IBC Meeting Minutes
Cleveland Clinic Main Campus

Date: Sept. 24th, 2025	**Location:** 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 S., Anna R.*, Jenn V.*, Nikki M.*, Abby B.*, Anna S.**, Dylan C.**, Sarah T.***

** Cleveland Clinic Main Campus*
*** Cleveland Clinic Florida Research & Innovation Center (FRIC)*

Call To Order: 2:29 PM	**Adjourn:** 3:27 PM

I. Review of August 27th, 2025 Meeting Minutes

Committee Comments: N/A				
Motion Approval:	**For:**	**Against:**	**Abstain:**	**Not Present:**
Approved	8	0	0	1

II. Administrative Business

a. Committee presented with Expedited Review items and personnel additions.

b. Incident Report: Members were informed of an incident involving a failure to follow general lab safety protocols. After the incident, personnel involved participated in safety refresher training. Members of the Biosafety and Compliance Departments walked through the laboratory area to ensure all deficiencies had been corrected.

c. Lab Audits: Members were informed of Annual Lab Audits occurring during the month of September 2025. No major deficiencies were identified.

III. Clinical Research:

a. Applications:

Clinical Application #1	**Protocol ID:** Application #1	**PI:** Caimi	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1, III-E

Project Title: A Phase 1b/2 Study of AZD0120 (also known as GC012F), a Chimeric Antigen Receptor T Cell Therapy Targeting CD19 and B cell Maturation Antigen in Participants with Relapsed or Refractory AL Amyloidosis.					
Associated Grant Numbers: Non-NIH Funding					
Protocol Summary: • Administration of replication defective lentivirus transduced cells 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: • Approved with no modifications					
Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

b. Amendments:

Clinical Amendment #1	**Protocol ID:** CTIBC037	**PI:** Anwer	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1, III-E
Project Titles: A Phase 1, Multicenter, Open-Label Study of CB-011, a CRISPR-Edited Allogeneic Anti-BCMA CAR-T Cell Therapy in Patients with Relapsed				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items:				

Administration of replication defective adeno-associated virus and Cas12 edited, transduced cells to humans.
Requested Additions/Changes: • Updated dose level • Updated inclusion/exclusion criteria • Updated study design • Administrative updates <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: • Approved with no modifications	

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Clinical Amendment #2	**Protocol ID:** CTIBC032	**PI:** Sauter	**Biosafety Level:** BSL2	**NIH Cat.:** III-C-1
Project Titles: KT-US-471-0140: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Axicabtagene Ciloleucel				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Administration of replication defective retrovirus transduced cells to humans.				
Requested Additions/Changes: • Transfer to of protocol to Caimi				

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:

- Approved with no modifications

Motion Approval: Approved	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
	8	0	0	0	1

Clinical Amendment #3	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	CTIBC033	Sauter	BSL2	III-C-1

Project Titles:

KT-US-472-0141: Expanded Access Study for the Treatment of Patients with Commercially Out-of-Specification Brexucabtagene Autoleucel

Associated Grant Numbers:

Non-NIH Funding

Summary of Approved Items:

Administration of replication defective retrovirus transduced cells to humans.

Requested Additions/Changes:

- Transfer to of protocol to Caimi

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: • Approved with no modifications	

Motion Approval: **Approved**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

IV. Non-Clinical Research:

a. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 1402	**PI:** Diaz-Montero	**Biosafety Level:** BSL2	**NIH Cat.:** III-D-1-a
Project Titles: T cell receptor induced immune responses in cancer				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: • Acquisition of replication defective retroviral and lentiviral particle • Transduction of tissue culture cells • 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications:	

• Please update lentiviral vector description to indicate they are self-inactivating via 3'LTR deletion. • Clarify tropism of retro- and lentiviral particles. • Administrative edits

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

Basic Research Renewal #2	**Protocol ID:** IBC 2128	**PI:** Wessely	**Biosafety Level:** BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-4-a, III-D-4-b

Project Titles:
Cell specific delivery of novel therapies to enhance and repair glomerular regeneration

Associated Grant Numbers:
RO1 DK-135716

Protocol Summary:

- Acquisition of replication deficient lentiviral particles
- Transduction of tissue culture cells
- Administration of transduced cells *in vivo*
- 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Update "Function" description for each gene to clarify known/hypothesized functions.
- Update *in vivo* procedures to specify how disinfection steps differ between spaces that do and do not have a BSC
- Administrative edits.

