# IBC Meeting Minutes
# Cleveland Clinic Main Campus

| **Date:** | **Location:** |
|---|---|
| July 30th, 2025 | Zoom |

**IBC Member Attendance:**

| | | |
|---|---|---|
| ☐ Ahern, Philip | ☒ DiDonato, Joseph | ☒ Dragan, Amanda (BSO) |
| ☒ Fox, Alan | ☒ Hajjar, Adeline | ☒ Heemers, Hannelore |
| ☒ Kerr, Travis | ☒ Lindner, Daniel | ☒ McDonald, Christine (IBC Chair) |
| ☒ Mortimer, Joanne | ☐ Southern, Brian | ☒ Speranza, Emily |
| ☒ Such, Kimberly | | |

*Guests: Anthony Santilli*, Anna Rietsch*, Jennifer Villette*, Nikki Meyer*, Anna Simko*, Abby Biffano*, Sara Tavakoli**, Dylan Champer***

** Cleveland Clinic Main Campus*
*** Cleveland Clinic Florida Research & Innovation Center (FRIC)*

| **Call To Order:** | **Adjourn:** |
|---|---|
| 2:31 pm | 4:38 pm |

## I. Review of June 25th, 2025 Meeting Minutes

| **Committee Comments:** N/A | | | |
|---|---|---|---|
| **Motion Approval:** | **For:** | **Against:** | **Abstain:** |
| **Approved** | 10 | 0 | 1 |

## II. Administrative Business

- **a.** Committee presented with Expedited Review items, personnel additions, and updates to programmatic SOPs
- **b.** Committee was presented with updated disinfection requirements for infectious agents.
- **c.** **Incident Report:** IBC Members were informed of incidents involving a failure to follow approved containment conditions and spill. The resulting risk assessments and corrective actions taken to prevent further occurrence were also presented.
- **d.** **Lab Audits:** Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of June, 2025**.** No major deficiencies identified.

## III. Clinical Research:

- **a.** **Applications:**

| Clinical Application #1 | Protocol ID: Application #1 | PI: Winter | Biosafety Level: BSL2 | NIH Cat.: III-C-1, III-E |
|---|---|---|---|---|

**Project Title:**
The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients

**Associated Grant Numbers:**
Non-NIH Funding

**Protocol Summary:**

- Administration of replication defective lentiviral transduced cells to humans

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**
N/A

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| PI/Supervisor Training (Y/N): | Handler Training (Y/N): |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| Motion Approval: | For: | Against: | Abstain: | Recuse: | Not Present: |
|---|---|---|---|---|---|
| Approved | 10 | 0 | 0 | 0 | 1 |

| Clinical Application #2 | Protocol ID: Application #2 | PI: Caimi | Biosafety Level: BSL2 | NIH Cat.: III-C-1, III-E |
|---|---|---|---|---|

**Project Title:**
A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, A CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy In Participants with Aggressive B-Cell Non-Hodgkin Lymphoma

**Associated Grant Numbers:**
Non-NIH Funding

**Protocol Summary:**

- Administration of replication defective lentiviral transduced cells to humans

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

| | | | | | |
|---|---|---|---|---|---|
| | | | | | |
| **Committee Comments:**<br>N/A | | | | | |
| **Facilities, Procedures, and Safety Practices Reviewed (Y/N):**<br>☒ Yes ☐ No | | | | | |
| **PI/Supervisor Training (Y/N):**<br>☒ Yes ☐ No | | | **Handler Training (Y/N):**<br>☒ Yes ☐ No | | |
| **Motion Approval:**<br>**Approved** | **For:**<br>10 | **Against:**<br>0 | **Abstain:**<br>0 | **Recuse:**<br>0 | **Not Present:**<br>1 |

