IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
10/29/2025	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	☒ Champers, Dylan (BSO)	

Guests: Anthony Santilli, Abby Bifano*, Anna Reitsch*, Sara Tavakoli***

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

Call To Order:	**Adjourn:**
2:30 PM	4:35 PM

I. Review of Sept. 24th, 2025 Meeting Minutes

Committee Comments: N/A			
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0

II. Administrative Business

a. Committee presented with Expedited Review items, personnel additions, and updates to programmatic SOPs

b. Committee was updated on institutional access to an oncogene database.

c. Incident Report: IBC Members were informed of incident involving battery failure of a PAPR unit. 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 occurring during the month of October 2025. No major deficiencies were identified.

III. Clinical Research:

a. Applications:

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

Project Title:
A Phase 2 Multicohort Trial to Further Characterize the Efficacy and Safety of Ciltacabtagene Autoleucel

Associated Grant Numbers:
N/A

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 ☐ 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:

- N/A

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

Clinical Application #2	**Protocol ID:** Application #2	**PI:** Aziz	**Biosafety Level:** BSL1	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 1b, Multicenter, Open-Label, Dose Finding Study to Investigate the Safety and Tolerability of a Single Intravenous Dose of SGT-501 in Patients with Catecholaminergic Polymorphic Ventricular Tachycardia

Associated Grant Numbers:
N/A

Protocol Summary:

- Administration of replication defective adeno-associated viral particles (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: • N/A					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Clinical Application #3	**Protocol ID:** Application #3	**PI:** Stevenson	**Biosafety Level:** BSL1	**NIH Cat.:** III-C-1, III-E
Project Title: MRK1525 - A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of V940 in Combination With Pembrolizumab and Chemotherapy as First-Line Treatment for Participants With Metastatic Squamous NSCLC (INTerpath-013) (013-00)				
Associated Grant Numbers: N/A				
Protocol Summary: • Administration of mRNA to humans <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ 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: • N/A					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Clinical Application #4	**Protocol ID:** Application #4	**PI:** Turowski	**Biosafety Level:** BSL1	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 2, Open-label, Multiple Ascending-Dose Study to Evaluate the Safety, Tolerability and Efficacy of ARCT-032 in People with Cystic Fibrosis

Associated Grant Numbers:
N/A

Protocol Summary:

- Administration of mRNA to humans via nebulizer

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:

- N/A

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

Clinical Application #5	**Protocol ID:** Application #5	**PI:** Isaacs	**Biosafety Level:** BSL1	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 1/2, Open-label, Multi-center, First-in-human Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Antitumor Activity of STX-001 Delivered by Intratumoral Injection in Patients with Advanced Solid Tumors as a Monotherapy or in Combination with Pembrolizumab

Associated Grant Numbers:
N/A

Protocol Summary:

- Administration of mRNA 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: • N/A					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

b. Amendments:

Clinical Amendment #1	**Protocol ID:** CTIBC 058	**PI:** Raza	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1, III-E
Project Titles: Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-BCMA-ALLO1 in Subjects with Relapsed / Refractory Multiple Myeloma (MM)				
Associated Grant Numbers: N/A				
Summary of Approved Items: Administration of plasmid and mRNA transfected cells to humans				
Requested Additions/Changes: • Updated dosage range • Administrative Update 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 (Y/N):** ☒ Yes ☐ No		
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No		
Discussion/Required Modifications: N/A					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Clinical Amendment #2	Protocol ID: CTIBC 015	PI: Kennedy	Biosafety Level: BSL2	NIH Cat.: III-C-1, III-E

Project Titles:
BETA-PRIME: A Phase I, First in Human, Study to Evaluate the Safety and Tolerability of AdAPT-001 in Subjects with Refractory Solid Tumors

Associated Grant Numbers:
N/A

Summary of Approved Items:
Administration of adenovirus to humans

Requested Additions/Changes:

- Location updates

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

Discussion/Required Modifications:
N/A

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

IV. Non-Clinical Research:

a. New Applications:

Basic Research Application #1	Protocol ID: Application #1	PI: Koeth	Biosafety Level: BSL1, BSL2, ABSL1, ABSL2	NIH Cat.: III-D-1-a, III-D-4-b, III-F-8

Project Title:
Genes and Nutrition: Dietary Choline, the Gut Microbiota, and AF

Associated Grant Numbers:
P01 HL 158502-01A1

Protocol Summary:

- Acquisition and propagation of recombinant *Bacteroides, Clostridium, Escherichia, Proteus,* and *Enorma spp.* and non-recombinant *Bifidobacterium, Collinsella,*

