IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
Sept. 30th, 2026	Zoom

IBC Member Attendance:

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

Guests: Anthony Santilli, Anna Rietsch*, Jennifer Villette*, Nikki Meyer*, Nicholas Evans*, Anna Simko*, Dylan Champer**, Sara Tavakoli***

** Cleveland Clinic Main Campus*
*** Cleveland Clinic Florida Research & Innovation Center*

Call To Order:	**Adjourn:**
2:31 PM	3:45 PM

I. Review of Aug. 26th, 2026 Meeting Minutes

Committee Comments:
No modifications requested

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Not Present:**
Approved	6	0	0	1

II. Administrative Business

- **a.** Introduction of new Assistant Biosafety Officer
- **b.** Committee presented with Subcommittee Review items and personnel additions.
- **c.** Lab Audits: Members were presented with and informed of Annual Lab Audits and Preliminary Audits occurring during the month of September 2026.

III. Non-Clinical Research:

a. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 2225	**PI:** Smith	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-1-a

Project Title:
Atrial Fibrillation Post GWAS: Mechanisms to Treatment

Associated Grant Numbers:
P01HL158502

Protocol Summary:

- Acquisition of adeno-associated viral particles
- Transduction of tissue culture cells
- Human-derived material.

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☐ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	5	0	0	0	2

b. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC 1907	**PI:** Chakraborty	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Epigenetic Dysregulation to Identify Targetable Vulnerabilities in Cancer

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells and administration of transduced cells *in vivo*. Non-K-12 *E. coli*; Human-derived materials.

Requested Additions/Changes:

- Replication defective lentiviral particles
- gene targets and genes for editing
- CRISPR libraries
- Human cell lines

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Modified:
☐ 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 agent inventory to describe all genes modified in new cell lines and being expressed from new plasmids

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 5	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #2	**Protocol ID:** IBC 1612	**PI:** Maytin	**Biosafety Level:** BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Photodynamic therapy of model tumors *in vivo*; Photodynamic therapy and photoinduced skin cancer in murine models

Associated Grant Numbers:
P01 CA084203

Summary of Approved Items:
Administration of commercially available lentiviral transduced cells *in vivo*. Human-derived materials

Requested Additions/Changes:
- Experimental procedures
- Room additions

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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 missing *in vivo* procedures	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	5	0	0	0	2

Basic Research Amendment #3	**Protocol ID:** IBC 2309	**PI:** Cheng	**Biosafety Level:** BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a

Project Titles:
Molecular and Genetic Mechanisms of Neurodegenerative Disease Using Recombinant DNA, CRISPR-Based Gene Modulation, and Human Cell Models

Associated Grant Numbers:
R01AG082211, RF1NS133812

Summary of Approved Items:
Acquisition of replication defective lentivirus particles and Adeno-Associated Virus particles (AAV) and transduction of tissue culture cells; Administration of AAV *in vivo*

Requested Additions/Changes:

- Generation of replication defective lentiviral particles
- Mammalian expression plasmids
- Gene targets and genes for editing
- CRISPR libraries
- Experimental procedures
- Recombinant and non-recombinant human cell lines
- Room additions

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☒ Structural ☒ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☒ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Modified:
☐ 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:

- Indicate if any items are being sent off site for characterization
- Administrative updates and revisions

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
Approved w/ Administrative Revisions	6	0	0	0	1

Basic Research Amendment #4	Protocol ID:	PI:	Biosafety Level:	NIH Cat.:
	IBC 2022	Jung	BSL-2, ABSL-2	III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Structural analysis and therapeutic nanobody development of KSHV G-protein coupled receptor

Associated Grant Numbers:
R01CA251275, R01CA251275

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 *in vivo*; Processing of human blood positive for EBV and Cytomegalovirus (CMV), Non K-12 E. coli; Human-derived material

Requested Additions/Changes:

- Replication defective lentiviral particles
- Gene targets
- Recombinant human cell line

