

IBC Meeting Minutes

Cleveland Clinic Main Campus

Date: August 26 th , 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 <i>Guests: Anthony Santilli*, Anna Rietsch*, Jennifer Villette*, Nikki Meyer*, Abby Bifano*, Andrew Goodman*, Dylan Champer**, Sara Tavakoli**</i> <i>* Cleveland Clinic Main Campus</i> <i>** Cleveland Clinic Florida Research & Innovation Campus</i>	
Call To Order: 2:30 PM	Adjourn: 4:23 PM

I. Review of July 29th, 2026 Meeting Minutes

Committee Comments: No edits requested			
Motion Approval: Approved	For: 10	Against: 0	Abstain: 0

II. Administrative Business

- a. Committee presented with Subcommittee Review items, personnel additions, and updates to programmatic SOPs
- b. 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.
- c. IBC was informed of new communication methods presented to labs to notify departmental administrative team when disposable PPE items need to be restocked.

III. Non-Clinical Research:

- a. **New Applications:**

Basic Research Application #1	Protocol ID: Application #1	PI: Fawzi	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-a	
Project Title: Exploring the angiogenesis-to-fibrosis transition in ischemic retinopathies					
Associated Grant Numbers: R01EY030121					
Protocol Summary: - Acquisition of replication defective adeno-associated viral (AAV) particles, transduction of tissue-culture cells, administration <i>in vivo</i> - Replication defective AAV plasmids - Tissue culture cell lines - Human-derived materials. <u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other					
<u>Species of Recombinant Genes:</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: - Clarify the type of secondary container used for agent transport and methods of disinfection - Include PPE for <i>in vivo</i> AAV infections - Indicated agents need to be exposed to fixative for a minimum of 15 min unless there is a specified reason for less. - Administrative updates and revisions					
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0
		Not Present: 0			

Basic Research Application #2	Protocol ID: Application #2	PI: Feng	Biosafety Level: BSL-1, BSL-2, BSL-2+, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b, III-E, III-E-1	
Project Title: Targeting cellular metabolic enzymes to improve antiviral therapy					

Associated Grant Numbers:

R01AI184716

Protocol Summary:

- Acquisition and Propagation of non-recombinant Zika virus, Murine cytomegalovirus (MCMV), Herpes simplex virus 1 (HSV-1), Influenza A virus (IAV) H1N1, Sendai virus, adenovirus, and SARS-CoV-2 and recombinant Kaposi sarcoma-associated herpesvirus (KSHV), Murine gammaherpesvirus 68 (MGHV68), and HSV-1
- Generation of recombinant HSV-1 and Epstein-Barr virus (EBV),
- Administration of HSV-1, IAV, and SARS-CoV-2 *in vivo*
- KSHV, MCMV, MGHV68, Sendai, Zika, EBV, and adenovirus for tissue culture infection
- Acquisition and propagation of *Aggregibacter*, *Porphyromonas*, *Neisseria*, and *Escherichia spp.* for tissue culture infection
- Acquisition of replication defective Adeno-associated viral particles, administration *in vivo*
- Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells
- Protein expression in non-K-12 *E. coli*
- Human derived materials

Function/Nature of Recombinant Genes:

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

Species of Recombinant Genes:

☐ 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:

- Include a description of individual retroviral vectors listed in the excel
- Update description of Raji cells to clarify they are positive for Epstein-Barr Virus
- Bleach inactivation requires 15% v/v Bleach for 30 min
- Indicate the following information for work with the cross-linker:
 - The equipment can fit inside a BSC
 - Sample containment
- Needles are not allowed in BSL-2+ facility. If something similar is needed, Biosafety office will work with lab on an appropriate alternative
- Update downstream analyses to indicate if agents are inactivated, and if so, include the methods. If not inactivated add description of procedures or if sent to a Core, indicate staff will be made aware of what agents are involved and any associated risks.

