IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
June 24th, 2026	Zoom

IBC Member Attendance:

☐ Ahern, Philip	☐ Bukavina, Laura	☐ DiDonato, Joseph
☐ Dragan, Amanda (BSO)	☒ Hajjar, Adeline	☒ Heemers, Hannelore (Acting Chair)
☒ Kerr, Travis	☒ Lindner, Daniel	☒ McDonald, Christine (IBC Chair)
☒ Mortimer, Joanne	☒ Urban Molly	☒ Such, Kimberly
☒ Champer, Dylan (Acting BSO)		

Guests: Anthony Santilli, Nikki Meyer*, Anna Rietsch*, Jennifer Veillette*, Sara Tavakoli***

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

Call To Order:	**Adjourn:**
2:30 PM	3:50 PM

I. Review of May 27th, 2026 Meeting Minutes

Committee Comments:
None

Motion Approval:	**For:**	**Against:**	**Abstain:**
Approved	6	0	0

II. Administrative Business

- **a.** Committee presented with Subcommittee Review items, personnel additions, and updates to programmatic SOPs
- **b.** Incident Report: IBC Members were informed of an incident involving the handling of an IBC regulated agent by unapproved personnel. The steps taken to correct this deficiency and prevent future occurrences were also presented to committee members.
- **c.** Lab Audits: Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of June 2026**.** No major deficiencies identified.

III. Non-Clinical Research:

a. New Applications:

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

Project Title:
Biofilm-Mediated and Planktonic Bacterial Modulation of Intravesical Gemcitabine Activity

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Propagation of recombinant *E. coli* and non-recombinant *Escherichia*, *Klebsiella,* and *Enterobacter spp*.; 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:

- Consult with EHS on disposal of chemical reagents associated with listed experiments.
- Confirm locations of indicated equipment
- Indicate steps for removing equipment from BSC after use
- Pieces from medical devices will need to be disposed of as solid biohazardous waste
- Confirm methods for inactivation of biological samples

Motion Approval: Approved w/ Administrative Revisions	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Application #2	**Protocol ID:** Application #2	**PI:** Feng	**Biosafety Level:** BSL1, 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, III-E-3

Project Title:
Innate Immune Signaling Pathways in Viral Infection and Host Antiviral Responses

Associated Grant Numbers:
R03DE034794

Protocol Summary:

- Generation of replication defective lentiviral particles and retroviral particles and transduction of tissue culture cells
- Acquisition and propagation of non-recombinant adenovirus, Murine Cytomegalovirus (MCMV), Influenza A Virus, recombinant modified Herpes Simplex Virus 1, Kaposi sarcoma-associated herpesvirus (KSHV), Murine gammaherpesvirus 68 (MGH-68)
- Administration of Influenza A Virus, recombinant modified, Herpes Simplex Virus 1, Murine gammaherpesvirus 68 (MGH-68) *in vivo*
- Acquisition of replication defective adeno-associated viral (AAV) particles and administration *in vivo*. Acquisition and propagation of non- recombinant Zika virus and Sendai Virus; propagation of *Aggregatibacter, Porphromonas,* and *Neisseria spp.* for viral co-infection of tissue culture cells. Protein purification from non-K12 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:

- Approval contingent of meeting with Assistant Biosafety Officer to discuss revisions
- Update the excel inventory for the following:
  - Distinguish between viral vectors and non-viral plasmids
  - Distinguish between recombinant and non-recombinant viruses
  - Identify vectors that are not self-inactivating
  - Identify cell lines that contain latent viruses and identify associated viruses
  - Include all genes for modification
  - Indicate what genes will be expressed by non-K-12 *E. coli*
- Confirm presence of BSCs in indicated space
- Add safety information and details for replication competency tests for non-self-inactivating viral vectors

- Add safety statement for Zika Virus
- Confirm location of indicated equipment
- Clarify fixation method for viral tittering and downstream analysis
- Indicate the use of lids for culture tubes
- Indicate types of sharps used and include recommended language for handling
- Administrative updates and revisions

Motion Approval: **Approved w/ Contingency**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

b. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 1422	**PI:** Van Wagoner	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a; III-E-1

Project Title:
Derivation of iPS cells for the creation of iPS-derived cardiac myocytes for studies of cardiac arrhythmia mechanisms

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Replication defective Sendai viral
- Vectors and mammalian expression plasmids in cell culture
- 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:

- Clarify the type modified DNA/RNA used for gene expression with viral vectors

Motion Approval:	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Approved w/ Administrative Revisions					

Basic Research Renewal #2	**Protocol ID:** IBC 1522	**PI:** DiDonato	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-4-b

