloves and protective eyewear to ensure safe handling of all reagents and samples."
4. **Descriptive Summary:** Remove extraneous statement "Lab safety, risks, and other concerns are discussed routinely during weekly “group” lab meetings. These are reserved for updates on projects, technical and safety practices."
5. **Descriptive Summary:** Vague statement "and observance to protocols that prevent aerosol generation and accidental exposure" What specific observances or steps to mitigate aerosol generation?
6. **Descriptive Summary:** Define specifics for "Waste DNA, RNA, and protein extracts are disposed in labelled, appropriate biohazard disposal containers in compliance with institutional safety protocols." (e.g., solid waste in biohazard "burn" boxes for EHS collection, liquid waste collected in carboy and decontaminated with 10% bleach (30 min), etc.)
7. **Descriptive Summary:** Remove non-descriptive statement "Appropriate biosafety measures are in place to protect laboratory personnel. "
8. **rDNA Work, Section 1:** Insufficient rDNA description of vectors Describe key elements of AAVS1 (map is not sufficient) for knock-in (transgene, selection marker, viral vector base) Describe key elements of expression vector (e.g., AAV, promoter to drive expression, selection marker) Lentivirus system (generation, number of plasmids, specific features like SIN LTR, envelope protein, selection marker, etc.).
9. **rDNA Work, Section 1:** rDNA description too sparse. "modulation" is not informative of the manipulations Explicitly list genes as targets for knock-down (shRNA) vs gene editing (CRISPR/Cas9) vs expression List of genes is dramatically different than the genes listed in the descriptive summary (e.g., MSH, TP53, etc).
10. **rDNA Work, Section 1:** Insufficient rDNA description of vectors including LV and AAV
	1. Describe key elements of AAVS1 (map is not sufficient) for knock-in (transgene, selection marker, viral vector base)
	2. Describe key elements of expression vector (e.g., AAV, promoter to drive expression, selection marker)
	3. Lentivirus system (generation, gag-pol on separate plasmids, specific features like SIN LTR, envelope protein, selection marker, etc.)
	4. AAV system (what backbone, key viral genes removed, envelope, etc)
11. **rDNA Work, Section 1:** Include microbes if any lentivirus or AAV plasmids are propagated in *E. Coli*.
12. **Exposure Assessment and PPE:** Exposure assessment lacks any risk assessment for AAV vectors
13. **Exposure Assessment and PPE:** Address risks to personnel if injected with specific transgenes employed in the study (i.e., what if TP53 expression, what about gene editing of DKK1, etc.)
14. **Exposure Assessment and PPE:** Remove justification statement "although this is rare." as that doesn't alleviate risk
15. **Exposure Assessment and PPE:** Why would the lentivirus carry a "toxin" as stated since no toxins were described
16. **Exposure Assessment and PPE:** Address level of risk with lentivirus based on the envelope protein employed (e.g., pan-tropic VSVg)
17. **Exposure Assessment and PPE:** "Infection risk is generally low unless the cell line is known to harbor a human pathogen" is incorrect. Cell lines can be an infection risk for unknown pathogens as well
18. **Exposure Assessment and PPE:** Define specifics risks with the cell lines used (including any transgenic manipulations) "While generally low-risk, risks to laboratory workers of spills or loss of containment include those associated with working with human source material." What are the risks for working with human source material (unknown pathogens, BBP, tumorigenic)
19. **NIH Section Designation:** D1 should be checked (Use of lentivirus)
20. **NIH Section Designation:** E1 should be checked if any plasmids contain less than 2/3 of the viral genome (e.g., lentivirus genome vector)
21. **Biohazard Identification:** Provide lentivirus and AAV specifics (e.g., lentivirus derived from HIV, AAV serotype

**Requirements to be completed:**NIH guideline training: [REDACTED]Lentiviral Training: [REDACTED]Occupational Health Risk Assessment Tool: CompletedResponsible Conduct of Research training: CompletedConflict of Interest disclosure: Completed |

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| **AMENDMENTS (ADMINISTRATIVELY APPROVED)**  |