Eggerthella, Olsenella, Slackia, Alistipes, Bacteroides, Parabacteroides, Poryphyromonas, Prevotella, Tanerella, Acidaminococcus, Anaerococcus, Anaerofustis, Anaerotruncus, Anaerostipes, Blautia, Byantella, Butyrivibro, Catenibacterium, Colstridium, Coprococcus, Dialister, Dorea, Emergencia, Enterococcus, Ethanoligenens, Eubacterium, Faecalibacterium, Gemella, Granulicatella, Holdemania, Lactobacillus, Marvinbryantia, Megamonas, Megasphera, Mitsuokella, Parvimonas, Roseburia, Ruminococcus, Solobacterium, Streptococcus, Subdoligranulum, Turicibacter, Veillonella, Vicitavillis, Acinetobacter, Desulfovibrio, Edwardsiella, Escherichia, Proteus, Campylobacter, Akkermensia, Aggregatibacter, Citrobacter, Enterobacter, Providencia, Neisseria, Heilcobater, Phaeobacter, Klebsiella, Fusobacterium, Treponema, Candida, and *Saccharomyces spp.*

- 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:

- Please review inventory for items that may require a permit
- Update disinfection description
- Update indicated steps to state they will occur within a BSC
- Add core facility personnel to protocol
- Administrative updates

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

b. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 0912	**PI:** Chandrasekharan	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** III-D-1-a, III-D-3-a
Project Title: Role of Tumor Necrosis Factor Alpha Receptor 2 (TNFR2) in Inflammation				
Associated Grant Numbers:				

Non-NIH Funding

Protocol Summary:

- Generation of replication defective lentiviral particles and 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:

- Update vector information

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

Basic Research Renewal #2	**Protocol ID:** IBC 1719	**PI:** Ivanov	**Biosafety Level:** BSL1, BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Title:

Regulation of the intestinal epithelial barrier during mucosal inflammation

Associated Grant Numbers:

R01DK131550

Protocol Summary:

- Acquisition and propagation of recombinant and non-recombinant bacteria *Citrobacter, Escherichia, and Salmonella spp.*, co-culture with cell lines and administration of bacteria *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: • Add missing gene information • Update Biological safety and special hazard sections for clarity	

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

Basic Research Renewal #3	**Protocol ID:** IBC 1802	**PI:** Shumacher-Bass	**Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Title:
Unique Domain Features of GRK2 and Roles in Cardiovascular Disease

Associated Grant Numbers:
R01 HL160755, P01 HL158502, R01HL173543

Protocol Summary:

- Acquisition of replication defective adenoviral particles, adeno-associated viral particles, lentiviral particles and administration *in vivo*
- Transduction of tissue culture cells with adenoviral particles, adeno-associated viral 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: • Update plasmid list • Clarify viral vector usage in *in vivo* experiments • Administrative edits	

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

Approved w/ Administrative Revisions					

Basic Research Renewal #4	**Protocol ID:** IBC 1406	**PI:** DiDonato	**Biosafety Level:** BSL1, ABSL1, ABSL2	**NIH Cat.:** III-D-4-b

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

Associated Grant Numbers:
P01HL147823, R01 HL103866, R01HL167831

Protocol Summary:

- Generation and propagation of recombinant and non-recombinant modified 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 ☒ 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:

- N/A

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

Basic Research Renewal #5	**Protocol ID:** IBC 0920	**PI:** Reizes	**Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Title:
Therapeutic target identification and validation in breast and gynecologic cancers for improving patient outcomes

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Generation of replication defective lentivirus particles, transduction of tissue culture cells, administration *in vivo*

- Administration of retroviral transduced cells *in vivo*
- Cholera Toxin in cell culture
- Acquisition of recombinant *Clostridium spp.* and non-recombinant *Escherichia, Clostridium, Lactobacillus, Mucispirillium, Eubacterium, Pseudoflavinofactor, Parabateroides, Faecalibaculum, Bifidobacterium, and Akkermensia spp.*, 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 BSL of agents in excel and application
- Include missing signs and symptoms
- Clarify *in vivo* handling and locations

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

c. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC 1209	**PI:** Perkins	**Biosafety Level:** BSL2, ABSL1, ABSL2	**NIH Cat.:** III-D-4-a, III-D-4-b

Project Titles:
Cilia Assembly and Transport in the Vertebrate Retina

Associated Grant Numbers:
R01EY030574, R01EY034755, R01EY034493, P30EY025585

Summary of Approved Items:
Generation of *in vivo* models; rDNA modification of tissue culture cells; human-derived materials.