Project Title:
Altering gut flora to influence cardiovascular disease

Associated Grant Numbers:
P01 HL147823

Protocol Summary:

- Acquisition and propagation of recombinant *Bacteroides, Clostridium, Escherichia, Proteus, Emergencia spp.* and non-recombinant *Acidaminococcus, Acinetobacter, Aggregatibacter, Akkermansia, Alistipes, Anaerococcus, Anaerofustis, Anaerostipes, Anaerotruncus, Bacteroides, Bifidobacterium, Blautia, Bryantella/Marvinbryantia, Butyrivibrio, Campylobacter, Candida, Catenibacterium, Citrobacter, Clostridium, Clostridium/Intestinibacter, Collinsella, Coprococcus, Desulfovibrio, Dialister, Dorea, Edwardsiella, Eggerthella, Emergencia, Enterobacter, Enterococcus, Escherichia, Ethanoligenens, Eubacterium, Eubacterium/Absiella, Eubacterium/Anaerobutyricum, Faecalibacterium, Fusobacterium, Gemella, Granulicatella, Helicobacter, Holdemania, Klebsiella, Lactobacillus, Lactococcus, Marvinbryantia, Megamonas, Megasphaera, Mitsuokella, Neisseria, Olsenella, Parabacteroides, Parvimonas, Phaeobacter, Porphyromonas, Prevotella, Proteus, Providencia, Roseburia, Ruminococcus, Saccharomyces, Slackia, Solobacterium, Streptococcus, Subdoligranulum, Tannerella, Treponema, Turicibacter, Veillonella, Victivallis spp.* 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 ☐ 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:

- Clarify the type modified DNA/RNA used for gene expression with viral vectors

Motion Approval: Approved w/ Administrative Revisions	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

c. Amendments Not Applicable to NIH Guidelines:

Basic Research Amendment #1	**Protocol ID:** IBC 1920	**PI:** Sangwan	**Biosafety Level:** BSL-2	**NIH Cat.:** N/A

Project Titles:
Nucleic acid extraction from polymicrobial community samples in the Microbial Sequencing & Analytics Resource Facility

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Nucleic acid extraction from human derived materials

Requested Additions/Changes:

- Administration of human derived material *in vivo*
- New Core facility

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:

- Clarify which core is performing indicated experiments
- Indicate samples are from patients with no known infections
- Clarify that lab may receive samples from *in vivo* procedures to send to an outside collaborator, but will not process them internally
- Administrative updates and revisions

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

Approved w/ Administrative Revisions	7	0	0	1	0

Basic Research Amendment #2	**Protocol ID:** IBC 2508	**PI:** Dhawan	**Biosafety Level:** BSL-2	**NIH Cat.:** N/A

Project Titles:
Genetic and Molecular Analysis of Tumors of the Nervous System and Their Coverings

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition, processing and storage of potentially infectious human specimens

Requested Additions/Changes:

- New location

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 requested

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

Basic Research Amendment #3	**Protocol ID:** IBC 1817	**PI:** Rieder	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** N/A

Project Titles:
Adherent-invasive *E. coli* (AIEC) induces intestinal fibrosis

Associated Grant Numbers:

Non-NIH Funding

Summary of Approved Items:
Propagation of adherent invasive E. coli and administration *in vivo*

Requested Additions/Changes:

- Expression of RG3 proteins in K-12 *E. coli*
- New locations

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 and revisions

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	8	0	0	0	1

Basic Research Amendment #4	**Protocol ID:** IBC 2114	**PI:** Vachharajani	**Biosafety Level:** BSL-2	**NIH Cat.:** N/A

Project Titles:
Immune response in sepsis

Associated Grant Numbers:
R01GM99807, R01AI153085

Summary of Approved Items:
Acquisition of samples from healthy and septic patients, process cells for analysis; Human-derived materials

Requested Additions/Changes:

- New location

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 requested

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

Basic Research Amendment # 5	**Protocol ID:** IBC 2127	**PI:** Vachharajani	**Biosafety Level:** BSL-2	**NIH Cat.:** N/A

Project Titles:
Immune response in sepsis

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of samples from healthy and septic patients, MRSA isolates, and Staphylococcus aureus, process cells for analysis; Human-derived materials

Requested Additions/Changes:
- New location

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 requested	

Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 0	Not Present: 1

d. Amendments:

Basic Research Amendment #6	Protocol ID: IBC 2602	PI: Vachharajani	Biosafety Level: BSL-1, BSL-2	NIH Cat.: III-D-1-a, III-D-3-a