| **Clinical Application #3** | **Protocol ID:**<br>Application #3 | **PI:**<br>Kennedy | **Biosafety Level:**<br>BSL2 | **NIH Cat.:**<br>III-C-1 |
|---|---|---|---|---|
| **Project Title:**<br>RPL2625: A Single Patient compassionate use of RP-1 for Metastatic Melanoma. | | | | |
| **Associated Grant Numbers:**<br>Non-NIH Funding | | | | |
| **Protocol Summary:**<br>• Administration of recombinant Herpes Simplex Virus to a single patient<br><br>Function/Nature of Recombinant Genes to be Expressed:<br>☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial<br>☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other<br><br>Species of Recombinant Genes to be Expressed:<br>☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☒ Viral ☐ Other | | | | |
| **Committee Comments:**<br>N/A | | | | |
| **Facilities, Procedures, and Safety Practices Reviewed (Y/N):**<br>☒ Yes ☐ No | | | | |
| **PI/Supervisor Training (Y/N):**<br>☒ Yes ☐ No | | | **Handler Training (Y/N):**<br>☒ Yes ☐ No | |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 11 | 0 | 0 | 0 | 0 |

## IV. Non-Clinical Research:

### a. New Applications not applicable to NIH Guidelines:

| **Basic Research Application # 1** | **Protocol ID:**<br>Application #1 | **PI:**<br>Dhawan | **Biosafety Level:**<br>BSL2 | **NIH Cat.:**<br>N/A |
|---|---|---|---|---|
| **Project Title:** Genetic and Molecular Analysis of Tumors of the Nervous System and Their Coverings | | | | |

**Associated Grant Numbers:**
N/A

**Protocol Summary:**

- Acquisition, processing, and storage of potentially infectious human specimens

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Minor administrative edits

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved w/ Administrative Revisions** | 10 | 0 | 0 | 0 | 1 |

**b. Renewals:**

| **Basic Research Renewal # 1** | **Protocol ID:** IBC 2122 | **PI:** Nemet | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Gut microbes and cardiometabolic disease

**Associated Grant Numbers:**
R01HL160747

**Protocol Summary:**

- Propagation of WT and recombinant bacteria and administration *in vivo*

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☐ Murine ☒ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Update general procedures to reference appropriate space

- Suggestion from committee to add additional room for *in vivo* work.

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** ☒ Yes ☐ No | **Handler Training (Y/N):** ☒ Yes ☐ No |
|---|---|

| **Motion Approval:** **Approved w/ Administrative Revisions** | **For:** 10 | **Against:** 0 | **Abstain:** 0 | **Recuse:** 1 | **Not Present:** 0 |
|---|---|---|---|---|---|

| **Basic Research Renewal #2** | **Protocol ID:** IBC 2121 | **PI:** Silver | **Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-4-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Remodeling host immunity in oral cancer with personalized RNA nanoparticle vaccines

**Associated Grant Numbers:**
Non-NIH Funding

**Protocol Summary:**

- Propagation of WT and recombinant bacteria, infection of cell culture cells
- Administration of bacteria and infected tissue culture cells *in vivo*
- Mammalian expression plasmids for generation of mRNA vaccines and administration *in vivo*
- Cholera Toxin in cell culture
- Human-derived materials

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☒ Murine ☒ Bacterial ☒ Viral ☐ Other

**Committee Comments:**

- Administrative edits
- Please identify the specific SOPs referenced in PPE description
- Update description of bacteria/tissue cells culturing
- Clarify *in vivo* fecal collection and disinfection steps

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** ☒ Yes ☐ No | **Handler Training (Y/N):** ☒ Yes ☐ No |
|---|---|

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Approved w/ Administrative Revisions** | 9 | 0 | 0 | 2 | 0 |

**c. Renewals Not Applicable to NIH Guidelines:**

| **Basic Research Renewal #3** | **Protocol ID:** IBC 2119 | **PI:** Markle | **Biosafety Level:** BSL2 | **NIH Cat.:** N/A |
|---|---|---|---|---|

**Project Titles:**
CRU procedures for known infectious agent: Clostridioides difficile (C. diff)

**Associated Grant Numbers:**
Non-NIH Funding

**Protocol Summary:**

- Acquisition of samples from *Clostridioides difficile* (C. diff) infected patients, handling, process and aliquoted, shipment or short term storage
- Human-derived materials.

