IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
April 29th, 2026	Online

IBC Member Attendance:

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

Guests: Anthony Santilli, Jennifer Veillette*, Nikki Meyer*, Anna Rietsch*, Anna Simko*, Sara Tavakoli**, Molly Urban****

** Cleveland Clinic*
*** Cleveland Clinic Florida Research and Innovation Center*
**** Community Member*

Call To Order:	**Adjourn:**
2:36 PM	4:29 PM

I. Review of March 25th, 2025 Meeting Minutes

Committee Comments:
None

Motion Approval:	**For:**	**Against:**	**Abstain:**
Approved	5	0	3

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 April 2026.
- **c.** Committee was informed of additional IBC meeting to be held in May.
- **d.** Updated forms for New Protocols/Renewals and Amendments were presented to committee members for review.

III. Non-Clinical Research:

- **a. Renewals:**

Basic Research Renewal #1	Protocol ID: IBC 1419	PI: Tam	Biosafety Level: BSL-1, BSL-2, ABSL-1, ABSL-2	NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-a, III-D-4-b, III-E-1

Project Title:
Ocular Inflammation, Immunity and Homeostasis

Associated Grant Numbers:
Non-NIH funding

Protocol Summary:

- Generation of recombinant bacteria and fungi
- Propagation of recombinant and non-recombinant bacteria and fungi for infection of tissue culture cells and administration *in vivo*
- Antimicrobial resistance development assay
- Generation of replication defective lentiviral and adenoviral particles for transduction of tissue culture cells
- Administration of adenoviral particles *in vivo*
- Acquisition of replication defective adeno-associated viral particles and administration *in vivo*
- Non-K-12 *E.coli*
- Human-derived material

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:

- Update RG of indicated agents in inventory
- Condense Biological Containment section to focus on relevant items
- Add statement that signage will be in place during incubation steps
- Review efficacy and contact time of disinfectants for agents used with *in vivo* experiments
- Minor administrative updates and revisions

Motion Approval:	For:	Against:	Abstain:	Recuse:	Not Present:
	8	0	0	0	0

Approve w/ Administrative Revisions					

Basic Research Renewal #2	**Protocol ID:** IBC 1819	**PI:** Davalos	**Biosafety Level:** BSL-1, ABSL-1, ABSL-2	**NIH Cat.:** III-D-4-a

Project Title:
Neuroimmune regulation of central nervous system function in physiology and disease

Associated Grant Numbers:
P50AA024333

Protocol Summary:

- Acquisition of replication defective adeno-associated viral particles and administration *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:

- Add suggested locations for *in vivo* experiments
- Clarify perfusion methods
- Minor administrative updates and revisions

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

Basic Research Renewal #3	**Protocol ID:** IBC 1425	**PI:** Stappenbeck	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-4-b

Project Title:
The relationship between immune dysregulation and autoimmune diseases

Associated Grant Numbers:

Non-NIH Funding

Protocol Summary:

- Generation of recombinant bacteria
- Propagation of recombinant and non-recombinant bacteria for administration *in vivo* and infection of tissue culture cells
- human-derived material

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:

- Clarify use of BSL1 agents inside a BSC
- Remove references to agents that are no longer used on the protocol
- Describe disinfection of stool collection beaker
- Clarify locations for ABSL-2 experiments
- Minor Administrative updates and revisions

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

Basic Research Renewal #4	**Protocol ID:** Lin	**PI:** IBC 1424	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-4-a, III-D-4-b, III-E-1

Project Title:
CD6 and CDCP1 in autoimmune diseases and cancer

Associated Grant Numbers:
R01EY025373

Protocol Summary:

- Acquisition of replication defective lentiviral particles and transduction of tissue culture cells

- Acquisition of replication defective adeno-associated viral particles and administration *in vivo*
- Bacterial expression plasmids and phage for nanobody generation
- Non-K-12 *E.coli*
- Human-derived material

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:

- Approval contingent on PI clarifying following aspects of nanobody-toxin fusion protein production:
  - How portion of toxin expressed differs from full protein
  - Agent toxicity, stability, and targets
  - Symptoms of exposure
  - Work moved to suggested BSL2 space or other similar location
  - Lysate handling and disinfection
- Clarify signage placement and removal for *in vivo* experiments
- Add statement that syringe flush will be disinfected with 15% v/v bleach for a 30 min contact time
- Please replace Solucide with an approved disinfectant
- Minor administrative updates and revisions

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

b. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC 2117	**PI:** Anand-Apte	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
FGF and hyaluronan-mediated alterations in epithelial-mesenchymal transition and metabolism of RPE cells in Sorsby Fundus Dystrophy

Associated Grant Numbers:
R01EY027083

Summary of Approved Items:
Generation of replication deficient lentiviral and adeno-associated viral (AAV) particles and transduction of tissue culture cells; administration of lentiviral and AAV particles *in vivo*; 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 (Y/N): ☒ Yes ☐ No	**Handler Training (Y/N):** ☒ Yes ☐ No

Discussion/Required Modifications:

- No modifications required

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

Basic Research Amendment #2	**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 *in vivo*; Acquisition of non-recombinant bacteria and generation of recombinant bacteria and co-culture with cells; Human-derived material.

Requested Additions/Changes:

- Replication defective lentiviral particles
- Gene targets
- 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:

- Update oncogene classification for indicated gene
- Minor administrative updates and revisions

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

Basic Research Amendment #3	**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:

- New administration route and 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:
- Add location for updated for *in vitro* experiments
- Add a stament regarding sharps safety for new model

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

Basic Research Amendment #4	**Protocol ID:** IBC 1510	**PI:** Heemers	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
RhoA signaling axis as a novel target for the treatment of prostate cancer

Associated Grant Numbers:
R01CA166440, R01CA248048

Summary of Approved Items:
Generation of replication defective lentiviral particles, transduction of tissue culture cells, and administration of transduced cells *in vivo*; Administration of plasmid transfected cells *in vivo*; Human-derived material.