• Indicate microscope location • Administrative updates and revisions					
Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Application #3	Protocol ID: Application #3	PI: Feng	Biosafety Level: BSL-1, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E	
Project Title: Targeting immune and metabolic enzymes to improve anti-improve immunotherapy using preclinical <i>in vivo</i> models					
Associated Grant Numbers: R01CA285192, RF1AG088625					
Protocol Summary: • Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, administration <i>in vivo</i> • Protein expression in non-K-12 <i>E. coli</i> • Human-derived materials					
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other					
<u>Species of Recombinant Genes:</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: • <i>In vivo</i> procedures involving KSHV+ cell lines need to occur in ABSL-2 facilities. • For <i>in vivo</i> procedures, clarify what steps are occurring before and after agents are transported to different locations • Reusable tools need to be disinfected with one of the approved disinfectants prior to further cleaning and sterilization • Administrative updates and revisions					
Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

b. New Applications not applicable to NIH Guidelines:

Basic Research Application #4	Protocol ID: Application #4	PI: Dobbs	Biosafety Level: BSL-2	NIH Cat.: N/A		
Project Title: Impact of early-life pathogen exposures on pre-erythrocytic malaria vaccine effectiveness in Kenyan infants, Modulation of Monocyte and T Cell Functions by Immune Inhibitory Receptors during Subclinical Malaria						
Associated Grant Numbers: R01AI189783-01, R21 AI182702						
Protocol Summary: - Acquisition and propagation of Plasmodium falciparum for infection of tissue culture cells - Potentially malaria infected human-derived materials.						
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other						
Species of Recombinant Genes: ☒ 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: - Include any other sources of infected human material - Indicate if any human materials with no known infections are being used - Differentiate between risk associated with malaria positive samples vs work with human materials in general - Indicate if cells are fixed prior to submission to Core. If live cells are being assessed, indicate staff will be made aware of what agents are involved and any associated risks - All human materials must be worked with inside a BSC until inactivated, even if no known infection is present - Clarify location and steps involved with indicated culturing procedures						
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

c. Renewals:

Basic Research Renewal #1	Protocol ID: IBC 1823	PI: Scott	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a, III-D-3-a	
Project Title: Analysis of cellular fitness under therapeutic pressure					
Associated Grant Numbers: R37CA244613					
Protocol Summary: • Generation of replication defective lentiviral particles, transduction of tissue culture cells • Human derived materials					
Function/Nature of Recombinant Genes: ☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other					
Species of Recombinant Genes: ☐ 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: • Indicated gene should be listed as a tumor suppressor in gene tab of inventory.					
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Renewal #2	Protocol ID: IBC 2223	PI: O'Toole	Biosafety Level: BSL-2	NIH Cat.: III-D-4-b	
Project Title: Cell Specific delivery of recombinant DNA to knockdown endogenous gene expression or introduce tagged-versions of endogenously expressed genes					
Associated Grant Numbers: R01DK135265					
Protocol Summary: • Storage of replication defective lentiviral particles					
Function/Nature of Recombinant Genes:					

☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☐ Other					
<u>Species of Recombinant Genes:</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: - Update Lay Description to indicate that this is now a storage protocol - Confirm all applicable materials for storage have been listed on the excel.					
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Renewal #3	Protocol ID: IBC 1829	PI: Brown	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
Project Title: The Role of Gut Microbe Derived Metabolites in Cardiometabolic Disease				
Associated Grant Numbers: R01HL179780, R01DK130227, P50AA024333				
Protocol Summary: Propagation of recombinant <i>Bacteroides</i>, <i>Clostridium</i>, <i>Escherichia</i>, <i>Eubacterium</i>, <i>Gemella</i>, <i>Lactobacillus</i>, and <i>Proteus spp.</i> and non-recombinant <i>Acidaminococcus</i>, <i>Acinetobacter</i>, <i>Acutalibacter</i>, <i>Adlercreutzia</i>, <i>Aggregatibacter</i>, <i>Akkermansia</i>, <i>Alistipes</i>, <i>Anaerococcus</i>, <i>Anaerofustis</i>, <i>Anaerostipes</i>, <i>Anaerotruncus</i>, <i>Atopobium</i>, <i>Bacteroides</i>, <i>Bifidobacterium</i>, <i>Bilophila</i>, <i>Blautia</i>, <i>Bryantella/ Marvinbryantia</i>, <i>Burkholderiales</i>, <i>Butyricimonas</i>, <i>Butyrivibrio</i>, <i>Campylobacter</i>, <i>Candida</i>, <i>Catenibacterium</i>, <i>Citrobacter</i>, <i>Clostridium</i>, <i>Clostridium/ Intestinibacter</i>, <i>Collinsella</i>, <i>Coprococcus</i>, <i>Desulfovibrio</i>, <i>Dialister</i>, <i>Dorea</i>, <i>Edwardsiella</i>, <i>Eggerthella</i>, <i>Emergencia</i>, <i>Enterobacter</i>, <i>Enterocloster</i>, <i>Enterococcus</i>, <i>Escherichia</i>, <i>Ethanoligenens</i>, <i>Eubacterium</i>, <i>Eubacterium/ Absiella</i>, <i>Eubacterium/ Anaerobutyricum</i>, <i>Faecalibacterium</i>, <i>Flavonifractor</i>, <i>Fusobacterium</i>, <i>Gemella</i>, <i>Granulicatella</i>, <i>Helicobacter</i>, <i>Heliobacter</i>, <i>Holdemania</i>, <i>Intestinimonas</i>, <i>Klebsiella</i>, <i>Lactobacillus</i>, <i>Lactococcus</i>, <i>Limosilactobacillus</i>, <i>Marvinbryantia</i>, <i>Megamonas</i>, <i>Megasphaera</i>, <i>Mitsuokella</i>, <i>Muribaculum</i>, <i>Neisseria</i>, <i>Odoribacter</i>, <i>Olsenella</i>, <i>Oscillibacter</i>, <i>Parabacteroides</i>, <i>Parvimonas</i>, <i>Phaeobacter</i>, <i>Porphyromonas</i>, <i>Prevotella</i>, <i>Proteus</i>, <i>Providencia</i>, <i>Pseudoflavonifractor</i>, <i>Roseburia</i>, <i>Ruminococcus</i>,				