Project Titles:
Viral Transduction of mammalian cells in sepsis

Associated Grant Numbers:
R01GM99807, 5R01AI153085

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

Requested Additions/Changes:
- New location

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 requested	

Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 0	Not Present: 1

Basic Research Amendment #7	Protocol ID: IBC 2201	PI: Vaccharajani	Biosafety Level: BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b

Project Titles:
Sepsis immune dysfunction & post-sepsis infections

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition and propagation of fungus and recombinant and non-recombinant bacteria, co-culture with cell lines and administration of bacteria and fungus *in vivo*; Human-derived material

Requested Additions/Changes:

- New locations
- Update BSL of previously approved spaces

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 requested

Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 0	Not Present: 1

Basic Research Amendment #8	Protocol ID: IBC 2044	PI: Miller	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a

Project Titles:
The Role of the Urinary Microbiome on BCG Response in Non-Muscle Invasive Bladder Cancer

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation of non-recombinant bacteria, infection of cells in culture including co-culturing; transformation of an attenuated strain of *Mycobacterium bovis* and infection of cells in culture. Human-derived materials

Requested Additions/Changes:

- New location

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 air flow correction

Motion Approval: **Approval w/ Contingency**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #9	**Protocol ID:** IBC 2222	**PI:** Stacy	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Oral microbiota-host interactions in periodontitis

Associated Grant Numbers:
R35GM160210, R01DE035865, R21DE035249, R21DE035242

Summary of Approved Items:
Generation and propagation of recombinant and non-recombinant modified bacteria; co-culture in-vitro, Gingiva-on-a-Chip; administration of bacteria *in vivo*; Human-derived materials

Requested Additions/Changes:

- *Aggregatibacter, Haemophilus,* and *Campylobacter spp.*
- New mutations of approved bacteria
- Dermestid beetles and experimental procedures
- New location

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:

- Work with biosafety office on spill release plan for dermestid beetles
- Include detail for disposal of beetle feed and frass as solid biohazard waste

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 2	**Not Present:** 1

Basic Research Amendment #10	**Protocol ID:** IBC 1209	**PI:** Perkins	**Biosafety Level:** BSL-1, ABSL-1	**NIH Cat.:** III-D-4-a, III-D-4-b

Project Titles:
Cilia Assembly and Transport in the Vertebrate Retina

Associated Grant Numbers:
R01EY034755, R01EY034493

Summary of Approved Items:
Generation and propagation of *in vivo* model; rDNA modification of tissue culture cells; human-derived materials

Requested Additions/Changes:

- Additional *in vivo* model
- New location

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 requested

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

Basic Research Amendment #11	**Protocol ID:** IBC 1603	**PI:** Tam	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Cytoskeletal Keratins in Corneal Immunity and Homeostasis

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation of recombinant and non-recombinant Herpes Simplex Virus subtype 1 (HSV-1) and transduction of tissue culture cells; administration of HSV-1 *in vivo*; Human-derived material

Requested Additions/Changes:
- 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 requested**	

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

Basic Research Amendment #12	**Protocol ID:** IBC 2204	**PI:** McGrail	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Investigation of disease mechanisms and therapeutic approaches

Associated Grant Numbers:
R37CA295609. R21DE035242

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, transfection of tissue culture cells, administration of transfected and transduced cells *in vivo*; Acquisition of non-recombinant bacteria and generation of recombinant bacteria and co-culture with cells; Human-derived material

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 requested	

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

Basic Research Amendment #13	**Protocol ID:** IBC 1510	**PI:** Heemers	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
RhoA signaling axis as a novel target for the treatment of prostate cancer

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of defective replication lentiviral particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*; Administration of plasmid transfected cells *in vivo*; Human-derived material

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 requested

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

Basic Research Amendment #14	**Protocol ID:** IBC 1203	**PI:** Lathia	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Connexins and glioblastoma progression

Associated Grant Numbers:
R01 NS127374, R35 NS127083, P01 CA245705, F32 CA287655, F31 NS141426, R03 NS135197, R01 CA308618

Summary of Approved Items:
Generation of replication defective lentivirus, transduction of tissue culture cells and administration of transduced cells *in vivo*; acquisition of recombinant and non-recombinant bacterial strains and administration *in vivo*; Administration of plasmid *in vivo*; Acquisition of Adeno-Associated Virus (AAV) particles and administration *in vivo*; Administration of Diphtheria Toxin (DT) *in vivo*; Human-derived material

Requested Additions/Changes:

