IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
August 27th, 2025	Zoom

IBC Member Attendance:

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

Guests: Anthony Santilli, Anna Rietsch*, Jennifer Veillette*, Nikki Meyer*, Anna Simko*, Abby Bifano*, Dylan Champer***

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

Call To Order:	**Adjourn:**
2:32 PM	4:22 PM

I. Review of July 30th, 2025 Meeting Minutes

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

II. Administrative Business

- **a.** Committee presented with Expedited Review items and personnel additions.
- **b.** Incident Report: No incidents were reported since the previous meeting.
- **c.** Lab Audits: Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of August 2025**.** No major deficiencies identified.

III. Clinical Research:

a. Applications:

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

A Multi-Center, Randomized, Double-Masked, Active-Comparator-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Ixoberogene soroparvovec (Ixo-vec) in Participants with Neovascular Age-Related Macular Degeneration (ARTEMIS)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of recombinant, replication-incompetent, adeno-associated virus (AAV) viral vector 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:
N/A

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

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

Project Title:
A Phase I, Multicenter, Open Label Study to Evaluate the Safety, Tolerability, Cellular Kinetics, and Pharmacodynamics of P-CD19CD20-ALLO1 in Patients with Multiple Sclerosis

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of Transposon modified and Cas-CLOVER edited 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 (Y/N):** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:
- Administrative edits and updates

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

Clinical Application #3	**Protocol ID:** Application #3	**PI:** Caimi	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1

Project Title:
Expanded Access Protocol for Product which does not conform to the TECELRA® (afamitresgene autoleucel, suspension for intravenous infusion) Commercial Release Specification

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:
- Administration of replication defective lentiviral transduced cells to humans

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:
- N/A

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

Approved	10	0	0	0	0

IV. Non-Clinical Research:

a. New Applications:

Basic Research Application #1	**Protocol ID:** Application #1	**PI:** Dhawan	**Biosafety Level:** BSL2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Title:
miRNA and mRNA affecting glioma survival

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Include a statement that Core facilities will be informed of BSL and origin of unfixed samples.

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

Basic Research Application #2	**Protocol ID:** Application #2	**PI:** Valujskikh	**Biosafety Level:** BSL1, ABSL1	**NIH Cat.:** III-D-4-a

Project Title:
Investigations into tumor development in transplant recipients

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of transduced cells *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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Update room location for *in vivo* procedures
- Update "Potential Route of Exposure" to reflect these cells are not considered a respiratory hazard.

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

Basic Research Application #3	**Protocol ID:** Application #3	**PI:** Tiek	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Title:
Targeting ferroptosis in glioma

Associated Grant Numbers:
4R00CA279896

Protocol Summary:

- Generation of replication defective lentiviral particles, transduction of tissue culture cells and administration of transduced cells *in vivo*
- transfection 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Clearly indicate if genes being transduced are oncogenes or tumor suppressor genes.
- Acronyms should be spelled out the first time they are used.
- Update catalog numbers for cell lines used, they do not match the listed cell line.
- Clarify in text what PPE is required for *in vivo* procedures vs what additional PPE lab is choosing to wear.
- Update to reflect that used disposable syringes will be discarded directly into a sharps container
- Administrative updates

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

Basic Research Application #4	**Protocol ID:** Application #4	**PI:** Stappenbeck	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-4-b

Project Title:
Ovarian, Breast, Lung, Colon, and Prostate Cancer Vaccination with Retired Protein Antigens and Combination Immunotherapy

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of lentiviral transduced cells *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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications: • Indicate IBC protocol will be ABSL2.	

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

b. New Applications not applicable to NIH Guidelines:

Basic Research Application #5	**Protocol ID:** Application #5	**PI:** Harrington	**Biosafety Level:** BSL2+	**NIH Cat.:** N/A

Project Title:
Evaluation of Optimized Statistical Process Control Methods and Whole Genome Sequencing for Multicenter Surveillance of Healthcare Facility-Associated nontuberculous Mycobacteria

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Non-tuberculosis (NTM) isolates and shipment of cultures to collaborators at Duke University
- Subculture of *Mycobacterium ssp*.