Slackia, Solobacterium, Streptococcus, Subdoligranulum, Tanerella, Treponema, Turicibacter, Turicimonas, Veillonella, Victivallis spp., administration in vivo

Function/Nature of Recombinant Genes:

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

Species of Recombinant Genes:

☐ 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:

- Confirm all applicable rooms have been listed in the application
- Update wording to reference Gnotobiotic working practices
- For spore forming bacteria, update inactivation methods since 100% Methanol is not sufficient. The Mass Spec Core does not accept non-inactivated samples.
- Administrative revisions and updates

Motion Approval:

Approved w/ Administrative Revisions

For:
10

Against:
0

Abstain:
0

Recuse:
0

Not Present:
0

Basic Research Renewal #4	Protocol ID: IBC 1825	PI: Cherepanova	Biosafety Level: BSL-1, BSL-2, ABSL-2	NIH Cat.: III-D-1-a
Project Title: Molecular mechanisms of vascular cell phenotypic transitions in pathological conditions				
Associated Grant Numbers: R01AG097492				
Protocol Summary: • Acquisition of replication defective lentiviral and adenoviral particles • Transduction of tissue culture cells • Administration of Diphtheria toxin <i>in vivo</i> • Human derived materials				
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☐ Other				

<u>Species of Recombinant Genes:</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 required					
Motion Approval: Approved	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Renewal #5	Protocol ID: IBC 1007	PI: Bao	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b	
Project Title: Molecular targeting of glioblastoma stem cells					
Associated Grant Numbers: R01 NS128938; R01 CA277966					
Protocol Summary: - Generation of replication defective lentiviral particles - Transduction of tissue culture cells, and administration of transduced cells <i>in vivo</i> - Human-derived material					
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other					
<u>Species of Recombinant Genes:</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 remove ABSL-1 space for indicated <i>in vivo</i> procedures, and update with an ABSL-2 location. Facility staff can consult on appropriate locations if needed					

Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0
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Basic Research Renewal #6	Protocol ID: IBC 1012	PI: Sakaguchi	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: III-D-4-a
Project Title: Forward genetic analysis of biliary system formation				
Associated Grant Numbers: R01DK103637				
Protocol Summary: Administration of morpholinos and guideRNA <i>in vivo</i>				
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other				
Species of Recombinant Genes: ☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0
				Not Present: 0

Basic Research Renewal #7	Protocol ID: IBC 1831	PI: Corey	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: III-D-4-a
Project Title: Genetic Modifiers for Cancer Stem Cells in Secondary MDS/AML				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary:				

