IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
January 28th, 2026	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, Jennifer Veillette*, Anna Rietsch*, Nikki Meyer*, Abby Bifano*, Dylan Champer***

** Cleveland Clinic Main Campus*
*** Cleveland Clinic Florida Research and Innovations Center*

Call To Order:	**Adjourn:**
2:31 pm	4:00 pm

I. Review of Dec. 17, 2025 Meeting Minutes

Committee Comments:
N/A

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Not Present:**
Approved	6	0	0	2

II. Administrative Business

- **a.** Committee presented with Expedited Review items, personnel additions, and updates to programmatic SOPs
- **b.** Incident Report: IBC Members were informed of two incidents not involving NIH Guidelines regulated items. The resulting risk assessments and corrective actions taken to prevent further occurrence were also presented.
- **c.** Lab Audits: Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of January 2025. No major deficiencies were identified.
- **d.** IBC committee was updated on disinfectants used within BSL-3 facility

III. Clinical Research:

- **a. Applications:**

Clinical Application #1	Protocol ID: Application #1	PI: Talcott	Biosafety Level: BSL-1	NIH Cat.: III-C-1, III-E

Project Title:
A Randomized Controlled, Partially Masked, Phase 3b Study to Assess the Injection Burden, Efficacy, Safety, and Long-Term Preservation of Visual Acuity of Surabgene Lomparvovec (ABBV-RGX-314) in a Real-World Context in Subjects with Neovascular Age -Related Macular Degeneration (nAMD)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication defective Adeno-Associated Virus (AAV) to humans.

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: Approved	For: 6	Against: 0	Abstain: 0	Recuse: 0	Not Present: 2

Clinical Application # 2	Protocol ID: Application #2	PI: Bukavina	Biosafety Level: BSL-2	NIH Cat.: III-C-1

Project Title:
A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of recombinant modified Bacillus Calmette-Guérin (BCG) to humans.

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

b. Amendments:

Clinical Amendment # 1	**Protocol ID:** CTIBC044	**PI:** Littlejohn	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Titles:
A Phase 1, Multicenter, Open-Label Study Of CC-97540 (BMS-986353), CD19-Targeted Nex-T Chimeric Antigen Receptor (CAR) T Cells, in Participants with Severe, Refractory Systemic Lupus Erythematosus, Idiopathic Inflammatory Myopathy, Systemic Sclerosis, or Rheumatoid Arthritis (Breakfree-1)

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Administration of replication defective lentiviral transduced cells to humans.

Requested Additions/Changes:

- Additional sites for blood draws
- Update to stepwise experimental procedures

Function/Nature of Recombinant Genes to be Expressed:

☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other Species of Recombinant Genes to be Expressed: ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • No modifications needed	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	0	1

IV. Non-Clinical Research:

a. New Applications:

Basic Research Application #1	**Protocol ID:** Application #1	**PI:** Rajappa	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Title:
Molecular and Genomic Analyses of Central Nervous System (CNS) Tumors

Associated Grant Numbers:
R01NS127984

Protocol Summary:

- Generation of replication defective lentiviral particles, transduction of tissue culture cells, administration *in vivo*
- Acquisition of avian cells transfected with retroviral particles, administration *in vivo*
- 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 ☒ Cell Metabolism ☒ Other

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- Approval contingent on clarifications of experimental descriptions and summaries.
- Clarify the following regarding the retroviral particles:
  - Confirm retroviral oncogenes were removed
  - Confirm the envelope subtype
  - Clarify how the resulting gene modifications are stable, yet transient and non-integrating
  - Clarify that retroviral particles are replication competent only within avian cells, not in the *in vivo* model.
- For the description of *in vivo* experiments:
  - Clarify how TV-a expression in model relates to viral targeting and infection
  - Update experiment description for clarity
  - Clarify expression of reporter genes for imaging studies
- Please elaborate on cell culturing and inactivation steps for ELISA
- Agent Inventory:
  - Elaborate on summary of indicated cell line
  - Rereview genes for oncogenes and tumor suppressor genes, several are seemingly marked incorrectly
  - Clarify that retroviral particles are replication competent only within avian cells, not in the *in vivo* model.
- Administrative edits

