IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
Dec. 17th, 2025	Zoom

IBC Member Attendance:

☒ Ahern, Philip	☒ DiDonato, Joseph	☒ Dragan, Amanda (BSO)
☒ Fox, Alan	☒ Hajjar, Adeline	☒ Heemers, Hannelore
☒ Kerr, Travis	☒ Lindner, Daniel	☒ McDonald, Christine (IBC Chair)
☒ Mortimer, Joanne	☐ Southern, Brian	☐ Speranza, Emily
☒ Such, Kimberly		

Guests: Anthony Santilli, Anna Rietsch*, Nikki Meyer*, Abby Bifano*, Jennifer Villette*, Dylan Champer***
**CCF Main Campus*
***CCF Florida Research & Innovation Center*

Call To Order:	**Adjourn:**
2:30 PM	3:44 PM

I. Review of Nov. 19th, 2025 Meeting Minutes

Committee Comments: N/A			
Motion Approval:	**For:**	**Against:**	**Abstain:**
Approved	9	0	1

II. Administrative Business

a. Committee presented with Expedited Review items, personnel additions, and updates to programmatic SOPs

b. Lab Audits: Members were presented with Annual Lab Audits and Preliminary Audits occurring during the month of Dec. 2025. No major deficiencies were identified.

III. Clinical Research

a. Amendment – Not Applicable to NIH Guidelines:

Clinical Research	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
Amendment #1	CTIBC052	Haywood	BSL2	N/A

Project Title:
A Phase 3, Open-Label, Multi-Center, Randomized Study Evaluating Efficacy and Safety of TAR-200 in Combination with Cetrelimab or TAR-200 Alone Versus Intravesical Bacillus Calmette-Guérin (BCG) in Participants with BCG-naïve High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC) (SunRISe-3)

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Administration of Non-FDA approved Danish 1331 strain of Bacillus Calmette-Guérin (BCG) to humans.

Requested Additions/Changes:

- Transfer of protocol to new PI: Campbell

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:

- None

Motion Approval: **Approved**	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

IV. Non-Clinical Research:

a. New Applications – Not applicable to NIH Guidelines:

Basic Research Application #1	**Protocol ID:** Application #1	**PI:** Asosingh	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** N/A

Project Title:
Flow Cytometry SRL IBC SOPS: Symphony A1 Operation

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- SOP for flow cytometry analysis of Risk Group 1, 2, and inactivated and validated 3 samples in the BSL-3 Facility. All agents have to be approved by the IBC for each investigator before use on Core equipment; 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:

- Application:
  - Clarify which facility and instruments the protocol and related SOPs are applicable to.
  - Remove reference to samples being BSL-3 since they will all samples will be inactivated prior to receiving.
  - Identify the types of samples the core is expecting to receive.
  - Update symptoms of exposure to reference agents within the facility.
  - Indicate that core is reliant upon the collaborating lab to properly inactivate all sample prior to receiving samples, and the core will review inactivation documentation.
- SOP:
  - Clarify only inactivated samples are being assessed
  - Add reference to facility specific SOPs.

Motion Approval: Approved w/ Administrative Revisions	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

b. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC2205	**PI:** Xie	**Biosafety Level:** BSL1, BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Title:
Organization, Dynamics and Mechanisms of Extrachromosomal DNA in Human Cancer

Associated Grant Numbers:
R01 NS145466-01, R21 NS144792-01

Protocol Summary:

- Generation of replication defective lentiviral and adeno-associated viral (AAV) particles, transduction of tissue culture cells, administration *in vivo*

- Transfection of tissue culture cells, administration *in vivo*
- 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:
- Indicate if gene targets are oncogenes or tumor suppressor genes
- Add facility specific disinfectants for equipment
- Live imaging of BSL2 items cannot occur in the indicated space. For recombinant modified BSL1 items, they can only be imaged if vectors used where replication deficient and >72 hrs. has passed since transduction.
- Indicate that core facilities will be made aware of risks associated with inactivated samples.
- Minor administrative revisions

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	10	0	0	0	1

Basic Research Renewal #2	**Protocol ID:** IBC1806	**PI:** Ahern	**Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Title:
Gut microbiome modulation of immune function in health and disease

Associated Grant Numbers:
R01DK126772, R01AI18138

Protocol Summary:
- Isolation of various human and rodent-derived material and microbial isolates, administration *in vivo*
- Generation and culturing of recombinant *Bacteroides, Escherichia, Salmonella, Vibiro spp.* and growth of non-recombinant *Adlercreutzia, Akkermansia, Alistipes,*