Generation of synthesized gRNA, plasmid DNA, CRISPR RNA/Cas9 complexes or morpholino and administration <i>in vivo</i>					
Function/Nature of Recombinant Genes: ☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other					
Species of Recombinant Genes: ☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Renewal #8	Protocol ID: IBC 1832	PI: Corey	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a, III-D-3-a	
Project Title: CSF3R variants and clonal evolution in inherited neutropenias and myeloid malignancies					
Associated Grant Numbers: R01 DK132812					
Protocol Summary: - Generation of replication defective lentivirus particles, transduction of cells in culture - Transfection of cells in culture with RNA oligos, gRNA and Cas9 - Human derived materials					
Function/Nature of Recombinant Genes: ☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other					
Species of Recombinant Genes: ☐ 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: - Items discussed with lab and addressed prior to IBC meeting: - Removed references to <i>in vivo</i> experiments that were discontinued for this removal					
Motion Approval: Approved	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Renewal #9	Protocol ID: IBC 1833	PI: Miller	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-4-b
Project Title: Elucidating the mechanisms of the oxalate-degrading microbial network				
Associated Grant Numbers: R01 DK121689				
Protocol Summary: - Propagation of recombinant <i>Mycobacterium Sp.</i> and non-recombinant <i>Acinetobacter</i>, <i>Actinomyces</i>, <i>Aerococcus</i>, <i>Bacillus</i>, <i>Bacteroides</i>, <i>Brevibacterium</i>, <i>Candidia</i>, <i>Coprococcus</i>, <i>Corynebacterium</i>, <i>Dermacoccus</i>, <i>Desulfovibrio</i>, <i>Enterobacter</i>, <i>Escherichia</i>, <i>Exiguobacterium</i>, <i>Geobacillus</i>, <i>Kocuria</i>, <i>Lactobacillus</i>, <i>Lysinibacillus</i>, <i>Methanobrevibacter</i>, <i>Micrococcus</i>, <i>Mycobacterium</i>, <i>Oxalobacter</i>, <i>Pseudoclavibacter</i>, <i>Rothia</i>, <i>Ruminococcus</i>, <i>Staphylococcus</i>, <i>Streptococcus</i>, and <i>Winkia spp.</i>, and administration <i>in vivo</i> - Human-derived material.				
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other				
Species of Recombinant Genes: ☐ 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: - Protocol approval contingent upon updated procedures for <i>in vivo</i> sample collection. Please consult with facility staff to discuss appropriate methods and available locations - Human materials should be listed as RG2 - Add brief summary of <i>in vivo</i> experiments to indicated section				

• Add references to recombinant bacteria in indicated sections • Indicated agents require a longer disinfectant contact time than what is listed. Please either update with suggested disinfectants and contact time, or provide an alternative effective means of disinfection • Update location for indicated procedures and equipment • Increase fixation time for indicated procedures • Add facility personnel as handlers on protocol					
Motion Approval: Approved w/ Contingency	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

d. Amendments:

Basic Research Amendment #1	Protocol ID: IBC 1209	PI: Perkins	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: III-D-4-a
Project Titles: Cilia Assembly and Transport in the Vertebrate Retina				
Associated Grant Numbers: R01EY034755, R01EY034493				
Summary of Approved Items: Generation and propagation of <i>in vivo</i> models				
Requested Additions/Changes: • New <i>in vivo</i> model				
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other				
<u>Species of Recombinant Genes:</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: 10	Against: 0	Abstain: 0	Recuse: 0
				Not Present: 0

Basic Research Amendment #2	Protocol ID: IBC 2509	PI: Dhawan	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a		
Project Titles: miRNA and mRNA affecting glioma survival						
Associated Grant Numbers: Non-NIH Funding						
Summary of Approved Items: Generation of replication defective lentiviral particles, transduction of tissue culture cells; Human-derived material						
Requested Additions/Changes: • Replication defective lentiviral particles • Mammalian expression plasmids • Genes for expression and gene targets • Experimental procedures • New locations						
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other						
Species of Recombinant Genes: ☐ 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: • Update gene list to included version of Cas9 expressed from new plasmid • Add brief description of gRNA barcoding library						
Motion Approval: Approved w/Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #3	Protocol ID: IBC 2022	PI: Jung	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E	
Project Titles: KSHV mediated regulation of proline metabolism					