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

Basic Research Renewal #3	Protocol ID: IBC 1407	PI: Byzova	Biosafety Level: BSL1, BSL2, ABSL1, ABSL2	NIH Cat.: III-D-1-a, III-D-4-b

Project Titles:
Phosphorylation and activation of B3 integrin in angiogenesis

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Acquisition of replication defective lentivirus particles
- Transduction of tissue culture cells

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 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Clarify description of 3' deletion on viral vectors.
- Update language for bleach disinfection of vacuum flask
- Update BSL classification of cell lines
- Administrative edits

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

<table>
<tr><td>Basic Research Renewal #4</td><td>Protocol ID:
IBC 2201</td><td>PI:
Vaccharajani</td><td>Biosafety Level:
BSL1, BSL2, ABSL1, ABSL2</td><td>NIH Cat.:
III-D-1-a, III-D-4-b</td></tr>
<tr><td colspan="5">Project Titles:
Sepsis immune dysfunction & post-sepsis infections</td></tr>
<tr><td colspan="5">Associated Grant Numbers:
Non-NIH Funding</td></tr>
<tr><td colspan="5">Protocol Summary:
Acquisition and propagation recombinant and non-recombinant Pseudomonas and Staphylococcus spp.
Acquisition and propagation of wild-type Candida spp.
Bacterial and Fungal co-culture with cell lines
Administration of bacteria and fungi in vivo
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 to be Expressed:</u>
☐ N/A ☐ Human ☐ Murine ☒ Bacterial ☐ Viral ☒ Other</td></tr>
<tr><td colspan="2">Risk Assessment Discussion:
☒ Yes ☐ No</td><td colspan="3">Facilities, Procedures, and Safety Practices Reviewed:
☒ Yes ☐ No</td></tr>
<tr><td colspan="2">PI/Supervisor Training:
☒ Yes ☐ No</td><td colspan="3">Handler Training:
☒ Yes ☐ No</td></tr>
<tr><td colspan="5">Discussion/Required Modifications:
Update bacteria list to indicate recombinant organisms.
Please clarify if information regarding Staphylococcus antibiotic resistance is a general statement, or specific to a certain organism being used.
Remove information not relevant to IBC review.
Administrative edits.</td></tr>
</table>

Motion Approval: Approved w/ Administrative Revisions	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 1

Basic Research Renewal # 5	**Protocol ID:** IBC 2126	**PI:** Karaayvas	**Biosafety Level:**	**NIH Cat.:**

			BSL2, ABSL2	III-D-1-a, III-D-3-a, III-D-4-b, III-E-1

Project Titles:
Identifying the Role of Fragile Site Instability in Inducing BRCA2 Haploinsufficiency, Leading to Novel Therapeutic Targets

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:
- Generation of replication defective lentiviral particles
- Transduction of tissue culture cells and administration *in vivo*
- Transfection of tissue culture cells
- Cholera Toxin in cell culture
- 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:
- Expand description and disposal of sharps in *in vivo* procedures.

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

b. Amendments:

Basic Research Amendment # 1	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	IBC 1518	Yuan	BSL1, ABSL1	III-D-4-a

Project Titles: *In vivo* retinal regeneration
Associated Grant Numbers: Non-NIH Funding
Summary of Approved Items: Transiently inhibition in *in vivo* eye model using synthetic oligo and electroporation.
Requested Additions/Changes: • Additional transgenic lines <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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Approved with no modifications

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

Basic Research Amendment # 2	Protocol ID:	PI:	Biosafety Level:	NIH Cat.:
	IBC 2023	Jung	BSL2, ABSL2	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, 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:

- Jamestown Canyon and Cache Valley viruses
- WT and recombinant human tissue culture cells
- Additional rooms and associated updates to safety information

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Approval contingent on confirmation whether permits are needed for the new viruses. If needed, relevant sections of application need to be completed.
- Reminder to lab: Please be sure that inactivation steps are performed prior to Core facilities receiving samples.
- Administrative edits

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

Basic Research Amendment # 3	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	IBC 2025	Jung	BSL2, ABSL2	III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-b

Project Titles:
Discovery of novel therapeutic strategies against airborne viruses