Requested Additions/Changes:
- Replication defective lentiviral particles
- Gene targets
- Human 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:
- No modifications requested

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

Basic Research Amendment #5	**Protocol ID:** IBC 1710	**PI:** Dana	**Biosafety Level:** BSL-1, BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-a

Project Titles:
Functional mapping of neuronal circuit activity in the rodent 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 particles
- Gene targets
- Updated *in vivo* procedures
- New locations

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:** 1

Basic Research Amendment #6	**Protocol ID:** IBC 1531	**PI:** DiDonato	**Biosafety Level:** BSL-2, ABSL-1, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-4-a

Project Titles:
Altering Gut Flora to Influence Pro-thrombotic and Atherosclerotic phenotypes

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Acquisition of Adeno-Associated Virus (AAV), transfection of tissue culture cells, administration of AAV *in vivo*; human-derived material

Requested Additions/Changes:

- Replication defective adeno-associated viral particles
- Gene target
- *In vivo* administration route

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:** 6	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 0

Basic Research Amendment #7	**Protocol ID:** IBC 2509	**PI:** Dhawan	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-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:
- New location

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 modification requested

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #8	**Protocol ID:** IBC 2124	**PI:** Chen	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Titles:
Melanoma Signaling Pathways

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:

- Replication defective lentiviral particles
- Mammalian expression plasmids for transfection of tissue culture cells and administration *in vivo*
- Gene targets and 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:

- No modifications requested

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #9	**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 lentivirus and retrovirus, 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
- Human 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:

- No modifications requested

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #10	**Protocol ID:** IBC 2513	**PI:** Tiek	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Targeting ferroptosis in glioma

Associated Grant Numbers:
K99/R00 4R00CA279896-03

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

Requested Additions/Changes:

- New Location

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:
- Clarify equipment being used in new location

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

Basic Research Amendment #11	**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:
Non-NIH Funding

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*; Cholera Toxin in cell culture; Human-derived materials

Requested Additions/Changes:
- Generation of replication defective lentiviral particles
- Transduction of tissue culture cells
- Human cell line
- Mammalian expression plasmids
- Gene targets and genes for editing
- New locations

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:

- Add location for incubators, viral titer assays, and flow cytometer
- Include core facilities that might be used for viral titers, and if samples given are live or inactivated
- Clarify *in vivo* vs *in vitro* use for new items
- Clarify use and disinfection of equipment used in viral titration

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

Basic Research Amendment #12	**Protocol ID:** IBC 1209	**PI:** Perkins	**Biosafety Level:** BSL-1, ABSL-1, ABSL-2	**NIH Cat.:** III-D-4-a, III-D-4-b

Project Titles:
Retina Regeneration in *in vivo* Models of Inherited Blindness

Associated Grant Numbers:
R01EY030574, R01EY034755, R01EY034493, P30EY025585

Summary of Approved Items:
Generation and breading of transgenic *in vivo* model; rDNA modification of tissue culture cells; human-derived materials

Requested Additions/Changes:

- New *in vivo* 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:
- No modifications requested

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Amendment #13	**Protocol ID:** IBC 1001	**PI:** Suh	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Brain-wise mapping of the hippocampal synaptic connections and neural circuits

Associated Grant Numbers:
R01AA27766, R01AA031028

Summary of Approved Items:
Generation of replication incompetent retroviral particles, lentiviral particles, rabies viral particles, and adeno-associated viral particles; administration of viral particles *in vivo*; administration of lentiviral transduced cells *in vivo*; human-derived materials

Requested Additions/Changes:
- Acquisition and *in vivo* administration of mouse α-Syn pre-formed fibrils
- New locations

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: • Update *in vivo* disinfection steps to include or clarify the use of 1% SDS					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

b. Amendments: Not Applicable to NIH Guidelines

Basic Research Amendment #14	**Protocol ID:** IBC 1309	**PI:** Lin	**Biosafety Level:** BSL-2	**NIH Cat.:** N/A
Project Titles: CD6 autoimmune disease models				
Associated Grant Numbers: R01AR061564, R01DK10358, R01EY025373				
Summary of Approved Items: Administration of Pertussis and Diphtheria toxin *in vivo*				
Requested Additions/Changes: • *C. difficile* toxins A and B for use in *in-vitro* • Human cell lines • Room renumbering updates <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: • Confirm room locations • Please reference/refer to SOPs for indicated safety descriptions • Please conduct work with toxin within a BSC in indicated location • Clarify if cultures containing toxin will be incubated within the BSC or elsewhere • Minor administrative updates and revisions				

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

IV. Clinical Research:

a. Applications:

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

Project Title:
A Phase 1b, Open-label, Multi-center, Randomized Study Evaluating the Safety and Tolerability of AZD0120, an Autologous CD19/BCMA Targeting Chimeric Antigen Receptor T-cells, in Adults with Refractory Relapsing or Progressing Multiple Sclerosis

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:** 1

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

Project Title:
Phase III Open-label, Randomized, Multicenter Study Comparing AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, versus Standard Regimens in Participants with Relapsed Refractory Multiple Myeloma (DURGA-4)

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: 1

b. Amendments:

Clinical Amendment #1	Protocol ID: CTIBC 074	PI: Isaacs	Biosafety Level: BSL-2	NIH Cat.: III-C-1, III-E

Project Titles:
A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)

Associated Grant Numbers:
Non-NIH Funding

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

Requested Additions/Changes:

- New replication defective lentiviral vector

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:** 1

V. Other Business

None