Associated Grant Numbers: R01 CA251275, R01 CA251275					
Summary of Approved Items: Generation of replication deficient lentiviral particles, transduction of tissue culture cells; 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 <i>in vivo</i> . Processing of human blood positive for EBV and Cytomegalovirus (CMV), Non K-12 <i>E.coli</i> ; Human-derived material					
Requested Additions/Changes: - Replication defective lentiviral particles - Gene targets and genes for editing - Human cell lines					
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
Species of Recombinant Genes: ☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #4	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 involve in viral-host interactions using infectious clones				
Associated Grant Numbers: Non-NIH Funding				
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 <i>E. coli</i> ; Human-derived material					
Requested Additions/Changes: - mRNA vaccine constructs - Human cell line					
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other					
Species of Recombinant Genes: ☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #5	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:				
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 <i>E. coli</i> ; Human-derived materials					
Requested Additions/Changes: - Experimental procedures - Protein vaccine constructs - New locations					
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
Species of Recombinant Genes: ☒ 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: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Amendment #6	Protocol ID: IBC 2315	PI: Jung	Biosafety Level: BSL-1, BSL-2, BSL-3, ABSL-3	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-3-b, III-D-4-b
Project Titles: Identifying effective drug targets against RNA viruses				
Associated Grant Numbers: R01 AI152190, R01 AI171201				
Summary of Approved Items: Propagation of non-recombinant SARS-CoV-2 isolates, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Powassan virus, Hantaan virus & Heartland virus; propagation of recombinant-modified Heartland virus, Severe fever with thrombocytopenia syndrome virus (SFTSV), SARS-CoV-2, SARS-CoV-2 isolates, SARS-CoV-2 animal adapted. Infection of cell lines: Co-infection with non-recombinant Oropouche Virus, La Crosse Virus, Utinga Virus,				

Simbu Virus, Manzanilla Virus, Lone Star Virus, Bunyamwera Virus and recombinant Uukuniemi virus; Acquisition of adenovirus and administration <i>in vivo</i> ; Administration of recombinant and non-recombinant viruses <i>in vivo</i> ; Human-derived materials						
Requested Additions/Changes: Mpox virus (Clade II) and associated updates to inactivation protocols.						
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other						
Species of Recombinant Genes: ☒ 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: Include the indicated language describing symptoms and vaccine availability for new agent						
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #7	Protocol ID: IBC 2037	PI: Keri	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b
Project Titles: Transcriptional repression of aggressive breast cancer phenotypes				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Acquisition and generation of replication defective lentivirus particles, transduction of tissue culture cells, and administration of transduced cells <i>in vivo</i> . Acquisition of replication defective adenovirus particles, transduction of tissue culture cells, administration of adenovirus <i>in vivo</i> , administration of adenovirus transduced cells <i>in vivo</i> ; Plasmid transfection in tissue culture and administration of plasmid transfected cells <i>in vivo</i> ; Human-derived materials.				
Requested Additions/Changes: - Replication defective lentiviral particles - Gene targets				

<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
<u>Species of Recombinant Genes:</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: Confirm name of new vectors					
Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #8	Protocol ID: IBC 2204	PI: McGrail	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b
Project Titles: Investigation of disease mechanisms and therapeutic approaches				
Associated Grant Numbers: R37CA295609, R00CA240689				
Summary of Approved Items: Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, transfection of tissue culture cells, administration of transfected and transduced cells <i>in vivo</i> ; Acquisition of non-recombinant bacteria and generation of recombinant bacteria and co-culture with cells; Human-derived material				
Requested Additions/Changes: - Human cell lines - Recombinant and non-recombinant bacteria strains - Gene targets and genes for editing - Experimental procedures				
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				

<u>Species of Recombinant Genes:</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: 1	Not Present: 0

Basic Research Amendment #9	Protocol ID: IBC 2110	PI: Wu	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E
Project Titles: Innate immune response in infection, autoimmune disease and cancer				
Associated Grant Numbers: R37CA288747				
Summary of Approved Items: Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, administration of transduced cells <i>in vivo</i> ; Generation of adeno-associated viral particles (AAV), transduction of tissue culture cells and administration of AAV <i>in vivo</i> ; Propagation of Herpes simplex virus 1, Vesicular stomatitis virus, Dengue virus 2, Zika virus, and recombinant Vaccinia virus and Sindbis virus; transduction of tissue culture cells; Administration of Herpes simplex virus 1 and Vesicular stomatitis virus <i>in vivo</i> ; Plasmid transfection of tissue culture cells and administration of transfected cells <i>in vivo</i> ; Human-derived materials.				
Requested Additions/Changes: - Replication defective lentiviral and adeno-associated viral particles - Gene targets and genes for editing, - Virus like particles - Mammalian expression plasmid - Tissue culture cell lines				
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other				
<u>Species of Recombinant Genes:</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 edits and revisions					
Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #10	Protocol ID: IBC 2210	PI: Melenhorst	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-b, III-D-4-b, III-E-1
Project Titles: Development, investigation, and evaluation of gene-modified cell therapies for efficacy against solid tumors and hematological malignancies				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Generation of replication-defective lentiviral and retroviral particles, transduction of tissue culture cells, plasmid transfection of tissue culture cells, and administration of cells <i>in vivo</i> ; Processing of potentially infectious or known infectious human material; Human-derived samples				
Requested Additions/Changes: - Replication defective lentiviral particles - Gene targets				
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other				
Species of Recombinant Genes: ☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #11	Protocol ID: IBC 1203	PI: Lathia	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b, III-E
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Project Titles:

