IBC Meeting Minutes
Cleveland Clinic Florida Research and Innovation Center

Date:	**Location:**
July 17th, 2025	Zoom

IBC Member Attendance:

☒ McDonald, Christine (IBC Chair)	☒ Li, Kun	☒ Such, Kimberly
☒ Champer, Dylan (BSO)	☒ Hajjar, Adeline	☐ Judd, Leslie
☒ Tavakoli, Sara	☒ O'Connor, Christine	☒ Doud, Melissa
☒ Stolley, Michael		

Guests: Amanda Dragan, Abby Bifano*, Anthony Santilli*, Jennifer Veillette*, Nikki Meyer**

**Cleveland Clinic Main Campus*

Call To Order:	**Adjourn:**
2:30 pm	3:02 pm

I. Review of June 9th , 2025 Meeting Minutes

Committee Comments:
None

Motion:	**For:**	**Against:**	**Abstain:**
Approval	8	0	1

II. Review of July 17th , 2025 Meeting Minutes

Committee Comments:
None

Motion:	**For:**	**Against:**	**Abstain:**
Approval	8	0	1

III. Administrative Business

a. Committee presented with personnel additions.

IV. Non-Clinical Research:

a. Renewals:

Basic Research Renewal # 1	**Protocol ID:** FLIBC013	**PI:** Choi	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Titles:
Lentivirus production and transduction for protein expression, knockdown, and knockout of target genes.

Associated Grant Numbers:
NIH: R01-AI171201-01, Non-NIH Funding

Protocol Summary:

- Generation of replication-defective lentiviral particles, transduction of tissue culture cells; Human derived materials

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

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

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

Discussion/Required Modifications:

- Administrative edits

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

Motion:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved with Administrative Revisions	8	0	0	0	1

b. Amendments:

Basic Research Amendment # 1	**Protocol ID:** FLIBC001	**PI:** Gack	**Biosafety Level:** BSL-1, BSL-2, BSL-2+, ABSL-2	**NIH Cat.:** III-F-1, III-F-2, III-F-3, III-F-8, III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-D-7, III-E

Project Titles:
Regulation of Host Antiviral Innate Immunity

Associated Grant Numbers:

NIH (2023): 5DP1AI169444-03, 5R01 AI148534-04, 5R01 AI165502-03, 5 R37 AI087846-14, 1 R21 AI174534-01A1 ; Non-NIH Funding

Summary of Approved Items:
Propagation of recombinant and non-recombinant viruses, transduction of tissue culture cells, administration of viruses and viral transduced cells *in vivo*; Generation and propagation of recombinant and wild type SARS-CoV-2 virus, infection of cell lines and experimental analyses, administration of recombinant and wild type SARS-CoV-2 virus *in vivo*; Human-derived materials.

Requested Additions/Changes:

- Addition of new flavivirus nonstructural proteins to be expressed in 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 ☐ Murine ☐ Rat ☐ Bacterial ☒ Viral ☐ Other

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

Discussion/Required Modifications:
None

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

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

Basic Research Amendment # 2	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	FLIBC017	Li	BSL-3, ABSL-3	III-D-1-b, III-D-4-b

Project Titles:
Host-pathogen interactions during Coronavirus infection

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition and Propagation of WT and recombinant human and mouse SARS-CoV-2 strains, MERS, infection of tissue culture cells, administrations *in vivo*; Human derived materials.

Requested Additions/Changes:

- Adding compounds for treatment in both in vitro and in vivo studies and administration routes

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

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

Discussion/Required Modifications:

- Administrative edits
- Contingent Items:
    - Update and review of safety procedures for described administration routes

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

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

Basic Research Amendment # 3	**Protocol ID:** FLIBC019	**PI:** Ross	**Biosafety Level:** BSL-2, BSL-2+, ABSL-2	**NIH Cat.:** III-E

Project Titles:
Influenza virus neutralization

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation and generation of recombinant Influenza A & B viral strains; Transduction of tissue culture cells; administration *in vivo*; human-derived materials.

Requested Additions/Changes:

- Addition of new viral subtypes

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

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

Motion:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved with Administrative Revisions	8	0	1	0	0

Basic Research Amendment # 4	**Protocol ID:** FLIBC025	**PI:** Ross	**Biosafety Level:** BSL-2, BSL-2+, ABSL-2	**NIH Cat.:** III-F-1, III-F-2, III-E-1

Project Titles:
Utilizing novel mRNA vaccines to protect against influenza infection

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation and generation of recombinant Influenza A & B viral proteins; Transduction of tissue culture cells; generation of mRNA LNPs encoding influenza A and B viral proteins; administration of mRNA and influenza particles to mice and ferrets; human-derived materials.

Requested Additions/Changes:
- Addition of new viral subtypes

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

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

Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 1	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment # 5	**Protocol ID:** FLIBC026	**PI:** Ross	**Biosafety Level:** BSL-1, BSL-2, BSL-2+, BSL-3, ABSL-2, ABSL-3	**NIH Cat.:** III-F-8, III-F-2, III-F-3, III-D-7, III-E, III-E-1

Project Titles:
H2 and H5 Influenza Virus Infection and Vaccination

Associated Grant Numbers:
Non-NIH Funded

Summary of Approved Items:
Propagation of H2N2, H2N3, H5N1 influenza virus and subsequent assessment *in vivo* vaccinated under FLIBC019, human-derived materials.

Requested Additions/Changes:

- Addition of new *in vivo* study

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

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

Discussion/Required Modifications:

- Administrative edits
- Inclusion of language for temporal spacing for proposed study
- Update procedures for bite glove removal

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

Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 1	**Recuse:** 0	**Not Present:** 0