Associated Grant Numbers: Non-NIH Funding
Summary of Approved Items: Propagation of Influenza A virus (H1N1), Enterovirus, human Parainfluenza Virus 4a, Adenovirus 10, human Metapneumovirus, human Rhinovirus (HRV-16), Respiratory syncytial virus (RSV), non-recombinant and recombinant modified Measles Virus; Transduction of cells in culture, administration *in vivo*. Generation of replication deficient lentiviral particles and transduction of tissue culture cells; acquisition and generation of adeno-associated viral particles and administration *in vivo*; Human-derived materials
Requested Additions/Changes: • Recombinant attenuated Measles virus 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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:
- Approved with no modifications

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	8	0	0	1	0

Basic Research Amendment # 4	**Protocol ID:**	**PI:**	**Biosafety Level:**	**NIH Cat.:**
	IBC 2026	Jung	BSL2, ABSL2	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, R01AI152190, R01AI171201

Summary of Approved Items: Generation of replication defective adeno-associated viral particles, transduction of tissue culture cells, and administration *in vivo*. 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 *in vivo*. Acquisition of Parainfluenza Type III (PIV3), Human Metapneumonia (hMPV) virus. Administration of plasmid infected cells expressing HBV *in vivo*. Generation and administration of mRNA vaccine *in vivo*. Generation of protein vaccine and administration *in vivo*; Protozoan Leishmania tarentolae protein expression system; Non-K12 E. coli; Human-derived materials.	
Requested Additions/Changes: • Adeno-associated virus (AAV) packaging plasmids and replication deficient viral particles <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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No
Discussion/Required Modifications: • Update viral particles entry in excel to match description in the application	

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

Basic Research Amendment # 5	**Protocol ID:** IBC 2204	**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:

- *Fannyhessa, Atopobium, Bergeyella, Actinobacillus, Megasphaera, Aggregatibacter, Lactobacillus, Gemella, Neisseria, Corynebacterium, Lautropia, Selenomonas spp.*
- Bacterial expression plasmids and gene targets
- Acquisition and generation of recombinant human papilloma pseudo-viruses
- Mammalian expression plasmids
- Tissue culture co-infection studies.

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: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No

Discussion/Required Modifications:

- Administrative edits

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

Basic Research Amendment # 6	Protocol ID:	PI:	Biosafety Level:	NIH Cat.:
	IBC2502	Sharma	BSL2	III-D-1-a, III-D-2-a, III-E-1

Project Titles:
Role of RPA1 in telomere biology

Associated Grant Numbers:

K08 DK134873					
Summary of Approved Items: Acquisition of replication deficient lentiviral particles and transduction of tissue culture cells; Human derived materials					
Requested Additions/Changes: • Replication defective lentiviral particles • Mammalian expression plasmids • 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: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No				
PI/Supervisor Training: ☒ Yes ☐ No	**Handler Training:** ☒ Yes ☐ No				
Discussion/Required Modifications: • Approved with no modifications					
Motion Approval: **Approved**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Basic Research Amendment # 7	**Protocol ID:** 1202	**PI:** Stappenbeck	**Biosafety Level:** BSL1, BSL2, ABSL2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b
Project Titles: Molecular mechanism of IL-17 and IL-1 signaling				
Associated Grant Numbers: PO1CA272161				
Summary of Approved Items: Generation of replication defective lentiviral particles, transduction of cell lines. Human-derived material				

<table>
<tr><td colspan="6">Requested Additions/Changes:
• WT and recombinant mammalian tissue culture cell lines
• Gene targets
• Administration of tissue culture cells in vivo
• In vivo imaging studies
• Rooms
• Updates to safety information for in vivo experiments.

<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</td></tr>
<tr><td colspan="3">Risk Assessment Discussion:
☒ Yes ☐ No</td><td colspan="3">Facilities, Procedures, and Safety Practices Reviewed:
☒ Yes ☐ No</td></tr>
<tr><td colspan="3">PI/Supervisor Training:
☒ Yes ☐ No</td><td colspan="3">Handler Training:
☒ Yes ☐ No</td></tr>
<tr><td colspan="6">Discussion/Required Modifications:
• Administrative edits</td></tr>
<tr><td>Motion Approval:
Approved w/ Administrative Revisions</td><td>For:
9</td><td>Against:
0</td><td>Abstain:
0</td><td>Recuse:
0</td><td>Not Present:
0</td></tr>
</table>

V. Other Business

None