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications: • N/A	

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

c. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 1809	**PI:** Piuzzi	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Efficacy of thermogel solution in *in vivo* model of knee periprosthetic joint infection (PJI)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of wild-type and recombinant *Staphylococcus spp. 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Indicate shoe covers will be removed prior to exiting the facility.
- If possible, syringes should be prepared outside of the facility to avoid unnecessary sharps manipulations during *in vivo* procedures.
- Update methods of disposal for biohazardous waste from *in vivo* procedures.

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

Basic Research Renewal #2	**Protocol ID:** IBC2124	**PI:** Chen	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Melanoma Signaling Pathways

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Generation of replication defective lentivirus particles, transduction of tissue culture cells and 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Confirm if genes are oncogenes or tumor suppressors and update relevant sections of application
- Indicate if gene is being partially expressed and used as a tag, or if the full gene is being expressed.
- Include a statement that Core facility will be made aware of BSL of samples being assessed.

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

d. Renewals Not Applicable to NIH Guidelines:

Basic Research Renewal #3	**Protocol ID:** IBC 1718	**PI:** Rieder	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** N/A

Project Titles:
The role of fungi in the pathogenesis of intestinal fibrosis

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Acquisition of *Candida spp.* for culturing and co-culture with 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Contact time for *Candida spp.* for chosen disinfectant is 10 min. Either update contact time or indicate an alternative disinfectant throughout protocol. Disinfectants available with a contact time of 1 min are available for these organisms.

Motion Approval: **Approved w/ Administrative Revision**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Renewal #4	**Protocol ID:** IBC2125	**PI:** Scott	**Biosafety Level:** BSL2	**NIH Cat.:** N/A

Project Titles:
The effect of genetic background on the evolution of antibiotic resistance and collateral sensitivity

Associated Grant Numbers:
R37 CA244613-01

Protocol Summary:

- Acquisition and propagation of bacteria in the presence of antibiotics.
- Identification of antibiotic-resistant isolates.
- Analysis of biofilm formation and antibiotic resistance

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Recommendation from IBC: Spray gloves with alternative disinfectant instead of 70% ethanol to disinfect. 70% can degrade gloves making more prone to break when handling items
- Recommendation from IBC: Follow waste disposal SOP unless there is a reason to deviate.
- If deviating from waste disposal SOP, please indicate/update sections highlighted in application
- Please update wording to reflect Bunsen burners are not being used within BSCs.
- Administrative edits and updates

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

e. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC2222	**PI:** Stacy	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Oral microbiota-host interactions in periodontitis

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:

- Non-recombinant *Pseudomonas* and *Enterococcus spp.*
- Recombinant *Neisseria* and *Fusobacterium spp.*
- Human tissue culture cells
- Updated to procedures for culturing and co-culturing wild type and recombinant bacteria ± tissue culture cells.

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ 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:	Handler Training:
☒ Yes ☐ No	☒ Yes ☐ No

Discussion/Required Modifications:

- An import permit is not necessary for these items, please update accordingly
- Include a brief description of changes to *in vivo* experiments
- Indicate which approved rooms are being used for co-culturing experiments in room table.
- Add a statement to the "Special Hazards" section that healthcare personnel will be informed in case of accidental exposure.
- Reference SOPs for ABSL2 areas in PPE section
- Use the following language for disposal of agar plates: Plates will be sealed to ensure the lids stay closed and dispose of into a red biohazard bag. At end of experiment, they will be tied shut, externally disinfected, and placed in nearby biohazard step-can.
- Remove statement about human samples no longer being considered hazardous after filtration. Certain microorganisms may not be captured by the filter.
- Indicate minimum contact time for fixation.
- Please indicate the use of a tray for co-culturing experiments using a syringe pump in case of spillage.

Motion Approval: Approved w/ Administrative Revisions	For:	Against:	Abstain:	Recuse:	Not Present:
	7	0	0	1	2

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

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

Associated Grant Numbers:
R01 AI140705, R01 AI52190, R01AI151013

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

Requested Additions/Changes:

- Recombinant modified Rhesus Rhadinovirus
- Mammalian tissue culture cells
- Updates to 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Confirm statement regarding changes to infectivity in recombinant viruses.