Requested Additions/Changes:

- Additional transgenic *in vivo* models

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

Discussion/Required Modifications:
N/A

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

Basic Research Amendment #2	**Protocol ID:** IBC 1815	**PI:** Matsuoka	**Biosafety Level:** BSL1, ABSL1	**NIH Cat.:** III-D-4-a

Project Titles:
Vascular and lymphatic morphogenesis around the developing central nervous system

Associated Grant Numbers:
R01 NS117510

Summary of Approved Items:
Inject synthesized mRNA, plasmid DNA, CRISPR RNA/Cas9 complexes, or morpholino antisense oligos (ASOs) into an *in vivo* model.

Requested Additions/Changes:

- Additional transgenic *in vivo* models.

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

Discussion/Required Modifications:
N/A

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

Approved	8	0	0	0	0

Basic Research Amendment #3	**Protocol ID:** IBC 2204	**PI:** McGrail	**Biosafety Level:** BSL1, BSL2, ABSL2	**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:
R00CA240689

Summary of Approved Items:
Generation of replication defective lentiviral particles 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:

- Human tissue culture cell lines with some positive for HPV
- Recombinant mammalian tissue culture cell lines
- Bacterial transposon mutant library

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 (Y/N):** ☒ 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:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 0

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:

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 material

Requested Additions/Changes:

- Recombinant *Fusobacterium* and *Campylobacter 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 (Y/N):** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
N/A

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

Basic Research Amendment #5	**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:

- Expression plasmids
- Gene targets
- Updated methods for electroporation
- Room Addition

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

Discussion/Required Modifications:
N/A

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

Basic Research Amendment #6	**Protocol ID:** IBC 2107	**PI:** Scheraga	**Biosafety Level:** BSL1, BSL2	**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 and adeno-associated viral (AAV) particles, propagation of wt Influenza Virus and wt and recombinant bacteria, infection of tissue culture cells; Human-derived materials

Requested Additions/Changes:

- Acquisition of infectious human samples
- Cas9-gRNA
- Gene targets and genes for editing
- Updated protocols for cell isolation and CRISPR modification.

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

☒ Yes ☐ No			☒ Yes ☐ No		
Discussion/Required Modifications: N/A					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #7	**Protocol ID:** 1918	**PI:** Dwidar	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Genetic engineering of commensal bacteria

Associated Grant Numbers:
Non-NIH Funding

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 and genes for editing
- Recombinant *Lactobacillus, Salmonella, Escherichia, Bacteroides, Proteus, Clostridium,* and *Enorma 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 (Y/N):** ☒ 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 #8	**Protocol ID:** IBC 1819	**PI:** Davalos	**Biosafety Level:**	**NIH Cat.:** III-D-1-a, III-D-4-b

			BSL1, BSL2, ABSL1, ABSL2	

Project Titles:
Neuroimmune regulation of central nervous system function in physiology and disease

Associated Grant Numbers:
R01-NS112525

Summary of Approved Items:
Acquisition of defective replication defective adeno-associated virus and administered *in vivo*.

Requested Additions/Changes:

- Replication deficient adeno-associated viral 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 ☐ Cell Metabolism ☐ Other

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

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

Discussion/Required Modifications:
N/A

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

Basic Research Amendment #9	**Protocol ID:** IBC 2218	**PI:** Kim	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** III-E

Project Titles:
Microfluidic culture of human cells and bacteria

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Culturing of bacteria; co-culture of human and mammalian tissue culture cells with bacteria; human-derived materials

Requested Additions/Changes:

- Non-K12 *E. coli*
- Gene targets
- Use of new core facilities

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

Discussion/Required Modifications:
- Protocol now subject to section III-E of the NIH Guidelines

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

Basic Research Amendment #10	**Protocol ID:** 2312	**PI:** Stolley	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-b

Project Titles:
Resident memory T cell immunosurveillance of the oral mucosa and periodontium

Associated Grant Numbers:
R00DE031014

Summary of Approved Items:
Propagation of recombinant modified Vesicular Stomatitis Virus (VSV) Indiana Serotype, administration *in vivo*; Acquisition of toxin and administration *in vivo*

Requested Additions/Changes:
- Wild type vesicular stomatitis virus, Indiana serotype

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

Discussion/Required Modifications:

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

V. Revised SOPs:

SOP a: Agent Hazard Information	**Comments:** N/A				
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

SOP b: Medical Surveillance Plan	**Comments:** N/A				
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

VI. Other Business

None