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Update disinfectant concentration and contact time.

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** ☒ Yes ☐ No | **Handler Training (Y/N):** ☒ Yes ☐ No |
|---|---|

| **Motion Approval: Approved w/ Administrative Revisions** | **For:** 10 | **Against:** 0 | **Abstain:** 0 | **Recuse:** 0 | **Not Present:** 1 |
|---|---|---|---|---|---|

| **Basic Research Renewal #4** | **Protocol ID:** IBC 2120 | **PI:** Markle | **Biosafety Level:** BSL2 | **NIH Cat.:** N/A |
|---|---|---|---|---|

**Project Titles:**
CRU procedures for Handling Samples from Patients with Known Infection

**Associated Grant Numbers:**
Non-NIH Funding

**Protocol Summary:**

- Acquisition of samples from patients with known infections (RG2 and HIV), handling, process and aliquoted, shipment or short term storage
- Human-derived materials.

Function/Nature of Recombinant Genes to be Expressed:

☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:

☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Update disinfectant concentration and contact time.

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**

☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved w/ Administrative Revisions** | 10 | 0 | 0 | 0 | 1 |

**d. Amendments:**

| **Basic Research Amendment #1** | **Protocol ID:** IBC 1909 | **PI:** Wang | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:** Novel immuno-prevention strategies for controlling lung cancer and pancreatic cancer

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of replication-defective lentivirus and retrovirus, transduction of tissue culture cells, plasmid transfection of tissue culture cells, and administration of transduced cells to animals; Propagation of rDNA modified Listeria monocytogenes and administration *in vivo*; Human-derived material.

**Requested Additions/Changes:**

- Mammalian tissue culture cells
- Genes targets

Function/Nature of Recombinant Genes to be Expressed:

☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:

| | | | | | |
|---|---|---|---|---|---|
| ☐ N/A ☐ Human ☒ Murine ☐ Bacterial ☐ Viral ☐ Other | | | | | |
| **Committee Comments:**<br>N/A | | | | | |
| **Facilities, Procedures, and Safety Practices Reviewed (Y/N):**<br>☒ Yes ☐ No | | | | | |
| **PI/Supervisor Training (Y/N):**<br>☒ Yes ☐ No | | | **Handler Training (Y/N):**<br>☒ Yes ☐ No | | |
| **Motion Approval:**<br>**Approved** | **For:**<br>9 | **Against:**<br>0 | **Abstain:**<br>0 | **Recuse:**<br>1 | **Not Present:**<br>1 |

| **Basic Research Amendment #2** | **Protocol ID:**<br>IBC1907 | **PI:**<br>Chakraborty | **Biosafety Level:**<br>BSL1, BSL2, ABSL1, ABSL2 | **NIH Cat.:**<br>III-D-1-a, III-D-3-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Epigenetic Dysregulation to Identify Targetable Vulnerabilities in Cancer

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of replication defective lentivirus and retrovirus, transduction of tissue culture cells and administration of transduced cells *in vitro*. Non-K-12 *E. coli*; Human-derived materials

**Requested Additions/Changes:**

- Replication defective lentiviral particles
- Gene targets

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☒ Murine ☐ Bacterial ☐ Viral ☐ Other

| | | | | | |
|---|---|---|---|---|---|
| **Committee Comments:**<br>N/A | | | | | |
| **Facilities, Procedures, and Safety Practices Reviewed (Y/N):**<br>☒ Yes ☐ No | | | | | |
| **PI/Supervisor Training (Y/N):**<br>☒ Yes ☐ No | | | **Handler Training (Y/N):**<br>☒ Yes ☐ No | | |
| **Motion Approval:**<br>**Approved** | **For:**<br>10 | **Against:**<br>0 | **Abstain:**<br>0 | **Recuse:**<br>0 | **Not Present:**<br>1 |

| **Basic Research Amendment #3** | **Protocol ID:**<br>IBC 1801 | **PI:**<br>Ivanov | **Biosafety Level:**<br>BSL1, BSL2 | **NIH Cat.:**<br>III-D-1-a |
|---|---|---|---|---|