Anaerostipes Anaerovoracaceae, Bacillus, Bacteroides, Bifidobacterium, Blautia, Butyricicoccaceae, Candidatus, Caprioiciproducens, Christensenellaceae, Citrobacter, Clostridia, Colidextribacter, Collinsella, Coriobacteriaceae, Defluviitaleaceae, Desulfovibrio, Dorea, Duncaniella, Eggerthella, Enterobacter, Enterococcus, Erysipelatoclostridiaceae, Escherichia, Eubacterium, Faecalibacterium, Helicobacter, Holdemania, Klebsiella, Lachnospiraceae, Lactobacillus, Ligilactobacillus, Limosilactobacillus, Muribaculum, Negativibacillus, Olsenella, Oscillospiraceae, Oxalobacter, Parabacteroides, Paramuribaculum, Parasutterella, Phocaeicola, Prevotella, Roseburia, Ruminiclostridium, Ruminococcus, Salmonella, Streptococcus, Subdoligranulum, Thauera, Veillonella, Vibrio spp. and administration *in vivo*
- Administration of recombinant tissue culture cell lines *in vivo*
- Administration of diphtheria, cholera, and pertussis toxins *in vivo*.

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:
- Please confirm the indicated cell line was intended.
- Minor administrative revisions

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 2	**Not Present:** 1

c. Renewals Not Applicable to NIH Guidelines:

Basic Research Renewal #3	**Protocol ID:** IBC2203	**PI:** Taylor	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** N/A

Project Title:
Correlation between Microbiome, Inflammatory Markers, and Brain Implant Recording Quality in an *in vivo* Model

Associated Grant Numbers:
R01-NS119160

Protocol Summary:
- Collection of *in vivo* samples
- Processing of un-fixed fecal samples and/or transfer to collaborator for analysis.

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:
- Minor administrative revisions

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

d. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC2406	**PI:** Ma	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-E

Project Titles:
Engineering human *in vitro* models of physiology and pathology for precision medicine

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of lentiviral particles, transduction of tissue culture cells. Human-derived materials

Requested Additions/Changes:
- Influenza A H1N1
- Human gammaherpesvirus 4
- Heat inactivated SARS-CoV-2
- Gene targets and genes for editing
- Updated procedures for viral infection 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: • Indicate the type of rDNA sequence being used for modifications • Indicate minimum detergent concentration needed for viral inactivation. • Add statement clarifying the use of BSL2 precautions for cell isolation procedures. • Minor administrative revisions					
Motion Approval: Approves w/ Administrative Revisions	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #2	**Protocol ID:** IBC1710	**PI:** Dana	**Biosafety Level:** BSL1, BSL2, ABSL1, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-a
Project Titles: Functional mapping of neuronal circuit activity in mammalian central and peripheral nervous system				
Associated Grant Numbers: R01NS134577, U01NS123658				
Summary of Approved Items: Generation of replication defective retroviral particles and acquisition of replication defective adeno-associated viral (AAV) particles; administration *in vivo*; Human derived materials.				
Requested Additions/Changes: • Replication defective adeno-associated viral (AAV) 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):	Handler Training (Y/N):
☒ Yes ☐ No	☒ Yes ☐ No
Discussion/Required Modifications: • None	

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
Approved	9	0	0	0	2

Basic Research Amendment #3	Protocol ID:	PI:	Biosafety Level:	NIH Cat.:
	IBC2107	Scheraga	BSL1, BSL2	III-D-1-a, III-D-3-a

Project Titles:
Molecular Mechanisms of Lung Injury

Associated Grant Numbers:
R01HL155064

Summary of Approved Items:
Generation of replication defective lentiviral and adeno-associated viral (AAV) particles, propagation of Influenza Virus and recombinant and non-recombinant bacteria, infection of tissue culture cells; Human-derived materials.

Requested Additions/Changes:
- Replication defective adenoviral particles
- Packaging plasmids
- Tissue culture cell lines
- Gene targets

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:	Facilities, Procedures, and Safety Practices Reviewed:
☒ Yes ☐ No	☒ Yes ☐ No
PI/Supervisor Training (Y/N):	**Handler Training (Y/N):**
☒ Yes ☐ No	☒ Yes ☐ No
Discussion/Required Modifications: • Update gene list to include reporter genes. • Indicate E. coli strain for electroporation. • Describe signage and sharps safety used during production of adenoviral particles.	

- Fixation time for tissue transduced with adenoviral particles is reduced compared to all other sections. Please either justify the reduced time, or update to match other sections.
- Minor administrative revisions

Motion Approval: Approved w/ Administrative Revisions	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #4	**Protocol ID:** IBC1927	**PI:** Vargas	**Biosafety Level:** BSL2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Titles:
Systematic delineation of activating mutations in oncogenes

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus particles and transduction of tissue culture cells; Human-derived materials

Requested Additions/Changes:
- Tissue culture cell line
- Genes for editing

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:
- Indicate if gRNA is being used in experiments.
- Minor administrative revisions.

