IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
June 25th, 2025	Zoom

IBC Member Attendance:

☒ Ahern, Philip	☐ DiDonato, Joseph	☒ Dragan, Amanda (BSO/Acting Chair)
☒ 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, Nikki Meyer*, Anna Rietsch*, Dylan Champer***

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

Call To Order:	**Adjourn:**
2:32 PM	3:12 PM

I. Review of May 28th, 2025 Meeting Minutes

Committee Comments: None presented				
Motion Approval: **Approved**	**For:** 9	**Against:** 0	**Abstain:** 0	**Not Present:** 2

II. Administrative Business

a. The committee was presented with Expedited Review items, personnel additions, and updates to programmatic SOPs.

b. **Incident Reports:** No incidents were reported for the month of June 2025.

c. **Lab Audits:** Members were informed of Annual Lab Audits and Preliminary Audits occurring during the month of June 2025**.** No major deficiencies were identified.

III. Clinical Research:

a. Applications:

Clinical Application #1	**Protocol ID:** Application #1	**PI:** Kennedy	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1, III-E
Project Title: RPL1625: (RP1-104) A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus				

Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]

Associated Grant Numbers:
N/A

Protocol Summary:

- Administration of recombinant, attenuated, and replication competent Herpes Simplex Virus - 1 (HSP-1) to humans.

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

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

Committee Comments:
None

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

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

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

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

Project Title:
A Phase 3, Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Safety of BMS-986393, a GPRC5D-directed CAR-T Cell Therapy, Versus Standard Regimens in Adult Participants with Relapsed or Refractory and Lenalidomide-refractory Multiple Myeloma

Associated Grant Numbers:
N/A

Protocol Summary:

- Administration of lentiviral transduced CAR T-Cells to humans
- Blood sample collection from participants

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

Species of Recombinant Genes to be Expressed:

☐ N/A ☒ Human ☐ Mouse ☐ Rat ☐ Bacterial ☐ Viral ☐ Other					
Committee Comments: None					
Facilities, Procedures, and Safety Practices Reviewed (Y/N): ☒ Yes ☐ No					
PI/Supervisor Training (Y/N): ☒ Yes ☐ No		**Handler Training (Y/N):** ☒ Yes ☐ No			
Motion Approval: **Approved**	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

IV. Non-Clinical Research:

a. New Applications:

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

Project Title:
The Impact of Dietary Fat and Obesity on Ovarian Cancer Progression

Associated Grant Numbers:
N/A

Protocol Summary:

- Acquisition of replication deficient lentiviral particles
- Transduction of tissue culture cells and administration *in vivo*
- Human tissue culture cells

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

☐ N/A ☐ Human ☒ Mouse ☐ Rat ☐ Bacterial ☐ Viral ☒ Other

Committee Comments:

- Administrative edits and updates to wording
- Sample preparation for unfixed BSL2 items need to be further described
  - Relevant SOPs will be provided to PI.

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

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

b. Renewals Not Applicable to NIH Guidelines:

Basic Research Renewal #1	Protocol ID: IBC 2127	PI: Vachharajani	Biosafety Level: BSL2	NIH Cat.: NA

Project Title:
Immune response in sepsis

Associated Grant Numbers:
R01GM99807

Protocol Summary:

- Sample acquisition from healthy and septic patients
- Acquisition and propagation of MRSA and *Staphylococcus spp.* for tissue culture infection
- Human and mammalian tissue culture cells lines

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

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

Committee Comments:

- Administrative edits
- Indicate use of MRSA *Staphylococcus spp.* as a new hazard
- Remove non-IBC *in vivo* procedures.

