

IBC Meeting Minutes

Cleveland Clinic Florida Research and Innovation Center

Date: September 18 th , 2025	Location: Zoom
IBC Member Attendance: ☐ McDonald, Christine (IBC Chair) ☒ Li, Kun ☒ Such, Kimberly ☒ Champer, Dylan (BSO/Acting Chair) ☒ Hajjar, Adeline ☒ Judd, Leslie ☒ Tavakoli, Sara ☒ O'Connor, Christine ☒ Doud, Melissa ☒ Stolley, Michael <i>Guests: Amanda Dragan*, Anthony Santilli*, Nikki Meyer*</i> <i>*Cleveland Clinic Main Campus</i>	
Call To Order: 2:33 pm	Adjourn: 3:12 pm

I. Review of August 21st, 2025 Meeting Minutes

Committee Comments: None			
Motion: Approval	For: 9	Against: 0	Abstain: 0

II. Non-Clinical Research:

a. Renewals:

Basic Research Renewal # 1	Protocol ID: FLIBC015	PI: Thomas	Biosafety Level: BSL-2, BSL-2+	NIH Cat.: III-D-1-a
Project Titles: Sample preparation, cell sorting and flow-cytometric analysis of unfixed samples requiring BSL-2/BSL-2+ containment				
Associated Grant Numbers: Non-NIH Funding				

Protocol Summary: 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.					
<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					
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 Renewal # 2	Protocol ID: FLIBC014	PI: Cao	Biosafety Level: BSL-3	NIH Cat.: III-D-1-a, III-D-4-b	
Project Titles: Live-cell imaging of samples requiring BSL-3 containment in order to interrogate the complex biological pathways involved in pathogenesis.					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: Imaging of live and fixed samples containing Risk Group 3 agents. All agents (ie. viruses, cells, or animals) must be approved by the IBC and/or IACUC for each investigator, before use on Core equipment; Human derived materials.					
<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					

Risk Assessment Discussion: ☒ Yes ☐ No		Facilities, Procedures, and Safety Practices Reviewed (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: • Administrative edits • Updated safety information in attached SOP • Addition of laboratory map					
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 Renewal # 3	Protocol ID: FLIBC016	PI: Li	Biosafety Level: BSL-2, BSL-2+	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a III-D-4-b, III-E	
Project Titles: Using pseudoviruses to verify virus entry and inhibitors					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: • Acquisition and propagation of SARS-CoV-2, administration to mice; Generation of recombinant Vesicular Stomatitis Virus (VSV), generation of SARS-CoV-2 and MERS-CoV pseudovirus particles in culture; infection of cell lines, <i>in vivo</i> administration. Transfection of cell lines; 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: • Biosafety level of cell lines • Clarification on bacteria					

- Safety practices for handling animals - 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: 0	Recuse: 0	Not Present: 1

Basic Research Renewal # 4	Protocol ID: FLIBC017	PI: Li	Biosafety Level: BSL-3	NIH Cat.: III-D-1-b, III-D-2-a, III-D-3-a, III-D-4-b	
Project Titles: Host-pathogen interactions during Coronavirus infection					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: Acquisition and propagation of wt and recombinant Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe acute respiratory syndrome-related coronavirus 2 (SARSr-CoV2), generation of SARS-CoV2 strains, transduction of tissue culture cells, administration of virus <i>in vivo</i>; Acquisition of adenovirus and administration to mice; Transfection of cell lines; 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: - Biosafety level of cell lines - Biosafety level of viruses - Permit information - Safety practices for handling animals - PPE for animal behavioral tests					

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

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 <i>in vivo</i> ; 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 <i>in vivo</i> ; Human-derived materials.				
Requested Additions/Changes: None				
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: Approval	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

III. Updated SOPs:

SOP a: Biomedical Waste Operating Plan	Comments: Administrative edits				
Motion: Approved with Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	

SOP b: Validation Procedures for 4% paraformaldehyde Fixation of Coronaviridae Infected Cells	Comments: Administrative edits				
Motion: Approved with Administrative Revisions	For: 8	Against: 0	Abstain: 1	Recuse: 0	