Motion Approval: **Approved w/ Contingency**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Application #2	**Protocol ID:** Application #2	**PI:** Vachharajani	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Title:
Viral Transduction of mammalian cells in sepsis

Associated Grant Numbers:
R01GM99807, R01AI153085

Protocol Summary:

- Generation of replication defective lentiviral and adeno-associated viral (AAV) particles
- Transduction of tissue culture cells
- 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 ☐ Cell Metabolism
☒ Other

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- Include statement that recombinant cell lines generated on this protocol may be transferred to a different IBC protocol
- An amendment to the receiving protocol is needed adding the cell lines generated on this protocol

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

b. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC2209	**PI:** Smith	**Biosafety Level:** BSL-1	**NIH Cat.:** III-E

Project Title:
Expression and Purification of apolipoprotein A-1 and Fam13b

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Protein expression in Non-K-12 *E. coli*

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • No modifications needed	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	0

Basic Research Renewal #2	**Protocol ID:** IBC1804	**PI:** Fox	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-b

Project Title:
Role of tumor microenvironment in initiation and progression of tumor growth

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:
- Generation of replication defective lentiviral particles
- Transduction of tissue culture cells
- Human-derived material

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • Please review agent inventory for oncogenes.	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	8	0	0	0	0

c. Renewals Not Applicable to NIH Guidelines:

Basic Research Renewal #3	Protocol ID: IBC1817	PI: Rieder	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: N/A

Project Title:
Adherent-invasive E. coli (AIEC) induces intestinal fibrosis; Specific pathogen induced intestinal fibrosis

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Propagation of adherent invasive E. coli 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 ☐ Cell Metabolism ☐ Other

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

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: Approved	For: 7	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Renewal #4	Protocol ID: IBC1414	PI: DiDonato	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: N/A

Project Title:
Impact of gut flora on disease, prevention, diagnosis and development

Associated Grant Numbers:
R01HL167831; R01 HL103866; P01 HL147823

Protocol Summary:

- Acquisition and processing of human fecal material and human dental plaque
- Administration *in vivo*

- Human-derived material

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- Update disinfectant list
- Recommendation to add additional types of sample containers
- Confirm room number
- Recommendation to add additional facility for *in vivo* experiments

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 0

d. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC1913	**PI:** Tam	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-E

Project Titles:
Identifying the host factors that are important for latent HIV transcription in microglia

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus and retrovirus particles, generation of replication incompetent HIV particles, transduction of tissue culture cells; Human derived materials

Requested Additions/Changes:
- Replication competent HIV particles
- Experimental procedures
- Additional rooms

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modification needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #2	**Protocol ID:** IBC2022	**PI:** Jung	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
KSHV mediated regulation of proline metabolism

Associated Grant Numbers:
R01DE028521, R01CA251275, R01AI151013, R01AI181758, R01CA295170

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

Requested Additions/Changes:
- Epstein Barr Virus (EBV) positive human tissue culture cells
- Mammalian expression plasmid

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

☐ Other

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #3	**Protocol ID:** IBC2026	**PI:** Jung	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Inflammation, cancer, and diabetes in *in vivo* models

Associated Grant Numbers:
R01AI140705, R01AI152190, R01AI171201

Summary of Approved Items:
Generation of replication defective adeno-associated viral particles, transduction of tissue culture cells, and administration *in vivo*. Generation of replication defective lentiviral particles and transduction of tissue culture cells. Acquisition of SARS-CoV-2 strains, generation of recombinant Hepatitis B Virus, human Respiratory Syncytial Virus (RSV), SARS-CoV-2 strains and Mumps Virus; administration of Hepatitis B Virus, SARS-CoV-2 *in vivo*. Acquisition of Parainfluenza Type III (PIV3), Human Metapneumonia (hMPV) virus. Administration of plasmid infected cells expressing HBV *in vivo*. Generation and administration of mRNA vaccine *in vivo*. Generation of protein vaccine and administration *in vivo*; Protozoan *Leishmania tarentolae* protein expression system; Non-K12 *E. coli*; Human-derived materials

