IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
February 25th, 2026	Zoom

IBC Member Attendance:

☒ Ahern, Philip	☐ DiDonato, Joseph	☒ Dragan, Amanda (BSO)
☒ 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*, Jennifer Veillette*, Nikki Meyer*, Abby Bifano*, Anna Simko*, Sara Tavakoli**, Dylan Champer***

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

Call To Order:	**Adjourn:**
2:31 PM	3:48 PM

I. Review of Jan. 28th, 2026 Meeting Minutes

Committee Comments:
None

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Not Present:**
Approved	7	0	0	2

II. Administrative Business

a. Committee presented with Expedited 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 Feb. 2026. No major deficiencies were identified.

III. Clinical Research:

a. Applications:

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

			BSL-2	

Project Title:
A 26-Week (with 26 Week Extension) Randomized, Multi-Center, Double-Blind Phase 2 Study to Evaluate the Efficacy and Safety of XC001 Gene Therapy as an Adjunct to Coronary Artery Bypass Graft Surgery for Patients with Symptomatic Coronary Artery Disease with Left Ventricular Dysfunction at Risk for Incomplete Revascularization

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication-deficient adenovirus 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:

- None

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

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

Project Title:
A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication-competent adenovirus 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:
- None

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

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

Project Title:
A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous Dual-Targeting CD19/CD20 CAR T-Cell Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (PiNACLE-H2H)

Associated Grant Numbers:
Non-HIN 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: • None	

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

IV. Non-Clinical Research:

a. Renewals:

Basic Research Renewal #1	**Protocol ID:** 2204	**PI:** McGrail	**Biosafety Level:** BSL-1, BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Title:
Investigation of disease mechanisms and therapeutic approaches

Associated Grant Numbers:
R37CA295609, R00CA240689

Protocol Summary:

- Generation of replication defective lentiviral and retroviral particles
- Transduction and transfection of tissue culture cells
- Administration of transfected and transduced cells *in vivo*
- Acquisition of recombinant *Escherichia*, and *Fusobacterium spp*. and non-recombinant *Actinobacillus, Actinomyces, Aggregatibacter, Atopobium, Bergeyella, Campylobacter, Capnocytophaga, Corynebacterium, Eubacterium, Fannyhessa, Filifactor, Fusobacterium, Gardnerella, Gemella, Haemophilus, Lacticaseibacillus, Lactiplantibacillus, Lactobacillus, Lautropia, Leptotrichia, Megashpera, Neisseria, Parvimonas, Peptostreptococcus, Porphyromonas, Prevotella, Rothia, Ruminococcus, Selenomonas, Streptococcus, Treponema, Veillonella*, and *Xylanibacter spp.*
- Generation of recombinant bacteria co-culture with cells
- Generation of non-infectious pseudo-viral particles
- 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 species of cells given *in vivo* and update ABSL as needed • Clarify vectors used for oncogenes and tumor suppressor genes • Indicate the Bleach will not be used in conjunction with H_2O_2 based disinfectants • Indicate the use of biocontainment lids or safety buckets for centrifuge.					
Motion Approval: Approved w/ Administrative Revisions	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 0

Basic Research Renewal #2	**Protocol ID:** 1815	**PI:** Matsuoka	**Biosafety Level:** BSL-1, ABSL-1	**NIH Cat.:** III-D-4-a

Project Title:
Vascular and lymphatic morphogenesis around the developing central nervous system

Associated Grant Numbers:
R01 NS117510

Protocol Summary:

- Injection of synthesized mRNA, plasmid DNA, CRISPR RNA/Cas9 complexes, or morpholino antisense oligos (ASOs) *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:

- None

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

b. Amendments:

Basic Research Amendment #1	Protocol ID: 1602	PI: Tam	Biosafety Level: BSL-2	NIH Cat.: III-D-1-a, III-D-3-a

Project Titles:
Cytoskeletal Keratins in Corneal Immunity and Homeostasis

Associated Grant Numbers:
R01 EY030577

Summary of Approved Items:
Generation of replication defective lentivirus particles, transduction of tissue culture cells. Reprogramming of iPSCs into oligodendrocytes for transduction; Human-derived materials.

Requested Additions/Changes:

- Replication defective lentiviral particles
- Packaging plasmids
- Genes for editing and gene targets
- Updated 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:	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 bleach concentration and contact time for disinfection

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

Basic Research Amendment #2	Protocol ID: 1603	PI: Tam	Biosafety Level: BSL-2, ABSL-2	NIH Cat.: III-D-1-a, III-D-4-b

Project Titles:
Cytoskeletal Keratins in Corneal Immunity and Homeostasis; Corneal Immunity and Homeostasis

Associated Grant Numbers:
R01 EY030577

Summary of Approved Items:
Propagation of recombinant and non-recombinant Herpes Simplex Virus subtype 1 (HSV-1) and transduction of tissue culture cells; and administration of HSV-1 *in vivo*; Human-derived material.