Functional Characterization of Gene Variants in Melanoma

Associated Grant Numbers:

R01 NS127374, R35 NS127083, P01 CA245705, F32 CA287655, F31 NS141426, R03 NS135197, R01 CA308618

Summary of Approved Items:

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

Requested Additions/Changes:

- Gene targets
- Experimental procedures

Function/Nature of Recombinant Genes:

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

Species of Recombinant Genes:

☐ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0
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Basic Research Amendment #12	Protocol ID: IBC 1202	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: Molecular mechanisms of IL-1 signaling				
Associated Grant Numbers: P01CA272161				
Summary of Approved Items: Generation of replication defective lentiviral particles, transduction of cell lines and administration <i>in vivo</i> ; Human-derived material				
Requested Additions/Changes: • Experimental procedures • New locations				
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				
Species of Recombinant Genes: ☒ 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: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0				

Basic Research Amendment #13	Protocol ID: IBC 1425	PI: Stappenbeck	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-4-b
Project Titles: The relationship between immune dysregulation and autoimmune diseases				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Generation of recombinant bacteria and propagation of recombinant and non-recombinant bacteria, administration <i>in vivo</i> ; infection of tissue culture cells; human-derived material				

Requested Additions/Changes: - Experimental procedures - New locations						
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other						
Species of Recombinant Genes: ☒ 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: Update room table to include all rooms mentioned in stepwise procedures						
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #14	Protocol ID: IBC 1926	PI: Stappenbeck	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
Project Titles: Microbes in the gut and control of Inflammatory Bowel Disease				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Isolation and growth of recombinant and non-recombinant bacterial strains, co-culture with tissue culture cells; administration of bacteria <i>in vivo</i> , treatment of tissue culture cells with bacterial isolate; Acquisition of cholera, diphtheria and Clostridium Difficile A & B toxin and administration <i>in vivo</i> ; Human-derived materials				
Requested Additions/Changes: - Experimental procedures - Non-recombinant <i>Akkermansia</i>, <i>Alistipes</i>, <i>Bifidobacterium</i>, <i>Lacrimispora</i>, <i>Enterocloster</i>, <i>Clostridium</i>, <i>Barnesiella</i> spp. - Updated bacteria sources of approved bacteria - New locations				
Function/Nature of Recombinant Genes:				

☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
<u>Species of Recombinant Genes:</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: Update proposed changes and room table to include all rooms mentioned in stepwise procedures					
Motion Approval: Approved w/ Administrative Revisions		For: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Amendment #15	Protocol ID: IBC 2511	PI: Stappenbeck	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-4-b
Project Titles: Ovarian, Breast, Lung, Colon, and Prostate Cancer Vaccination with Retired Protein Antigens and Combination Immunotherapy				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Administration of lentiviral transduced cells <i>in vivo</i>				
Requested Additions/Changes: New locations				
<u>Function/Nature of Recombinant Genes:</u> ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				
<u>Species of Recombinant Genes:</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: Update room table to include all rooms mentioned in stepwise procedures					
Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #16	Protocol ID: IBC 1305	PI: Yu	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b	
Project Titles: Glioblastoma stem cell maintenance					
Associated Grant Numbers: R01 NS145466, R01 NS124081, R01 NS130798, U54 CA274513					
Summary of Approved Items: Generation of replication defective lentiviral and retroviral 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 - Human tissue culture cell lines - Experimental procedures - New locations					
<u>Function/Nature of Recombinant Genes:</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:</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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #17	Protocol ID: IBC 2106	PI: Scheraga	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b
Project Titles: Mechanisms of Lung Injury After Infection				
Associated Grant Numbers: R01 HL155064				
Summary of Approved Items: Acquisition of non-recombinant and recombinant bacteria, Adeno-Associated Viral particles (AAV), non-recombinant Influenza Virus; administration <i>in vivo</i> ; Human-derived materials				
Requested Additions/Changes: • Replication defective adeno-associated viral particles • Administration of replication defective lentiviral and adenoviral particles <i>in vivo</i>				
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other				
Species of Recombinant Genes: ☒ 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: 1
Not Present: 0				