Requested Additions/Changes:
- Non-K-12 *E. coli*
- Bacterial expression plasmids
- Gene targets
- Human and mammalian cell lines
- Additional experimental and *in vivo* procedures

Function/Nature of Recombinant Genes to be Expressed:

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- Approval contingent on clarifications to *in vivo* experiments.
- Update room list for *in vivo* experiments
- Confirm strains of Non-K-12 *E. coli* used
- Clarify details regarding cell isolation kit
- Update new *in vivo* experiments for clarity
- Clarify sample inactivation steps

Motion Approval: **Approved w/ Contingency**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #4	**Protocol ID:** IBC2210	**PI:** Melenhorst	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-b, III-D-4-b

Project Titles:
Development, investigation, and evaluation of gene-modified cell therapies for efficacy against solid tumors and hematological malignancies

Associated Grant Numbers:
R01CA241762

Summary of Approved Items:
Generation and validation of CAR-T cells targeting specific tumor markers. Generation of lentiviral particles and transduction of tissue culture cells, administration *in vivo*, electroporation using a CRISPR/Cas9 system into tissue culture cells; processing of potentially infectious or known infectious human material; Human-derived samples

Requested Additions/Changes:

- Replication defective lentiviral particles

Function/Nature of Recombinant Genes to be Expressed:

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #5	**Protocol ID:** IBC2309	**PI:** Cheng	**Biosafety Level:** BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Alzheimer's brain cell type-specific interactome map initiative

Associated Grant Numbers:
R01AG082211

Summary of Approved Items:
Acquisition of replication defective lentivirus particles and Adeno-Associated Virus particles (AAV) and transduction of tissue culture cells; Administration of AAV *in vivo*

Requested Additions/Changes:
- Adeno-Associated Viral vector, gene targets

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No

PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No
Discussion/Required Modifications: • Administrative edits	

Motion Approval: Approved w/ Administrative Revisions	For: 8	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #6	Protocol ID: IBC2408	PI: Dang	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: III-D-4-b

Project Titles:
Bariatric Surgery *in vivo*

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of retro and lentiviral transduced cells, administration *in vivo*

Requested Additions/Changes:
- Updated experimental procedures
- Room Additions

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No
Discussion/Required Modifications: • Update location for equipment • Update disinfectant list	

Motion Approval: Approved w/ Administrative Revisions	For: 7	Against: 0	Abstain: 0	Recuse: 0	Not Present: 1

Basic Research Amendment #7	Protocol ID: IBC2502	PI: Sharma	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-E-1, III-D-4-b

Project Titles:
Role of RPA1 in telomere biology; Impact of SMARCAL1 germline mutations on genome stability

Associated Grant Numbers:
K08 DK134873

Summary of Approved Items:
Acquisition of replication deficient lentiviral particles and transduction of tissue culture cells; Human derived materials

Requested Additions/Changes:

- *In vivo* experiments
- Room additions

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	Handler Training (Y/N): ☒ Yes ☐ No

Discussion/Required Modifications:

- Confirm species or origin for cells
- Remove indicated language

Motion Approval: Approved w/ Administrative Revisions	For: 7	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Amendment #8	Protocol ID: IBC1926	PI: Stappenbeck	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b

Project Titles:

Microbes in the gut and control of Inflammatory Bowel Disease

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Isolation and growth of recombinant and non-recombinant bacterial strains, co-culture with tissue culture cells; administration of bacteria *in vivo*, treatment of tissue culture cells with bacterial isolate; Acquisition of cholera, diphtheria and Clostridium Difficile A & B toxin and administration *in vivo*; Human-derived materials