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| **Protocol** | **Protocol Title and Information** | **Date of Determination** |
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| **2019R0086-R1-AM2** | **Study the role of endoplasmic reticulum stress in cancer (Renewal 1)** Feng Hong  | 06/05/2025 |
| **2024R0067-AM2** | **Therapeutic effect of synthetic nanoparticles and extracellular vesicle particles in cancer and inflammatory diseases** Mengying Hu  | 06/05/2025 |
| **2024R0039-AM2** | **Eisenmann Lab: Evaluating the neurotoxicity of targeted and cytotoxic chemotherapeutics and the contribution of drug transporters** Eric Eisenmann  | 06/05/2025 |
| **2017R0017-R1-AM2** | **PATHOGENESIS AND VACCINE STUDY OF HIGHLY PATHOGENIC AVIAN INFLUENZA VIRUSES (Renewal 1)** Scott Kenney  | 06/06/2025 |
| **2020R0057-AM5** | **RNA modifications in SARS-CoV-2 and vaccine against COVID-19** Jianrong Li  | 06/06/2025 |
| **2013R0052-R2-AM5** | **Molecular Markers of Radiation and Chemotherapy Resistance (Renewal 2)** Jessica Fleming  | 06/13/2025 |
| **2020R0131-AM12** | **Distinct functions for CD8 T cells in cutaneous leishmaniasis** Fernanda Novais  | 06/13/2025 |
| **2024R0020-AM1** | **Foodborne Pathogen and Microbial Genomics of Livestock Production Systems** Renukaradhya Gourapura  | 06/13/2025 |
| **2017R0085-R1-AM1** | **Editing and Functional Analysis of Innate Immunity Genes (Renewal 1)** Scott Kenney  | 06/13/2025 |
| **2019R0018-R1-AM2** | **Transcriptional regulation and metabolic function of cardiomyokines (Renewal 1)** Kedryn Baskin  | 06/13/2025 |
| **2020R0113-AM1** | **Studies of protein synthesis in the Bacteroidia** Kurt Fredrick  | 06/23/2025 |
| **2007R0029-R2-AM1** | **MOLECULAR BASIS OF INTRACELLULAR PARASITISM BY LISTERIA MONOCYTOGENES (Renewal 2)** Stephanie Seveau  | 06/24/2025 |
| **2016R0105-R1-AM7** | **Visualization at The Small Animal Imaging Core Facility (Renewal 1)** Thomas Hund  | 06/27/2025 |
| **2012R0022-R1-AM8** | **Stem cell therapy for cardiac repair (Renewal 1)** Mahmood Khan  | 06/27/2025 |
| **2025R0017-AM1** | **Rodent Osteomyelitis Research** Sara McBride-Gagyi  | 06/27/2025 |
| **2020R0083-AM6** | **Mechanisms of Memory T Cell Development during Infection and Tumorigenesis** Gang Xin  | 06/27/2025 |
| **2021R0045-AM4** | **Viral Transfection for the Study of the Nervous System** Cole Vonder Haar  | 06/27/2025 |
| **2023R0022-AM5** | **OSU-22362: A Multicenter, Phase I, Open-label, Dose-escalation and Expansion Study of TNB-486, a Bispecific Antibody Targeting CD19 in Subjects with Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma** Yazeed Sawalha  | 06/27/2025 |
| **2020R0051-AM4** | **Defining the role of the microbiome in COVID-19 risk in health care workers** Karen Dannemiller  | 06/27/2025 |
| **2013R0121-R2-AM2** | **Manipulating human lung cancer and human lung epithelial cells by transfection, and retroviral and lentiviral transduction. (Renewal 2)** David Carbone  | 06/27/2025 |
| **2023R0038-AM1** | **OSU-23030 (ALG.APV-527-101): A First-in-human, Multicenter, Open-label, Dose Escalation and Dose Expansion Phase I Study in Patients with Advanced Solid Tumors to Evaluate the Safety of Intravenously Administered ALG.APV-527** Asrar Alahmadi  | 06/27/2025 |
| **2021R0018-AM5** | **The pathobiology in the brain during Covid-19 infection** Amal Amer  | 06/27/2025 |
| **2020R0094-AM12** | **Regulation of type I and III IFN responses** Adriana Forero  | 06/27/2025 |
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| **PROTOCOLS & AMENDMENTS (ADMINISTRATIVELYAPPROVED-EXEMPT)** |

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| **Protocol** |  **Protocol Title and Information** |  **Date of****Determination** |
| **2013R0079-AM6** | **Dried Blood Spots & Salivary Collection** Baldwin Way Biosafety Level: BSL- 2Type of Research: human source material | 06/05/2025 |
| **2025R0028** | **C4N Research Sample Processing Laboratory** Ruth Barrientos Biosafety Level: BSL- 2Type of Research: human source material | 06/05/2025 |
| **2011R0043-AM4** | **IBRC IBC Protocol** Amanda Agnew Biosafety Level: BSL- 2Type of Research: human source material | 06/05/2025 |
| **2023R0102-AM2** | **Oligodendroglia in inflammation and aging** Cole Harrington Biosafety Level: BSL- 1Type of Research: human source material, rodent gene transfer | 06/11/2025 |
| **2014R0087-AM4** | **Role of microRNAs in Regulating Mechanically Induced Inflammation of the Pulmonary Epithelium** Samir Ghadiali Biosafety Level: BSL- 1Type of Research: exempt rDNA, human source material, rodent gene transfer | 06/11/2025 |
| **2020R0005-AM3** | **Ticks and tick-borne disease** Risa Pesapane **Biosafety Level: BSL- 1****Type of Research:** animal, biohazard | 06/11/2025 |
| **2025R0038** | **Correlates of the AC/A Ratio** Donald MuttiBiosafety Level: BSL- 2Type of Research: human source material | 06/30/2025 |
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