- Gene targets
- Experimental procedures
- New locations

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 requested

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

Basic Research Amendment #15	**Protocol ID:** IBC 1719	**PI:** Ivanov	**Biosafety Level:** BSL-1, BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Regulation of intestinal epithelial barrier during mucosal inflammation

Associated Grant Numbers:
R01DK131550

Summary of Approved Items:
Acquisition and propagation of recombinant and non-recombinant bacteria, co-culture with cell lines and administration of bacteria *in vivo*; human-derived material

Requested Additions/Changes:

- Replication defective adeno-associated viral particles (AAV)
- Gene targets and genes for editing
- Administration of 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 ☐ 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 requested

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

Basic Research Amendment #16	**Protocol ID:** IBC 1918	**PI:** Dwidar	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Genetic engineering of commensal bacteria; Cancer-specific bacteria as tools to target chemotherapeutic drugs

Associated Grant Numbers:
R35GM156762

Summary of Approved Items:
Isolation, culturing and archiving of microbes from human-derived materials; Genetic engineering of bacteria, culturing and archiving of recombinant modified strains; administration of bacteria *in vivo*; human-derived material

Requested Additions/Changes:

- Gene targets for generation of recombinant bacteria

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 requested

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

Basic Research Amendment #17	**Protocol ID:** IBC 2106	**PI:** Scheraga	**Biosafety Level:** BSL-1, BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
TRPV4 Mediates the Bacterial Pneumonia and Viral Response; Mechanisms of Lung Injury after Infection

Associated Grant Numbers:
R01HL155064

Summary of Approved Items:
Acquisition of wt and recombinant bacteria, Adeno-Associated Viral particles (AAV), non-recombinant Influenza Virus; administration *in vivo*; Human-derived materials

Requested Additions/Changes:

- New location

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 requested

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

Basic Research Amendment #18	**Protocol ID:** IBC 2107	**PI:** Scheraga	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Titles:
Molecular Mechanisms of Lung Injury

Associated Grant Numbers:
R01HL155064

Summary of Approved Items:
Generation of replication defective lentiviral, adenoviral and adeno-associated viral (AAV) particles, propagation of Influenza Virus and recombinant and non-recombinant bacteria, infection of tissue culture cells; Human-derived materials

Requested Additions/Changes:
- New locations

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):	**Handler Training (Y/N):**

☒ Yes ☐ No	☒ Yes ☐ No

Discussion/Required Modifications:
- No modifications requested

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
Approved	9	0	0	0	0

Basic Research Amendment #19	Protocol ID:	PI:	Biosafety Level:	NIH Cat.:
	IBC 2039	Stappenbeck	BSL-2, ABSL-2	III-D-1-a, III-D-4-b

Project Titles:
Virus in the gut and control of Inflammatory Bowel Disease

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of Simian Rotavirus and Murine Rotavirus, recombinant and non-recombinant vesicular stomatitis Virus (Indiana), transduction of tissue culture cells, administration *in vivo*

Requested Additions/Changes:
- Murine betaherepesvirus 1
- Murine cell line
- Updated experimental methods
- New location

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 requested

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
Approved	9	0	0	0	0

Basic Research Amendment #20	**Protocol ID:** IBC 0912	**PI:** Chandrasekharn	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a. III-D-3-a

Project Titles:
Role of Tumor Necrosis Factor Alpha Receptor 2 (TNFR2) in Inflammation

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentiviral, adenoviral and adeno-associated viral (AAV) particles, propagation of Influenza Virus and recombinant and non-recombinant bacteria, infection of tissue culture cells; Human-derived materials

Requested Additions/Changes:

- New locations

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 requested

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

Basic Research Amendment #21	**Protocol ID:** IBC 1829	**PI:** Brown	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b, III-F-2, III-F-8

Project Titles:
The Role of Bacterial Choline Metabolism in Host Stress Response

Associated Grant Numbers:
R01HL179780

Summary of Approved Items:
Growth of recombinant and non-recombinant bacteria and fungi and administration *in vivo*

Requested Additions/Changes:

- Recombinant and non-recombinant defined bacterial community
- Mutant *Lactobacillus* and *Escherichia spp.*

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 requested

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

IV. Clinical Research:

a. Applications:

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

Project Title:
A Phase 1 Study of Allogeneic (γ/δ) BAFF CAR-T Cells (LMY-922) for Treatment of Refractory Hematologic Malignancies

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of transposon system transfected 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 ☐ 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 locations of biohazard waste containers	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	9	0	0	0	0

V. Revised SOPs:

SOP a: L.PLAN.401.08 BSL-3 Medical Surveillance	**Comments:** No Modifications Requested				
Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	9	0	0	0	0

VI. Other Business

None