

IBC Meeting Minutes

Cleveland Clinic Main Campus

Date:
July 29th, 2026

Location:
Zoom

IBC Member Attendance:

☒ Ahern, Philip	☐ Bukavina, Laura	☐ DiDonato, Joseph
☒ Dragan, Amanda (BSO)	☒ Hajjar, Adeline	☒ Heemers, Hannelore
☒ Kerr, Travis	☒ Lindner, Daniel	☒ McDonald, Christine (IBC Chair)
☐ Mortimer, Joanne	☒ Urban Molly	☒ Such, Kimberly

Guests:

Anthony Santilli, Anna Rietsch*, Jennifer Villette*, Nikki Meyer*, Andrew Goodman*
Dylan Champer**, Sara Tavakoli***

** Cleveland Clinic Main Campus*

*** Cleveland Clinic Florida Research & Innovation Campus*

Call To Order:
2:34 PM

Adjourn:
3:51 PM

I. Review of June 24th, 2026 Meeting Minutes

Committee Comments:

No changes requested

Motion Approval:

Approved

For:

8

Against:

0

Abstain:

0

Not Present:

1

II. Administrative Business

- a. Committee presented with Subcommittee Review items, personnel additions, and updates to programmatic SOPs
- b. Incident Report: IBC Members were informed of an incident involving improper waste disposal. The resulting risk assessments and corrective actions taken to prevent further occurrence were also presented.
- c. Lab Audits: Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of July 2026. No major deficiencies identified.

III. Non-Clinical Research:

a. New Applications:

Basic Research Application #1	Protocol ID: Application #1	PI: Rotroff	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a, III-D-3
Project Title: Developing Splice Switching Oligonucleotide Therapies for Hepatocellular Carcinoma				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: Generation of replication defective lentiviral particles, and transduction of 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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No	
Discussion/Required Modifications: - For the agent inventory: - Update BSL for indicated cell line to match supplier - Update description of genes that will be modified, some are not complete - For work with live cell imager, please indicate room number and sample transport				
Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0				

Basic Research Application #2	Protocol ID: Application #2	PI: Elias	Biosafety Level: BSL-1, BSL-2	NIH Cat.: III-E
Project Title: Ovary targeted polyplex nanoparticle mediate gene therapy for classical galactosemia associated premature ovarian insufficiency				
Associated Grant Numbers: R21HD113931				

Protocol Summary: - Gene editing using plasmid transfection in tissue culture - 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 ☒ Cell Metabolism ☐ Other						
<u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other						
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: Please update lay description to simplify technical language						
Motion Approval: Approved w/ Administrative Revisions		For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

b. Renewals:

Basic Research Renewal #1	Protocol ID: IBC 2222	PI: Stacy	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
Project Title: Oral microbiota-host interactions in periodontitis				
Associated Grant Numbers: R35GM160210, R01DE035865, R21DE035249, R21DE035242				
Protocol Summary: - Generation and propagation of recombinant <i>Aggregatibacter</i>, <i>Escherichia</i>, <i>Fusobacterium</i>, <i>Klebsiella</i>, <i>Neisseria</i>, <i>Campylobacter</i>, and <i>Enterococcus</i> spp. and non-recombinant <i>Aggregatibacter</i>, <i>Escherichia</i>, <i>Filifactor</i>, <i>Fusobacterium</i>, <i>Lactobacillus</i>, <i>Neisseria</i>, <i>Rothia</i>, <i>Streptococcus</i>, <i>Pseudomonas</i>, <i>Enterococcus</i>, <i>Haemophilus</i> spp. for use in co-culture in-vitro and Gingiva-on-a-Chip - Administration of bacteria <i>in vivo</i> - Dermestid beetles - Human-derived material				

<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other						
<u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Human ☐ Murine ☒ Bacterial ☐ Viral ☒ Other						
Risk Assessment Discussion: ☒ Yes ☒ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: - For the bacteria indicated in the agent inventory, will only the recombinant modified version be given <i>in vivo</i>, or will the WT also be administered? - Please add the indicated Core Facility personnel - Administrative updates and suggestions						
Motion Approval: Approved w/ Administrative Revisions		For: 7	Against: 0	Abstain: 0	Recuse: 2	Not Present: 0