**Project Titles:**
Regulation of the intestinal epithelial barrier during mucosal inflammation

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells; Human-derived material

**Requested Additions/Changes:**

- Replication defective lentiviral particles
- Mammalian expression plasmids
- Gene targets and genes for editing

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Update room locations and BSL

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved w/ Administrative Revisions** | 10 | 0 | 0 | 0 | 1 |

| **Basic Research Amendment #4** | **Protocol ID:** IBC 2222 | **PI:** Stacy | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Oral microbiota-host interactions in periodontitis

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation and culturing of recombinant and non-recombinant modified bacteria; various human and rodent-derived material; administration *in vivo*; Human-derived material.

**Requested Additions/Changes:**

- Wild-type *Pseudomonas spp.*
- Recombinant *Neisseria spp.*

Function/Nature of Recombinant Genes to be Expressed:

☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:

☐ N/A ☐ Human ☐ Murine ☒ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Description of *in vitro* bacterial assays is insufficient. All experiments and safety information needs to be outlined in the stepwise protocols for both WT and recombinant bacteria.
- Updated safety information for *Pseudomonas spp.*

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**

☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Tabled, PI to address comments and resubmit.** | 0 | 8 | 0 | 2 | 1 |

| **Basic Research Amendment #5** | **Protocol ID:** IBC 2117 | **PI:** Anand-Apte | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:** FGF and hyaluronan-mediated alterations in epithelial-mesenchymal transition and metabolism of RPE cells in Sorsby Fundus Dystrophy

**Associated Grant Numbers:**

R01 EY027083

**Summary of Approved Items:**

Generation of replication deficient Lentiviral and Adeno-Associated viral (AAV) particles and transduction of tissue culture cells; administration of lentiviral and AAV particles *in vivo*; Human-derived materials.

**Requested Additions/Changes:**

- Generation of point mutation on approved gene target

Function/Nature of Recombinant Genes to be Expressed:

☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:

☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

| |
|---|
| **Committee Comments:**<br>N/A |
| **Facilities, Procedures, and Safety Practices Reviewed (Y/N):**<br>☒ Yes ☐ No |
| **PI/Supervisor Training (Y/N):**<br>☒ Yes ☐ No — **Handler Training (Y/N):** ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 10 | 0 | 0 | 0 | 1 |

| **Basic Research Amendment #6** | **Protocol ID:** IBC 2406 | **PI:** Ma | **Biosafety Level:** BSL1, BSL2 | **NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-E |
|---|---|---|---|---|

**Project Titles:**
Engineering human in vitro models of physiology and pathology for precision medicine

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of lentiviral particles, transduction of tissue culture cells. Human-derived materials

**Requested Additions/Changes:**

- Recombinant and WT human tissue culture cells

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

**Committee Comments:**
N/A

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

**PI/Supervisor Training (Y/N):**
☒ Yes ☐ No — **Handler Training (Y/N):** ☒ Yes ☐ No

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 10 | 0 | 0 | 0 | 1 |

| **Basic Research Amendment #7** | **Protocol ID:** IBC 1104 | **PI:** Lindner | **Biosafety Level:** BSL2, ABSL1, ABSL2 | **NIH Cat.:** III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Molecular determinants of tumor growth

**Associated Grant Numbers:**
P30CA043703-32, R35HL135795-06, R01 CA257544-02

**Summary of Approved Items:**
Administration of non-recombinant and recombinant modified cells *in vivo*; Human-derived materials

**Requested Additions/Changes:**

- Recombinant mammalian tissue culture cells

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☒ Murine ☐ Bacterial ☐ Viral ☒ Other