Requested Additions/Changes:

- *Turicibacter sanguinis*
- human derived materials
- Bacteria identified in tissue using 16S rRNA sequencing
- Room specific SOPs
- Updated experimental procedures

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #9	**Protocol ID:** IBC2213	**PI:** Foo	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Titles:
Role of ZIKV viral determinants on immune rewiring of prenatal immunity

Associated Grant Numbers:

Non-NIH Funding

Summary of Approved Items:
Propagation of recombinant Zika virus, Oropouche virus and West Nile virus; transduction of cells in culture; Human-derived material

Requested Additions/Changes:
- Protocol transfer to Jung

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications Needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #10	**Protocol ID:** IBC2214	**PI:** Foo	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Titles:
Identifying viral determinants involved in ZIKV-induced immune rewiring

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:
- Protocol transfer to Jung

Function/Nature of Recombinant Genes to be Expressed:

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #11	**Protocol ID:** IBC2207	**PI:** Chen	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3

Project Titles:
Identifying viral mechanisms of osteo-immunopathogenesis using infectious clones

Associated Grant Numbers:
K99DE028573, R00DE028573

Summary of Approved Items:
Propagation of recombinant Zika virus, transduction of cells in culture; Generate and propagate recombinant DENV, CHIKV vaccine strain 181/25 (BSL2), RRV and MAYV from infectious cDNA clones; Overexpression of gene targets from Zika, Dengue Virus, SARS-CoV-2, Ross River virus, St. Martin chikungunya strain, Chikungunya vaccine strain 181/25, and Mayaro virus; Human-derived material

Requested Additions/Changes:
- Protocol transfer to Jung

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • No modifications needed	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	0

Basic Research Amendment #12	**Protocol ID:** IBC2208	**PI:** Chen	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Molecular regulatory mechanisms during vector-borne virus infection and pathogenesis

Associated Grant Numbers:
K99DE028573, R00DE028573

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

Requested Additions/Changes:
- Protocol transfer to Jung

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • No modifications needed	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	0	0

e. Amendments Not Applicable to NIH Guidelines:

Basic Research Amendment #13	**Protocol ID:** IBC2212	**PI:** Foo	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** N/A

Project Titles:
Immune repercussion of ZIKV infection on mother and child

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation of Zika Virus, Dengue Virus strains and Yellow Fever Virus (Vaccine Strain); transduction of cells in culture and administration *in vivo*; Human-derived material

Requested Additions/Changes:

- Protocol transfer to Jung

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #14	**Protocol ID:** IBC2206	**PI:** Chen	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** N/A

Project Titles:
Molecular regulatory mechanisms during vector-borne virus infection and pathogenesis

Associated Grant Numbers:
K99DE028573, R00DE028573

Summary of Approved Items:
Propagation of non-recombinant Zika Virus, Dengue Virus, Una Virus, Mayaro Virus, Chikungunya Vaccine Strain, Sindbis Virus and Ross River Virus, transduction of cells in culture and administration *in vivo*; Acquisition of patient derived tissue with known infection, generation of primary cell; Human-derived material

Requested Additions/Changes:

- Protocol transfer to Jung

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

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

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications needed

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #15	**Protocol ID:** IBC1008	**PI:** Bowler	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** N/A

Project Titles:
Identification and characterization of individuals at genetic risk for cancer and related diseases

Associated Grant Numbers:
RO1CA118980, PO1CA124570

Summary of Approved Items:
Immortalization of cells using Epstein-Bar virus in tissue culture; Human-Derived Material

Requested Additions/Changes:

- Protocol transfer to Jung

Function/Nature of Recombinant Genes to be Expressed:

☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other <u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other					
Risk Assessment Discussion: ☒ Yes ☐ No		**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No		**Handler Training (Y/N):** ☒ Yes ☐ No			
Discussion/Required Modifications: • No modifications needed					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

V. Other Business

None