Basic Research Amendment #18	Protocol ID: IBC 2047	PI: Wu	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b
Project Titles: Elucidating the mechanisms of intrinsic stem cell resistance to virus infection				
Associated Grant Numbers: R01 AA031226				
Summary of Approved Items:				

Generation of replication defective lentivirus, transduction of tissue culture cells and administration <i>in vivo</i> ; Generation of attenuated Yellow Fever Virus 17D, recombinant respiratory syncytial virus (RSV) and infection of tissue culture cells; Human-derived materials					
Requested Additions/Changes: Updated <i>in vivo</i> procedures					
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
Species of Recombinant Genes: ☒ 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: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Amendment #19	Protocol ID: IBC 1525	PI: Zhao	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b
Project Titles: Elucidating the Role of Deregulated Genes in Cancer				
Associated Grant Numbers:				
Summary of Approved Items: Generation of replication defective lentivirus, transduction of tissue culture cells, and administration of transduced cells <i>in vivo</i> ; Administration of plasmid transfected cells <i>in vivo</i> ; Administration of adenovirus <i>in vivo</i> ; Human-derived materials				
Requested Additions/Changes: - Human and mammalian cell lines - Experimental procedures				
Function/Nature of Recombinant Genes: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism				

☐ Other <u>Species of Recombinant Genes:</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: - Items discussed with lab and addressed prior to IBC meeting: - Removed references to <i>in vivo</i> work not being performed at this time					
Motion Approval: Approved		For: 10	Against: 0	Abstain: 0	Recuse: 0
Not Present: 0					

Basic Research Amendment #20	Protocol ID: IBC 2408	PI: Dang	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: III-D-4-b
Project Titles: Bariatric Surgery <i>in vivo</i>				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Acquisition of retro and lentiviral transduced cells, administration <i>in vivo</i>				
Requested Additions/Changes: - Experimental procedures, - Recombinant modified murine cell line - New locations				
<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other				
<u>Species of Recombinant Genes:</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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #21	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: - Experimental procedures - Recombinant murine cell line - New locations				
Function/Nature of Recombinant Genes: ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other				
Species of Recombinant Genes: ☐ 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: - Items discussed with lab and addressed prior to IBC meeting: - Updated language for sharps disposal.				
Motion Approval: Approved	For: 8	Against: 0	Abstain: 0	Recuse: 2
Not Present: 0				

e. Amendments Not Applicable to NIH Guidelines:

Basic Research Amendment #22	Protocol ID: IBC 2102	PI: Cresci	Biosafety Level: BSL-1, ABSL-1	NIH Cat.: N/A
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Project Titles: Probiotics, prebiotics, symbiotic and gut microbiota fermentation byproducts on gut-organ injury					
Associated Grant Numbers:					
Summary of Approved Items: Propagation and administration of non-recombinant RG1 bacteria <i>in-vivo</i>					
Requested Additions/Changes: <i>Akkermansia spp.</i>					
Function/Nature of Recombinant: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other					
Species of Recombinant Genes: ☒ 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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

IV. Clinical Research:

a. Applications:

Clinical Application #1	Protocol ID: Application #1	PI: Thomas	Biosafety Level: BSL-1	NIH Cat.: III-C-1, III-E
Project Title: A Phase 1/2 Multicenter, First-in-human, Ascending Dose Trial Evaluating the Safety, Tolerability, and Efficacy of a Lipid Nanoparticle Formulation of CRISPR–Guide RNA–Cas9 Nuclease (CTX340) for In Vivo Editing of the Angiotensinogen (AGT) Gene in Participants with Hypertension				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: Administration of CRISPR-cas9 mRNA to humans				

<u>Function/Nature of Recombinant Genes:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☒ Other					
<u>Species of Recombinant Genes:</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: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

V. Other Business

N/A