**Committee Comments:**
N/A

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 8 | 0 | 0 | 2 | 1 |

| **Basic Research Amendment #8** | **Protocol ID:** IBC 2226 | **PI:** Poplawski | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a, III-D-4-b, III-E-1 |
|---|---|---|---|---|

**Project Titles:**
Investigation of molecular and cellular mechanisms of neurodegeneration/regeneration

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation and acquisition of Adeno-Associated Viral particles and administration *in vivo*; propagation of replication deficient lentiviral particles, transduction of tissue culture cells, and administration of transduced cells *in vivo.* Human-derived material

**Requested Additions/Changes:**

- Mammalian expression plasmids
- Gene targets and genes for editing
- *In vivo* administration route and phototherapy
- Room additions

Function/Nature of Recombinant Genes to be Expressed:

☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☒ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**
N/A

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 9 | 0 | 0 | 1 | 1 |

| **Basic Research Amendment #9** | **Protocol ID:** Jung | **PI:** IBC 2023 | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-E |
|---|---|---|---|---|

**Project Titles:** Identifying viral determinants involved in viral-host interactions using infectious clones

**Associated Grant Numbers:**
R01 AI140705, R01 AI52190, R01AI151013

**Summary of Approved Items:**
Propagation of non-recombinant Murine Coronavirus, Human Coronavirus, La Crosse Virus, Utinga Virus, Simbu Virus, Manzanilla Virus, Buttonwillow Virus, Ingwavuma Virus, rodent herpesvirus Peru E and L virus, Oropouche Virus and Uukuniemi Virus. Propagation of recombinant Zika virus, Kaposi's Sarcoma associated herpesvirus, Murine Gammaherpesvirus 68 (MuHV-68), Measles virus, Mumps virus, Oropouche Virus (OROV), and Herpesvirus; Generation of replication competent Retroviral particles; Handling of Measles, Mumps, HRTV, SFTSV Viral Vector vaccines; Generation of mRNA vaccines; Administration of all agents to mice. Acquisition and processing of Epstein – Barr virus positive samples, Non K-12 E. coli; Human-derived material

**Requested Additions/Changes:**
- WT and Recombinant Herpes Simplex Virus-1 and Lab Adapted Indiana Vesiculovirus
- Generation of Potosi Virus
- Generation of replication defective lentivirus particles and transduction of tissue culture cells
- Gene targets and genes for editing
- mRNA vaccine constructs
- Human tissue culture cells

Function/Nature of Recombinant Genes to be Expressed:

☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☒ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Administrative edits
- Please update hazard section to include additional information for Potosi Virus
- Clarify description of sample container disinfection steps

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 9 | 0 | 0 | 1 | 1 |

| **Basic Research Amendment #10** | **Protocol ID:** IBC 2315 | **PI:** Jung | **Biosafety Level:** BSL1, BSL2, BSL3, ABSL3 | **NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-3-b, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Identifying effective drug targets against RNA viruses

**Associated Grant Numbers:**
R01 AI52190, R01 AI140705, R01 AI171201

**Summary of Approved Items:**
Propagation of non-recombinant SARS-CoV-2 isolates, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Powassan virus & Heartland virus; propagation of recombinant-modified Heartland virus, Severe fever with thrombocytopenia syndrome virus (SFTSV), SARS-CoV-2, SARS-CoV-2 isolates, SARS-CoV-2 mouse adapted. Infection of cell lines; Infection with non-recombinant Oropouche Virus, La Crosse Virus, Utinga Virus, Simbu Virus, Manzanilla Virus, Lone Star Virus, Bunyamwera Virus and recombinant Uukuniemi virus; Acquisition of adenovirus and administration *in vivo*; Administration of recombinant and non-recombinant viruses *in vivo*; Human-derived materials.