Motion Approval: Approved w/ Administrative Revisions	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #5	Protocol ID: 1622	PI: Gong	Biosafety Level: BSL2, ABSL2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
DNA repair pathway as targets for therapy-resistant ovarian cancer

Associated Grant Numbers:
R01 CA222195

Summary of Approved Items:
Generation of replication defective lentivirus particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*; human derived material

Requested Additions/Changes:

- Cholera toxin in cell culture
- Room addition

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:

- Provided lab with additional options for agent storage
- Clarified bleach concentration for toxin vs infectious agents and sharps disposal

Motion Approval: Approved w/ Administrative Revisions	For: 10	Against: 0	Abstain: 0	Recuse: 0	Not Present: 1

Basic Research Amendment #6	Protocol ID: IBC2044	PI: Miller	Biosafety Level: BSL2	NIH Cat.: III-D-1-a

Project Titles:
The Role of the Urinary Microbiome on BCG Response in Non-Muscle Invasive Bladder Cancer

Associated Grant Numbers:

Non-NIH Funding

Summary of Approved Items:
Propagation and transformation of an attenuated strain of *Myobacterium bovis* and infection of cells in culture. Human-derived materials

Requested Additions/Changes:

- *Acinetobacter, Actinomyces, Aerococcus, Bacillus, Brevibacterium, Cadida, Corynebacterium, Dermacoccus, Escherichia, Exiguobacterium, Geobacillus, Kocuria, Lysinibacillus, Micrococcus, Pseudoclavibacter, Rothia, Staphylococcus, Winkia*
- Tissue culture cell lines
- Bioreactor model of biofilm formation
- 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:

- Remove references to BSL2 work in BSL1 spaces and add an alternative BSL2 space.
- Clarify that when working with cultures containing both BSL1 and 2 items, that BSL2 precautions are used.
- Include statement that no isolates are propagated or kept from bacterial co-culture experiments.
- Update Sign/Symptoms of exposure to include missing organisms.
- Provide a picture or more detailed schematic of bioreactor.
- Indicate waste containers are housed within secondary containment and will be emptied prior to reaching a total volume of 10L.
- Indicate that both the bead beater and screw cap vials have sealable lids, preferably with an O-ring or gasket.
- Minor administrative edits.

Motion Approval: Approved w/ Administrative Revisions	**For:** 10	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #7	Protocol ID: IBC2210	PI: Melenhorst	Biosafety Level: BSL2, ABSL2	NIH Cat.: III-D-1-a, III-D-3-b, III-D-4-b

Project Titles:
Development, investigation, and evaluation of gene-modified cell therapies for efficacy against solid tumors and hematological malignancies

Associated Grant Numbers:
R01CA241762

Summary of Approved Items:
Generation and validation of CAR-T cells targeting specific tumor markers. Generation of lentiviral particles and transduction of tissue culture cells, administration *in vivo*, electroporation using a CRISPR/Cas9 system into tissue culture cells; processing of potentially infectious or known infectious human material; Human-derived samples.

Requested Additions/Changes:

- Recombinant mammalian and human tissue culture cell lines
- Packaging plasmids
- Room additions and associated updates to 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:

- Please clarify that only chemicals are being administered *in vivo* within a fume hood.
- Minor administrative revisions

Motion Approval: Approved w/ Administrative Revisions	For: 11	Against: 0	Abstain: 0	Recuse: 0	Not Present: 0

Basic Research Amendment #8	Protocol ID: IBC2023	PI: Jung	Biosafety Level: BSL2, ABSL2	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 *in vivo*. Acquisition and processing of Epstein – Barr virus positive samples, Non K-12 E. coli; Human-derived material.

Requested Additions/Changes:
- Recombinant tissue culture cell lines
- Additional injection route for *in vivo* infection model

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:
- None

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	10	0	0	1	0

Basic Research Amendment #9	**Protocol ID:** IBC2047	**PI:** Wu	**Biosafety Level:**	**NIH Cat.:**

			BSL2	III-D-1-a, III-D-2-a, III-D-3-a

Project Titles:
Elucidating the mechanisms of intrinsic stem cell resistance to virus infection

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentivirus and transduction of tissue culture cells;
Generation of attenuated Yellow Fever Virus 17D and infection of tissue culture cells;
Human-derived materials.

Requested Additions/Changes:

- Recombinant Respiratory Syncytial Virus
- Human tissue culture cell lines

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:

- Minor administrative revisions

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 11	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment #10	**Protocol ID:** IBC2204	**PI:** McGrail	**Biosafety Level:** BSL1, BSL2, ABSL2	**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:
R00CA240689

Summary of Approved Items:
Generation of replication defective lentiviral particles and retroviral particles, transduction of tissue culture cells, transfection of tissue culture cells, administration of transfected and transduced cells *in vivo*; Acquisition of non-recombinant bacteria and generation of recombinant bacteria and co-culture with cells; Human-derived material.

Requested Additions/Changes:

- Human Papilloma Pseudovirus plasmids
- Expression plasmids
- Human and mammalian tissue culture cell lines.

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:

- None

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	10	0	0	1	0

V. Other Business

None