Requested Additions/Changes:

- Recombinant modified 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 bleach concentration and contact time for disinfection
- Administrative edits

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

Basic Research Amendment #3	Protocol ID: 2501	PI: Williams	Biosafety Level: BSL-1, ABSL-1, ABSL-2	NIH Cat.: III-D-4-a

Project Titles:

Modulation of inflammation by central nervous system glia; The impact of astrocytic neuroinflammatory changes on cognition

Associated Grant Numbers:
K00 NS120365, R01 NS119178

Summary of Approved Items:
Acquisition of replication deficient adeno-associated (AAV) viral particles and administration *in vivo*.

Requested Additions/Changes:

- Replication defective adeno-associated viral particles
- Gene targets
- New *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:

- None

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

Basic Research Amendment #4	**Protocol ID:** 2312	**PI:** Stolley	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b

Project Titles:
Resident memory T cell immunosurveillance of the oral mucosa and periodontium

Associated Grant Numbers:
R00DE031014

Summary of Approved Items:

Propagation of non-recombinant and recombinant modified Vesicular Stomatitis Virus (VSV) Indiana Serotype, administration *in vivo*; Acquisition of bacteria community (human dental plaques), generation of heat killed bacteria and administration *in vivo*; Acquisition of saporin toxin and administration *in vivo*.

Requested Additions/Changes:

- Recombinant Vesicular Stomatitis Virus
- Updated experimental procedures
- Use of core facility

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:

- Complete sections related to imports and permits
- Add description for updated *in vivo* procedures

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #5	**Protocol ID:** 2108	**PI:** Dasarathy	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-2-a, III-D-3-a, III-E

Project Titles:
Genome wide CRISPR-Cas9 library Screening to Identify Genetic Changes in Response to Hyperammonemia

Associated Grant Numbers:
R01 DK133905, R01 DK113196, K08 AA028794

Summary of Approved Items:
Generation of replication defective lentiviral particles, transduction of tissue culture cells; plasmid transfection of tissue culture cells; Human-derived materials.

Requested Additions/Changes:

- Replication defective adeno-associated viral particles
- 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:
- None

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #6	**Protocol ID:** 2210	**PI:** Melenhorst	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-b, III-D-4-b

Project Titles:
In vitro testing of gene-modified T cells 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:
- Replication defective lentiviral particles
- Recombinant and non-recombinant tissue culture cells
- 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:
- None

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

Basic Research Amendment #7	**Protocol ID:** 1203	**PI:** Lathia	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Targeting mechanisms that maintain glioblastoma stem cells

Associated Grant Numbers:
R01 CA184090, P30 CA043703, R01 NS109742, R01 NS089641, R01 NS096376, R01 NS117104

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

Requested Additions/Changes:
- 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 usage in new space.
- Administrative edits

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	7	0	0	0	2

Basic Research Amendment #8	**Protocol ID:** 2101	**PI:** Wu	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-b, III-D-4-b

Project Titles:
Modeling liver diseases using a human pluripotent stem cell derived-multicellular platform

Associated Grant Numbers:
Non-NIH Funding

Summary of Approved Items:
Generation of adeno-associated virus (AAV) and administration *in vivo*; Generation of replication defective lentivirus particles, propagation of recombinant modified Hepatitis B Virus, Hepatitis C Virus and Hepatitis E Virus and transduction of tissue culture cells, co-infection of viruses *in-vitro*; Acquisition of Norwegian Rat Hepatitis Virus and administration *in vivo*; Human-derived materials.

Requested Additions/Changes:

- Transgenic *in vivo* model expressing full genome of HBV
- Updated experimental 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:

- Complete sections for Imports and Permits
- Update section for equipment disinfection to include new items
- Remove locations not approved for this *in vivo* work
- Update sharps usage and description of secondary containment to match SOPs
- Administrative edits

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	7	0	0	0	2

Basic Research Amendment #9	**Protocol ID:** 1927	**PI:** Vargas	**Biosafety Level:** BSL-2	**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:

- Replication defective lentiviral vector particles
- 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: • None					
Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

c. Amendments Not Applicable to NIH Guidelines:

Basic Research Amendment #10	**Protocol ID:** 2228	**PI:** Lin	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** N/A
Project Titles: Mechanisms of autoimmune uveitis *in vivo*				
Associated Grant Numbers: R01 EY032882				
Summary of Approved Items: Administration of pertussis toxin *in vivo*				
Requested Additions/Changes: • New location • Updated 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: • Administrative edits				
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 2

V. New SOPs:

SOP a: Pertussis Toxin – Safe Use	**Comments:** None				
Motion Approval: Approved	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

SOP b: Cholera Toxin – Safe Use	**Comments:** None				
Motion Approval: Approved	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

SOP c: Diphtheria Toxin – Safe Use	**Comments:** • **Refer to PI's related IBC for work in specified locations**				
Motion Approval: Approved	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

SOP d: Tetrodotoxin – Safe Use	**Comments:** None				
Motion Approval: Approved	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 0

VI. Other Business

None