Basic Research Renewal #2	Protocol ID: IBC 1427	PI: Bonilha	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a
Project Title: Regulation of Oxidative Stress in Health and Disease				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: - Acquisition of replication defective lentivirus particles and transduction of cells in culture - Human-derived material				
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☐ Other				
<u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other				

Risk Assessment Discussion: ☒ Yes ☐ No		Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: Administrative updates and revisions					
Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

c. Renewals Not Applicable to NIH Guidelines:

Basic Research Renewal #3	Protocol ID: IBC 1828	PI: Brown	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: N/A	
Project Title: The Role of Bacterial Choline Metabolism in Host Stress Response					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: - Administration of human fecal material <i>in vivo</i> - 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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Renewal #4	Protocol ID: IBC 2221	PI: Hashimoto	Biosafety Level: BSL-2	NIH Cat.: N/A	
Project Title: Potential biomarkers in the flushing solution of liver grafts to predict post-transplant outcomes					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: - Processing and analyzing human-derived patient samples potentially positive for Hepatitis C Virus, Hepatitis B Virus, Cytomegalovirus, and Epstein-Barr Virus - 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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

d. Amendments:

Basic Research Amendment #1	Protocol ID: IBC 2604	PI: Feng	Biosafety Level: BSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a, III-E
Project Titles: Innate Immune Signaling Pathways in Viral Infection and Host Antiviral Responses				
Associated Grant Numbers: R03DE034794				

Summary of Approved Items: Generation of replication defective lentiviral particles and retroviral particles and transduction of tissue culture cells; Acquisition and propagation of non-recombinant Murine Cytomegalovirus (MCMV), Influenza A Virus, recombinant modified Herpes Simplex Virus 1, Kaposi sarcoma-associated herpesvirus (KSHV), Murine gammaherpesvirus 68 (MHV-68); administration of Influenza A Virus, recombinant modified, Herpes Simplex Virus 1, Murine gammaherpesvirus 68 (MHV-68) <i>in vivo</i> ; acquisition of replication defective adeno-associated viral (AAV) particles and administration <i>in vivo</i> . Acquisition and propagation of non-recombinant Zika virus and Sendai Virus; propagation of non-recombinant bacteria for viral co-infection of tissue culture cells. Protein purification from non-K12 <i>E. Coli</i> .						
Requested Additions/Changes: <i>In vivo</i> behavior experiments - Room additions						
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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested						
Motion Approval: Approved		For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #2	Protocol ID: IBC 1526	PI: Rezaee	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
Project Titles: Investigating mechanisms of airway barrier regulation in response to environmental stimuli				
Associated Grant Numbers: N/A				
Summary of Approved Items:				

Propagation of non-recombinant and recombinant Human Respiratory Syncytial Virus (RSV), infection of tissue culture cells, administration of RSV <i>in vivo</i> ; CRISPR Cas9 gene editing via mammalian expression plasmid, expression vectors; human derived materials.					
Requested Additions/Changes: Protocol transfer to Dr. Scheraga					
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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved		For: 9	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Amendment #3	Protocol ID: IBC 1104	PI: Lindner	Biosafety Level: BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-4-b
Project Titles: Molecular determinants of tumor growth				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Administration of non-recombinant and recombinant modified cells <i>in vivo</i> ; Human-derived materials.				
Requested Additions/Changes: - Human and murine cell lines <i>In vivo</i> blood collection methods				
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						
<u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other						
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested						
Motion Approval: Approved		For: 7	Against: 0	Abstain: 0	Recuse: 2	Not Present: 0

Basic Research Amendment #4	Protocol ID: IBC 2205	PI: Xie	Biosafety Level: BSL-1, BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E
Project Titles: Organization, Dynamics and Mechanisms of Extrachromosomal DNA in Human Cancer				
Associated Grant Numbers: DP2 GM154017, R21 NS144792-01, R01 NS145466				
Summary of Approved Items: Generation of replication defective lentiviral and adeno-associated viral (AAV) particles, transduction of tissue culture cells, administration <i>in vivo</i> ; Transfection of tissue culture cells, administration <i>in vivo</i> ; Human-derived materials.				
Requested Additions/Changes: - Mammalian expression plasmids - Gene targets - Human cell lines <i>In vivo</i> cell administration route				
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other				
<u>Species of Recombinant Genes to be Expressed:</u>				

☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other					
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No		
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: - Indicate anesthesia method for <i>in vivo</i> experiments - Administrative edits and revisions					
Motion Approval: Approved w/ Administrative Revisions		For: 8	Against: 0	Abstain: 0	Recuse: 1
					Not Present: 0

Basic Research Amendment #5	Protocol ID: IBC 1510	PI: Heemers	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b
Project Titles: RhoA signaling axis as a novel target for the treatment of prostate cancer				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Generation of defective replication lentiviral particles, transduction of tissue culture cells, and administration of transduced cells <i>in vivo</i> ; Administration of plasmid transfected cells <i>in vivo</i> ; Human-derived material.				
Requested Additions/Changes: - Replication defective lentiviral particles - Gene targets				
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other				
<u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other				
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No	

PI/Supervisor Training (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Amendment #6	Protocol ID: IBC 2023	PI: Jung	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-E
Project Titles: Identifying viral determinants involved 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, Jamestown Canyon, Cache Valley Viruses 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 <i>in vivo</i> . Acquisition and processing of Epstein – Barr virus positive samples, Non K-12 E. coli; Human-derived material.				
Requested Additions/Changes: - Recombinant modified Potosi and Cache Valley virus - Updated experimental procedures - Room additions				
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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No				
Discussion/Required Modifications: No modifications requested						
Motion Approval: Approved		For: 8	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Amendment #7	Protocol ID: IBC 2026	PI: Jung	Biosafety Level: BSL-2, ABSL-2	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, R01AI116585, R01AI140718				
Summary of Approved Items: Generation of replication defective adeno-associated viral particles, transduction of tissue culture cells, and administration <i>in vivo</i> . 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 <i>in vivo</i> . Acquisition of Parainfluenza Type III (PIV3), Human Metapneumonia (hMPV) virus. Administration of plasmid infected cells expressing HBV <i>in vivo</i> . Generation and administration of mRNA vaccine <i>in vivo</i> . Generation of protein vaccine and administration <i>in vivo</i> ; Protozoan Leishmania tarentolae protein expression system; Non-K12 E. coli; Human-derived materials.				
Requested Additions/Changes: 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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #8	Protocol ID: IBC 2128	PI: Wessely	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-4-b
Project Titles: Cell specific delivery of novel therapies to enhance and repair glomerular regeneration				
Associated Grant Numbers: R01 DK-135716				
Summary of Approved Items: Acquisition of lentiviral particles, transduction of tissue culture cells, administration of transduced cells <i>in vivo</i> . Human-derived materials				
Requested Additions/Changes: - Replication defective lentiviral particles - Gene targets - Updated experimental 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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: No modifications requested				

Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0
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Basic Research Amendment #9	Protocol ID: IBC 2037	PI: Keri	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
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Project Titles:

Transcriptional repression of aggressive breast cancer phenotypes

Associated Grant Numbers:

Non-NIH Funding

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:

- Updated experimental 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 (Y/N):

☒ Yes ☐ No

Handler Training (Y/N):

☒ Yes ☐ No

Discussion/Required Modifications:

- Additional information for sample inactivation is needed

Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0
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Basic Research Amendment #10	Protocol ID: IBC 2017	PI: Corey	Biosafety Level: BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b	
Project Titles: Developing more effective therapy for sarcoma					
Associated Grant Numbers: Non-NIH Funding					
Summary of Approved Items: Injection mRNA and plasmid DNA to generate transgenic <i>in vivo model</i> , propagation and crossing of transgenic <i>in vivo model</i> ; Acquisition and administration of lentiviral transduced human cells <i>in vivo</i> . Human-derived materials.					
Requested Additions/Changes: Updated transgenic model list					
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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: Administrative updates and revisions					
Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #11	Protocol ID: 2040	PI: Stappenbeck	Biosafety Level: BSL-1, BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b
Project Titles: Shaping immune response by select members of the mycobiome				