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Modified:
☐ 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: • No modifications requested					
Motion Approval: **Approved**	**For:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #5	**Protocol ID:** IBC 1924	**PI:** Arbesman	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Functional Characterization of Gene Variants in Melanoma

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:

- Generation of replication defective adeno-associated viral (AAV) particles
- Replication defective lentiviral particles
- Mammalian expression plasmids
- Gene targets

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☒ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:**☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications: • No modifications requested					
Motion Approval: **Approved**	**For:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #6	**Protocol ID:** IBC 2307	**PI:** Brown	**Biosafety Level:** BSL-1, ABSL-1, ABSL-2	**NIH Cat.:** III-D-4-a

Project Titles:
The Role of Gut Microbe-Derived Metabolites in Cardiometabolic Disease

Associated Grant Numbers:
R01HL179780

Summary of Approved Items:
Acquisition of replication defective adeno-associated virus particles, administration *in vivo*

Requested Additions/Changes:

- Genes for editing

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☒ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☐ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	6	0	0	0	1

Basic Research Amendment #7	**Protocol ID:** IBC 2121	**PI:** Silver	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-D-4-a, III-D-4-b

Project Titles:
Remodeling host immunity in oral cancer with personalized RNA nanoparticle vaccines

Associated Grant Numbers:
R37CA317177

Summary of Approved Items:
Propagation of recombinant and non-recombinant bacteria, infection of cell culture cells; administration of bacteria, infected tissue culture cells *in vivo*; Mammalian expression plasmids for generation of mRNA vaccines and administration *in vivo*; Generation of replication defective lentiviral particles, transduction of tissue culture, and administration *in vivo*; Cholera Toxin in cell culture; Human-derived materials

Requested Additions/Changes:

- Tissue culture cells
- Genes targets
- mRNA vaccine constructs

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism
☐ Other

Species of Recombinant Genes to be Modified:
☐ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	5	0	0	1	1

Basic Research Amendment #8	**Protocol ID:** 2601	**PI:** Rajappa	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Molecular and Genomic Analyses of Central Nervous System (CNS) Tumors

Associated Grant Numbers:
R01NS127984

Summary of Approved Items:
Generation of replication defective lentiviral particles, transduction of tissue culture cells, administration *in vivo*; Acquisition of transfected avian cells, administration *in vivo*; Human-derived materials

Requested Additions/Changes:
- New source of replication defective lentiviral particles
- Gene targets
- Human cell line

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism
☐ Other

Species of Recombinant Genes to be Modified:
☐ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	6	0	0	0	1

Basic Research Amendment #9	**Protocol ID:** 1407	**PI:** Byzova	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a

Project Titles:
Phosphorylation and activation of B3 integrins in angiogenesis

Associated Grant Numbers:
R01AG082382

Summary of Approved Items:
Acquisition of replication defective lentivirus particles, transduction of tissue culture cells

Requested Additions/Changes:
- Replication defective lentiviral particles
- Gene targets and genes for editing
- Human cell lines

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism
☒ Other

Species of Recombinant Genes to be Modified:
☐ 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:
- Add information all genes being expressed or modified

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
	6	0	0	0	1

Approved w/ Administrative Revisions					

Basic Research Amendment #10	**Protocol ID:** IBC 2053	**PI:** Chan	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Translational science specialist in genitourinary cancers

Associated Grant Numbers:
U54CA274513, R01HL164516, U54CA274513, R50CA293821, R35CA232097, R50CA251961

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles; transduction of tissue culture cells, and administration *in vivo*; acquisition of and adeno-associated viral (AAV) particles and transduction of tissue culture cells; administration of plasmid DNA via electroporation *in vivo*; generation and propagation of phage; administration of AAV and lentiviral particles *in vivo*; administration of wt bacteria *in vivo*; Generation and administration of mRNA & saRNA vaccines *in vivo*; generation of humanized *in vivo* model; Human-derived materials