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

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

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

c. Amendments:

Basic Research Amendment #1	Protocol ID: IBC 2047	PI: Wu	Biosafety Level: BSL2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a

Project Title:
Elucidating the mechanisms of intrinsic stem cell resistance to virus infection

Associated Grant Numbers:
NA

Summary of Approved Items:
Generation of replication defective lentiviral particles and transduction of tissue culture cells; Generation of attenuated Yellow Fever Virus (YFV) and infection of tissue culture cells; Human-derived materials

Requested Additions/Changes:

- Updated procedures for propagation of YFV
- Mammalian tissue culture cells
- Updates to research activity locations
- Room additions

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

☒ N/A ☐ Human ☐ Mouse ☐ Rat ☐ Bacterial ☐ Viral ☐ Other

Committee Comments:
None

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

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

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

Basic Research Amendment #2	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	IBC 2022	Jung	BSL2, ABSL2	III-D-1-a, III-D-4-b, III-E

Project Titles:
Molecular basis of cancer-associated viruses

Associated Grant Numbers:
R01DE028521, R01CA251275, R01AI151013, R01AI181758-01A1, R01CA295170-01

Summary of Approved Items:
Propagation of Hepatitis B Virus (HBV) particles and recombinant modified and WT Orf Virus (ORFV) and Kaposi's sarcoma-associated herpes virus (KSHV) particles, and infection of tissue culture cells; acquisition of WT and recombinant modified cell lines that are positive for KSHV, Epstein Barr Virus (EBV); Administration of cells *in vivo*. Processing of human

blood positive for EBV and Cytomegalovirus (CMV), Non K-12 *E.Coli*; Human-derived material.

Requested Additions/Changes:

- Generation of replication deficient lentiviral particles for tissue transduction.
- Mammalian expression plasmids
- Gene expression library
- Human tissue culture cells
- Updates to safety information and disinfectant list.

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

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

Committee Comments:
None

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

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

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

Basic Research Amendment #3	**Protocol ID:** IBC 1407	**PI:** Byzova	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a III-D-4-b

Project Titles:
Phosphorylation and activation of B3 integrins in angiogenesis

Associated Grant Numbers:
R01 HL071625

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

Requested Additions/Changes:

- Replication deficient lentiviral vectors.
- Updated procedures for lentiviral transduction of tissue culture.

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

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

Committee Comments:

- Clarify disinfection of liquid waste disposal
- Clarify time frame of tissue transduction

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

PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No		
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #4	**Protocol ID:** IBC 2124	**PI:** Chen	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Targeting ZDHHC13-activated palmitoylation for melanoma treatment

Associated Grant Numbers:
R00CA234097

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

Requested Additions/Changes:

- Gene targets
- 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 ☒ Other

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

Committee Comments:
None

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

Basic Research Amendment #5	**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 PTEN-regulated MDSCs in glioblastoma

Associated Grant Numbers:
R01 NS127824, R01 NS124594

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

Requested Additions/Changes:

- Replication defective lentiviral particle
- Gene targets

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

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

Committee Comments:
None

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

Basic Research Amendment #6	**Protocol ID:** IBC 1203	**PI:** Lathia	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:

Interrogating the interface between cancer stem cells and the immune system

Associated Grant Numbers:
R01 CA184090, R01 NS089641, R01 NS096376, P30 CA043703, R01 NS109742, R01 NS117104

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

Requested Additions/Changes:

- Human cytomegalovirus (HCMV) infected human tissue culture cells for *in vivo* administration
- Gene targets
- Updated stepwise procedures

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

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

Committee Comments:

- Administrative edits
- Add HCMV infected cells to "New Hazards" section
- **Contingent Items**: Updates needed for ABSL2 cell administration:
  - Clarify what locations sample processing is occurring in. If being performed in ABSL2 facility, contact facility representatives for proper transport of equipment and other items into and out of the location.
  - Identify steps that generate liquid waste and how it is being collected.

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

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

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Contingency. **Rereview needed prior to approval**	10	0	0	1	0

V. New SOPs:

SOP a: ABSL2 Autoclave SOP	**Comments:** Administrative edits			
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 1

VI. Updated SOPs:

SOP b: ABSL1/2 Waste Disposal	**Comments:** None			
Motion Approval: **Approved**	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 1