Associated Grant Numbers: R01-AI168411					
Summary of Approved Items: Acquisition and propagation of non-recombinant bacteria and yeast, generation of recombinant modified yeast strains, infection of cell lines, and administration <i>in vivo</i> ; Generation of replication defective lentiviral particles, transduction of tissue culture cells, administration <i>in vivo</i> ; Human-derived material.					
Requested Additions/Changes: - Non-recombinant yeast strains - Room additions					
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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: <i>In vivo</i> experiments involving new agents need to be in ABSL2 facilities.					
Motion Approval: Approved w/ Administrative Revisions	For: 8	Against: 0	Abstain: 0	Recuse: 1	Not Present: 0

Basic Research Amendment #12	Protocol ID: IBC 1903	PI: Messer	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b, III-E
Project Titles: Host-microbe interactions at mucosal barriers				
Associated Grant Numbers: R01HL178625				
Summary of Approved Items: Growth of recombinant and non-recombinant bacteria and fungi strains and infection of tissue culture cells; administration of bacteria <i>in vivo</i> ; Human- derived materials.				

Requested Additions/Changes: - Updates to stepwise procedures - Room additions						
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other						
<u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other						
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested						
Motion Approval: Approved		For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #13	Protocol ID: IBC 2218	PI: Kim	Biosafety Level: BSL-1, BSL-2	NIH Cat.: III-D-3-a, III-E
Project Titles: Microfluidic culture of human cells and bacteria				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Generation of replication-deficient lentiviral particles, transduction of tissue culture cells; Culturing of recombinant and non-recombinant bacteria, co-culture of tissue culture cells with bacteria; human-derived materials.				
Requested Additions/Changes: Room additions				
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				

<u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other						
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested						
Motion Approval: Approved		For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #14	Protocol ID: IBC 1308	PI: Lee	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3a, III-D-4-b
Project Titles: Targeting the oncogenic signaling pathways in the brain tumor; Targeting oncogenic dopamine receptor signaling in glioblastoma				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Generation and propagation of replication defective lentiviral particles, transduction of tissue culture cells, and administration of transduced cells <i>in vivo</i> ; Human-derived material.				
Requested Additions/Changes: Room additions				
<u>Function/Nature of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				
<u>Species of Recombinant Genes to be Expressed:</u> ☒ N/A ☐ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other				
Risk Assessment Discussion: ☒ Yes ☐ No			Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No	
PI/Supervisor Training (Y/N):			Handler Training (Y/N):	

☒ Yes ☐ No		☒ Yes ☐ No			
Discussion/Required Modifications: Sections from a previous version of the document were removed. Confirm if those are no longer being performed or should be added back.					
Motion Approval: Approved w/ Administrative Revisions	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #15	Protocol ID: IBC 2004	PI: Wang	Biosafety Level: BSL-1	NIH Cat.: III-E	
Project Titles: Structural Studies of Protein-Drug Complexes for Drug Discovery					
Associated Grant Numbers: N/A					
Summary of Approved Items: Non-K12 <i>E. coli</i>					
Requested Additions/Changes: Protocol transfer to Dr. Goins					
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 (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

IV. Clinical Research:**a. Applications:**

Clinical Application #1	Protocol ID: Application #1	PI: Hanna	Biosafety Level: BSL-1	NIH Cat.: III-C-1, III-E	
Project Title: Precision Analysis of fusion genes in Ewing Sarcoma (ES) and Desmoplastic Small Round Cell Tumor (DSRCT), then EWSR1 Immunotherapy without or with anti-CTLA-4 (botensilimab) and Anti-PD1 (balstilimab)					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: Administration of self-amplified mRNA (saRNA) to humans <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other <u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other					
Risk Assessment Discussion: ☒ Yes ☐ No		Facilities, Procedures, and Safety Practices Reviewed: ☒ Yes ☐ No			
PI/Supervisor Training (Y/N): ☒ Yes ☐ No		Handler Training (Y/N): ☒ Yes ☐ No			
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Clinical Application #2	Protocol ID: Application #2	PI: Caimi	Biosafety Level: BSL-2	NIH Cat.: III-C-1, III-E
Project Title: A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucl versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis				

Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: Administration of replication defective lentivirus 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 (Y/N): ☒ Yes ☐ No			Handler Training (Y/N): ☒ Yes ☐ No		
Discussion/Required Modifications: No modifications requested					
Motion Approval: Approved	For: 9	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0