Requested Additions/Changes:

- *Rothia* and *Campylobacter spp.*
- Tissue culture cell lines
- Room additions

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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:

- Add sources for new bacteria
- Add separate entries for each room and include all applicable information
- Update BSL for the indicate rooms
- Administrative updates and revisions

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
	5	0	0	1	1

Approved w/ Administrative Revisions					

Basic Research Amendment #11	**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
- Gene targets and genes for editing
- Experimental methods

Function/Nature of Recombinant Genes to be Modified:
☐ N/A ☒ Oncogene ☒ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other

Species of Recombinant Genes to be Modified:
☐ 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:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #12	**Protocol ID:** IBC 2608	**PI:** Fawzi	**Biosafety Level:** BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-a

Project Titles:
Exploring the angiogenesis-to-fibrosis transition in ischemic retinopathies

Associated Grant Numbers: R01EY030121
Summary of Approved Items: Acquisition of replication defective adeno-associated viral (AAV) particles and administration *in vivo*; transduction of tissue-culture cells; Human derived materials
Requested Additions/Changes: • Experimental procedures • Room additions Function/Nature of Recombinant Genes to be Modified: ☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other Species of Recombinant Genes to be Modified: ☒ 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: • Review edits for *in vivo* procedures • Confirm Core is aware of proposed procedures	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Contingency	6	0	0	0	1

c. Amendments Not Applicable to NIH Guidelines:

Basic Research Amendment #13	**Protocol ID:** IBC 2505	**PI:** Bukavina	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** N/A
Project Titles: Mouse Microbiome				
Associated Grant Numbers: Non-NIH Funding				
Summary of Approved Items: Acquisition and propagation of bacteria, acquisition of patient samples, administration *in vivo*; Human-derived materials				
Requested Additions/Changes: • New source of approved bacteria				

- Experimental procedures
- Human-derived material
- Room additions

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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:
- Identify location for indicated procedure
- Confirm Core is aware of proposed procedures or provide an alternative location

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Contingency	7	0	0	0	0

Basic Research Amendment #14	**Protocol ID:** IBC 1718	**PI:** Rieder	**Biosafety Level:** BSL1, BSL2	**NIH Cat.:** N/A

Project Titles:
The role of fungi in the pathogenesis of intestinal fibrosis

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of Candida albicans, culturing and co-culture with cells; Human-derived materials

Requested Additions/Changes:
- Patient derived tissue samples
- Fungal communities
- Experimental procedures
- Room additions

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:

☒ 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 reference to samples being screened • Add reference to working in a BSC for processing samples					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

IV. Clinical Research:

a. Applications:

Clinical Application #1	**Protocol ID:** Application 1	**PI:** Pasquini	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E
Project Title: A Phase III, Open-label, Multicentre, Randomised Study Comparing Consolidation Treatment with AZD0120, an Autologous Dual Targeting Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Autologous Stem Cell Transplant (ASCT) in Participants with Newly Diagnosed Multiple Myeloma who are Transplant Eligible (TE NDMM) (DURGA-6)				
Associated Grant Numbers: Non-NIH Funding				
Protocol Summary: • Administration of replication defective lentiviral transduced cells to humans <u>Function/Nature of Recombinant Genes to be Expressed:</u> ☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other <u>Species of Recombinant Genes to be Expressed:</u> ☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other				
Risk Assessment Discussion: ☒ Yes ☐ No		**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No		
PI/Supervisor Training (Y/N): ☒ Yes ☐ No		**Handler Training (Y/N):** ☒ Yes ☐ No		
Discussion/Required Modifications:				

• No modifications requested					
Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Clinical Application #2	**Protocol ID:** Application 2	**PI:** Caimi	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 1, Multicenter, Open-Label Study of Zolacabtagene Autoleucel (BMS986353), CD19-Targeted NEX-T CAR T Cells, in Participants with Ulcerative Colitis (UC) or Crohn's Disease (CD)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication defective lentiviral transduced cells to humans