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	1	2

Basic Research Amendment #3	**Protocol ID:** IBC 2026	**PI:** Jung	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Identifying host determinants involved in immunoregulation

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*; Non-K12 E. coli; Human-derived materials

Requested Additions/Changes:

- *Leishmania tarentolae* protein expression system and associated protocols
- Mammalian expression plasmids
- 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Update statement regarding hazards associated with expressed proteins
- In special hazards section, indicate *Leishmania tarentolae* is a gecko pathogen, and that personnel handling the organism should be aware it is potential pet pathogen.

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #4	**Protocol ID:** IBC 2113	**PI:** Jung	**Biosafety Level:** BSL2	**NIH Cat.:** III-D-1-a, III-D-3-a

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

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus viral particles and transduction of tissue culture cells; propagation of recombinant hepatitis B virus, herpes simplex virus – 1 and acquisition of recombinant Kaposi Sarcoma Associated Herpesvirus (KSHV) and infection of tissue culture cells; Human-derived materials

Requested Additions/Changes:

- Replication deficient lentiviral particles
- Gene targets
- Human tissue culture cell line
- Update to 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Confirm whether lentiviral particles are replicated deficient or not.
- Confirm all genes expressed by new vectors are listed.
- Confirm inactivation steps are compatible with p24 assay.

Motion Approval: **Approved w Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #5	**Protocol ID:** IBC 2210	**PI:** Melenhorst	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
In vitro testing of gene-modified T cells 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 deficient lentiviral particles
- Gene targets
- Wild type and recombinant mammalian tissue culture cell lines

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- N/A

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

Basic Research Amendment #6	**Protocol ID:** IBC 2037	**PI:** Keri	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Transcriptional repression of aggressive breast cancer phenotypes

Associated Grant Numbers:
R01CA257502, R21CA288795

Summary of Approved Items:
Acquisition of replication defective lentivirus particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*. Acquisition of replication defective adenovirus particles, transduction of tissue culture cells, administration of adenovirus *in vivo*, administration of adenovirus transduced cells *in vivo*; Plasmid transfection in tissue culture and administration of plasmid transfected cells *in vivo*; Human-derived materials.

Requested Additions/Changes:

- Replication deficient lentiviral particles
- Gene targets
- Human tissue culture cell line

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:
- N/A

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

Basic Research Amendment #7	**Protocol ID:** IBC 1926	**PI:** Stappenbeck	**Biosafety Level:** BSL2, ABSL2	**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 wt and 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:
- New source of stool samples

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications: • Please reach out to EHS regarding whether an import permit is needed.	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	1	2

Basic Research Amendment #8	**Protocol ID:** IBC 2409	**PI:** Chen	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Mechanism and therapeutic potential of microglia regulation in glioblastoma

Associated Grant Numbers:
R01 NS127824, R01 NS124594, Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus particles, transduction of tissue culture cells, and administration of transduced *in vivo*. Human-derived materials.

Requested Additions/Changes:
- Room additions
- Update to disinfectants used

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications: • Confirm rooms listed in table and stepwise are accurate • Update boxes indicating if rooms are in open spaces.	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	8	0	0	0	2

Basic Research Amendment #9	Protocol ID: IBC 2226	PI: Poplawski	Biosafety Level: BSL2, ABSL2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a, III-D-4-b, III-E-1

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

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:

- Updates to procedures
- 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:** ☒ Yes ☐ No
PI/Supervisor Training: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Update disinfectant for BSC, bleach can corrode the surface.
- Clarify meaning of "labeled liquid bleach"
- Include statement that cuvettes will be disinfected prior to removing from BSC.

Motion Approval: Approved w/ Administrative Revisions	For: 7	Against: 0	Abstain: 0	Recuse: 1	Not Present: 2

V. Revised SOPs:

SOP a: Biological Waste Disposal	Comments: • Update Title

	• 6.1: Clarify aerosol generation is a syringe hazard • 8.3.2.1: Clarify if meaning full pipettes or pipette tips. • 8.3.3.1: Update to the following: "temporary containers must be disposed of at the end of a work session". • 8.5.1.4: Indicate applicable autoclaves are not certified for solid/infectious waste sterilization.				
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

SOP b: ABSL2 Operations	**Comments:** N/A				
Motion Approval: Approved	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 2

VI. Other Business

None