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, Anna Rietsch*, Abby Bifano*, Anthony Santilli*, Jennifer Veillette*, Nikki Meyer**

**Cleveland Clinic Main Campus*

Call To Order:	**Adjourn:**
2:31 pm	3:40 pm

I. Review of June 9th , 2025 Meeting Minutes

Committee Comments:
None

Motion:	**For:**	**Against:**	**Abstain:**
Approval	8	0	2

II. Administrative Business

a. Committee presented with personnel additions.

III. Non-Clinical Research:

a. Amendments:

	Protocol ID:	**PI:**	**Biosafety Level:**	**NIH Cat.:**
Basic Research Amendment # 1	FLIBC001	Gack	BSL-1, BSL-2, BSL-2+, ABSL-2	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 BSL-1 laboratory space to the protocol.

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

Basic Research Amendment # 2	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	FLIBC011	Cao	BSL-1, BSL-2, BSL-2+, ABSL1, ABSL-2	N/A

Project Titles:
Live-cell imaging of samples requiring BSL2/BSL-2+ containment in order to interrogate the complex biological pathways involved in pathogenesis.

Associated Grant Numbers:
N/A

Summary of Approved Items:
Imaging of live and fixed samples containing Risk Group 1 or 2 agents; human-derived materials.

Requested Additions/Changes:

- Addition of BSL-1 laboratory space to the protocol.

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

Basic Research Amendment # 3	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	FLIBC015	Thomas	BSL-1, BSL-2, BSL-2+	N/A

Project Titles:

Sample preparation, cell sorting and flow-cytometric analysis of unfixed samples requiring BSL-2/BSL-2+ containment.

Associated Grant Numbers:

N/A

Summary of Approved Items:

Sample preparation, cell sorting and flow cytometric analysis of fixed and unfixed samples containing Risk Group 2/2+ agents. All agent has to be approved by the IBC for each investigator, before use on Core equipment; Human derived materials.

Requested Additions/Changes:

- Addition of BSL-1 laboratory space to the protocol.

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	**For:** 7	**Against:** 0	**Abstain:** 1	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment # 4	**Protocol ID:** FLIBC008	**PI:** Zhao	**Biosafety Level:** BSL-1, BSL-2, BSL-2+, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Manipulation of Innate Immunity and Metabolism by Viruses and Cancers

Associated Grant Numbers:
NIH/NIDCR DE028973, NIH/NIDCR DE033632

Summary of Approved Items:
Generation of replication defective lentivirus, transduction of tissue culture cells and administration of transduced cells to mice; EBV+, KSHV+, and KSHV+/EBV+ cell lines, non-K12 E.coli, Mammalian expression vectors; Human-derived materials.

Requested Additions/Changes:

- Addition of Tissue culture cell line and administration route to mice

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	**For:** 7	**Against:** 0	**Abstain:** 1	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment # 5	**Protocol ID:** FLIBC017	**PI:** Li	**Biosafety Level:** BSL-3, ABSL-3	**NIH Cat.:** 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, infection of tissue culture cells, administrations *in vivo*; Human derived materials.

Requested Additions/Changes:

- Adding new cell lines and three strains of MERS to the protocol

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 experimental usage for new agent and cell lines
- Confirm cell line information

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

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

Motion:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved with Administrative Revisions	7	0	1	0	0

Basic Research Amendment # 6	**Protocol ID:** FLIBC022	**PI:** Speranza	**Biosafety Level:** BSL-1, BSL-2, BSL-2+, BSL-3, ABSL-2, ABSL-3	**NIH Cat.:** III-D-1-a

Project Titles:
Spatial and transcriptional response to viral infections at barrier tissue sites

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Propagation of non-recombinant Vesicular Stomatitis Virus, West Nile Virus, Chikungunya Virus, and SARS-CoV-2 strains; administration *in vivo*. Propagation of recombinant Vesicular Stomatitis Virus; Acquisition of inactivated Ebola Virus and inactivated Lassa Virus samples for histology and sequencing; human-derived materials.

Requested Additions/Changes:

- Adding validation and inactivation procedures of Togaviridae infected single cell suspension using parse biosciences' cell fixation reagent

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:

- Contingent Items:
  - Approval of revised SOP "L.SOP.506.01-Validation Procedures for Inactivation of Togaviridae Infected Single Cell Suspension Using Parse Biosciences' Cell Fixation Reagent"

Facilities, Procedures, and Safety Practices Reviewed (Y/N):

☒ Yes ☐ No

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

Motion:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved with Contingency	7	0	1	0	0

Basic Research Amendment # 7	**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 proteins for in vitro and in vivo studies

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					
Facilities, Procedures, and Safety Practices Reviewed (Y/N): ☒ Yes ☐ No					
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No		
Motion: Approved with Administrative Revisions	**For:** 7	**Against:** 0	**Abstain:** 1	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment # 8	**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 Influenza Virus Infection and Vaccination					
Associated Grant Numbers: **Non-NIH Funded**					
Summary of Approved Items: Propagation of H2N2 and H2N3 influenza virus and subsequent assessment *in vivo* vaccinated under FLIBC019, human-derived materials.					
Requested Additions/Changes: • Addition of H5N1 to the protocol for in vitro and in vivo use • Protocol title change <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Other <u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☒ Rat ☐ Bacterial ☐ Viral ☐ Other					
Committee Comments: • Administrative edits • Update working procedures for using multiple subtypes • Clarify inventory recording • Update doffing procedures					
Facilities, Procedures, and Safety Practices Reviewed (Y/N): ☒ Yes ☐ No					
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			**Handler Training (Y/N):** ☒ Yes ☐ No		
Motion:	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:**

Approved with Administrative Revisions					0

IV. Updated SOPs:

SOP a: Disinfectants for Biological Materials	**Comments:** Administrative edits			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP b: BSL-3 Training Procedures	**Comments:** Administrative edits			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP c: Agent Inventory	**Comments:** Administrative edits			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP d: Policy for HPAI Quarantine	**Comments:** Clarify definition of "Susceptible Species"			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP e: Validation Procedures for Formalin Fixation of Orthomyxoviridae Infected Tissues	**Comments:** • Administrative edits • Verify viral titer provided			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP f: Validation Procedures for Inactivation of Togaviridae Infected Single Cell Suspension Using Parse Biosciences' Cell Fixation Reagent	**Comments:** • Administrative edits • Update volume amounts and time points			
Motion: Approved with Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0

SOP g: Inactivation Procedures for Formalin Fixed Tissues	**Comments:** • Administrative edits • Contingent Items:

	○ Validation of inactivation procedures			
Motion: Approved with Contingency	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0