**Requested Additions/Changes:**

- Hantaan Virus
- Addition of RT-qPCR instrument and procedures in BSL3 location

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:

☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Contingent Items:
  - Occupational Health providing exposure procedures for new pathogen to the biosafety office.
  - Please confirm and provide supporting documentation for the fatality rate of the strain being added, the CDC has a higher rate listed than what was provided in the application. If a less pathogenic strain is available, either (a) can it be used instead or (b) Please include a justification for why the more pathogenic version is necessary.

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved w/ Contingency. Rereview needed prior to approval** | 11 | 0 | 0 | 0 | 0 |

| **Basic Research Amendment #11** | **Protocol ID:** IBC 2022 | **PI:** Jung | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E |
|---|---|---|---|---|

**Project Titles:**
Molecular basis of cancer-associated viruses

**Associated Grant Numbers:**
R01 DE02852, R35 CA200422, R01 CA251275

**Summary of Approved Items:**
Generation of replication deficient lentiviral particles, transduction of tissue culture cells; Propagation of Hepatitis B Virus (HBV) particles and recombinant modified and WT Orf Virus (ORFV) and Kaposi's sarcoma-associated herpes virus (KSHV) particles, and infection of tissue culture cells; acquisition of WT and recombinant modified cell lines that are positive for KSHV, Epstein Barr Virus (EBV); Administration of cells *in vivo*. Processing of human blood positive for EBV and Cytomegalovirus (CMV), Non K-12 E.coli; Human-derived material

**Requested Additions/Changes:**

- Replication deficient lentiviral particles
- Mammalian expression plasmids

<u>Function/Nature of Recombinant Genes to be Expressed:</u>
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 11 | 0 | 0 | 0 | 0 |

| **Basic Research Amendment #12** | **Protocol ID:** IBC 1916 | **PI:** Hajjar | **Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-4-a, III-D-4-b, III-E |
|---|---|---|---|---|

**Project Titles:**
Microbial Engineering and Transplantation Core (Core C)

**Associated Grant Numbers:**
P01 HL147823

**Summary of Approved Items:**
Various human and mammalian-derived material, microbial isolates, primary microbial isolates; generation and culturing of various recombinant modified bacteria and growth of non-recombinant bacteria; administration *in vivo*; Human-derived materials.

**Requested Additions/Changes:**

- *Proteus spp.* and *E. coli*
- WT and recombinant bacterial communities
- Acquisition of replication deficient adeno-associated viral particles and administration *in vivo*
- Surgical procedures
- New Rooms

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☐ Human ☒ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Contingent Items - For the ABSL2 room location, one of two options is needed:
    - Option 1 Update ABSL2 work to the suggested appropriate space if equipment can be moved there by the applicable PI. Consult with area staff on procedures for working in the suggested space, and update application to include those steps as needed.

- Option 2 Remove all BSL2/ABSL2 work involving the assay and associated equipment. Only work in the approved ABSL1 space would be allowed, and an amendment would be needed at a later date once an alternative space for ABSL2 procedures is identified.
- Administrative edits
- Update disinfectant list

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved w/ Contingency. Rereview needed prior to approval** | 9 | 0 | 0 | 2 | 0 |

| **Basic Research Amendment #13** | **Protocol ID:** IBC 2308 | **PI:** Yildirim | **Biosafety Level:** BSL1, ABSL1, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Cortical circuits and information flow during task-free locomotion and memory-guided perceptual decision-making in health and disease

**Associated Grant Numbers:**
5R00EB027706-04, Non-NIH Funding

**Summary of Approved Items:**
Acquisition of commercially available replication defective adeno-associated virus (AAV) particles and administration of adeno-associated virus particles *in vivo*.