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial
☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism
☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:**☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications requested

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

Clinical Application #3	**Protocol ID:** Application 3	**PI:** Raza	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Title:
A Randomized Phase 3 Study to evaluate the efficacy and safety of NXC-201 compared with Daratumumab with Cyclophosphamide, Bortezomib and Dexamethasone (CyBorD) in Newly Diagnosed Systemic AL Amyloidosis [NEXICART-3]

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication defective retroviral transduced cells to humans

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications requested

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	0	0

Clinical Application #4	**Protocol ID:** Application 4	**PI:** Sharma	**Biosafety Level:** BSL-1	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 1/2, study to evaluate the safety, tolerability, and efficacy of one-time intravitreal dose of SAR446597 in participants with geographic atrophy secondary to age-related macular degeneration

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication defective Adeno-Associated Virus (AAV) to humans

Function/Nature of Recombinant Genes to be Expressed:

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

Species of Recombinant Genes to be Expressed:

☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N):	**Handler Training (Y/N):**

☒ Yes ☐ No	☒ Yes ☐ No
Discussion/Required Modifications: • Indicate sharps disposal location	

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

Clinical Application #5	**Protocol ID:** Application 5	**PI:** Hatipoglu	**Biosafety Level:** BSL-1	**NIH Cat.:** III-C-1, III-E

Project Title:
A Phase 1/2 Dose-Exploration and Dose-Expansion Study to Evaluate the Safety and Efficacy of BEAM-302 in Adult Patients with Alpha-1 Antitrypsin Deficiency (AATD)-Associated Lung Disease and/or Liver Disease

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of lipid nanoparticles containing gRNA and mRNA to humans

Function/Nature of Recombinant Genes to be Expressed:
☐ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Expressed:
☐ N/A ☒ Human ☐ Murine ☐ Bacterial ☐ Viral ☐ Other

Risk Assessment Discussion: ☒ Yes ☐ No	**Facilities, Procedures, and Safety Practices Reviewed:** ☒ Yes ☐ No
PI/Supervisor Training (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No
Discussion/Required Modifications: • No modifications requested	

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	0	0

b. Amendments:

Clinical Amendment #1	**Protocol ID:** CTIBC 073	**PI:** Brunstein	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Titles:

A Phase 1, Open-label Study to Evaluate the Safety and Clinical Activity of Azercabtagene Zapreleucel in Participants with B-cell Mediated Autoimmune Disorders

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Administration of ARCUS nuclease edited and adeno-associated virus (AAV) transduced cells to humans.

Requested Additions/Changes:

- Administrative and editorial changes
- Updated dosing levels
- Updates to inclusion and exclusion criteria

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	0	0

Clinical Amendment #2	**Protocol ID:** CTIBC 100	**PI:** Brunstein	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Titles:
A Phase 1/2a, Open-Label, Dose-Escalation Study to Evaluate the Safety and Preliminary Efficacy of TRX319 in Subjects with Primary or Secondary Progressive Multiple Sclerosis

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Administration of replication defective lentiviral transduced cells to humans

Requested Additions/Changes:

- Room addition

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	7	0	0	0	0

Clinical Amendment #3	**Protocol ID:** CTIBC 056	**PI:** Raza	**Biosafety Level:** BSL-2	**NIH Cat.:** III-C-1, III-E

Project Titles:
Phase 1b/2 Study of NXC-201 for the Treatment of Patients with Relapsed or Refractory AL Amyloidosis [NEXICART-2]

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Administration of replication defective retroviral transduced cells to humans

Requested Additions/Changes:
- Updated procedures

Function/Nature of Recombinant Genes to be Modified:
☒ N/A ☐ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☐ Immunomodulatory ☐ Toxin ☐ Antibiotic Resistance ☐ Reporters ☐ Cell Metabolism ☐ Other

Species of Recombinant Genes to be Modified:
☒ 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:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

V. Other Business

None