**Requested Additions/Changes:**
- Probiotic (RG1) bacteria mixture for administration *in vivo*

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**
- Administrative edits

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|

| ☒ Yes ☐ No | | | ☒ Yes ☐ No | | |
|---|---|---|---|---|---|
| **Motion Approval: Approved w/ Administrative Revisions** | **For:** 11 | **Against:** 0 | **Abstain:** 0 | **Recuse:** 0 | **Not Present:** 0 |

| **Basic Research Amendment #14** | **Protocol ID:** IBC 2101 | **PI:** Wu | **Biosafety Level:** BSL2, ABSL2 | **NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4a |
|---|---|---|---|---|

**Project Titles:**
Modeling liver diseases using a human pluripotent stem cell derived-multicellular platform

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of replication defective lentivirus particles, propagation of recombinant modified Hepatitis B Virus, Hepatitis C Virus and Hepatitis E Virus and transduction of tissue culture cells, co-infection of viruses in-vitro; Acquisition of Norwegian Rat Hepatitis Virus and administration *in vivo*; Human-derived materials

**Requested Additions/Changes:**

- Generation of replication deficient adeno-associated viral particles and administration *in vivo*
- Gene targets
- New rooms

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

**Committee Comments:**

- Administrative edits
- Update room list
- Update indicated disinfection steps and locations
- Clarify inactivation method
- Specify equipment location

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** ☒ Yes ☐ No | | | **Handler Training (Y/N):** ☒ Yes ☐ No | | |
|---|---|---|---|---|---|
| **Motion Approval: Approved w/ Administrative Revisions** | **For:** 11 | **Against:** 0 | **Abstain:** 0 | **Recuse:** 0 | **Not Present:** 0 |

| Basic Research Amendment #15 | Protocol ID: IBC 1622 | PI: Gong | Biosafety Level: BSL2, ABSL2 | NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
DNA repair pathway as targets for therapy-resistant ovarian cancer

**Associated Grant Numbers:**
R01 CA222195

**Summary of Approved Items:**
Generation of replication defective lentivirus particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*; human derived material.

**Requested Additions/Changes:**

- Generation of immunodeficient animals engrafted with functional human biological systems and administration of tissue culture cells.
- Human and mammalian tissue culture cells
- New rooms
- Updated disinfectant and safety information

Function/Nature of Recombinant Genes to be Expressed:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other

Species of Recombinant Genes to be Expressed:
☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

**Committee Comments:**

- Administrative edits
- Please confirm cell lines BSL with supplier, work may potentially be used at a lower BSL/ABSL.
- Clarify location of inactivation steps for BSL1 vs. BSL2 items

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| PI/Supervisor Training (Y/N): | Handler Training (Y/N): |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| Motion Approval: Approved w/ Administrative Revisions | For: | Against: | Abstain: | Recuse: | Not Present: |
|---|---|---|---|---|---|
| | 11 | 0 | 0 | 0 | 0 |

| Basic Research Amendment #16 | Protocol ID: IBC 2205 | PI: Xie | Biosafety Level: BSL2, ABSL2 | NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b |
|---|---|---|---|---|

**Project Titles:**
Organization, Dynamics and Mechanisms of Extrachromosomal DNA in Human Cancer

**Associated Grant Numbers:**
Non-NIH Funding

**Summary of Approved Items:**
Generation of replication defective lentiviral and adeno-associated viral (AAV) particles, transduction of tissue culture cells and administration *in vivo*; Transfection of tissue culture cells; Human-derived materials.

**Requested Additions/Changes:**

- Mammalian expression plasmids
- Gene targets and genes for editing
- Administration route for AAV *in vivo*

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☒ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial
☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☒ Bacterial ☐ Viral ☒ Other

**Committee Comments:**
N/A

**Facilities, Procedures, and Safety Practices Reviewed (Y/N):**
☒ Yes ☐ No

| **PI/Supervisor Training (Y/N):** | **Handler Training (Y/N):** |
|---|---|
| ☒ Yes ☐ No | ☒ Yes ☐ No |

| **Motion Approval:** | **For:** | **Against:** | **Abstain:** | **Recuse:** | **Not Present:** |
|---|---|---|---|---|---|
| **Approved** | 11 | 0 | 0 | 0 | 0 |

## V. Other Business

None