IBC Meeting Minutes
Cleveland Clinic Main Campus

Date:	**Location:**
November 19, 2025	Zoom

IBC Member Attendance:

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

Guests: Anthony Santilli, Abby Bifano*, Anna Rietsch*, Nikki Meyer*, Dylan Champer**, Sara Tavakoli***

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

Call To Order:	**Adjourn:**
2:30 PM	3:58 PM

I. Review of October 29th, 2025 Meeting Minutes

Committee Comments:
No Comments

Motion Approval:	**For:**	**Against:**	**Abstain:**
Approved	8	0	1

II. Administrative Business

- **a.** Committee presented with Expedited Review items and personnel additions.
- **b.** IBC Members were updated on the status of and IBC protocol probationary period.
- **c.** IBC Members were presented with an incident involving improper PPE donning.
- **d.** Lab Audits: Members were informed of Annual Lab Audits and Preliminary Audits occurring during the month of November 2025. No major deficiencies were identified.

III. Clinical Research:

a. Applications:

Clinical Application #1	**Protocol ID:** Application #1	**PI:** Torres-Trejo	**Biosafety Level:**	**NIH Cat.:** III-C-1

			BSL-2	

Project Title: Open-Label, Single-Arm Phase 2 Study of Nogapendekin Alfa Inbakicept, PD-L1 t-haNK, Bevacizumab and Randomized Phase 2B Study of Nogapendekin Alfa Inbakicept, Bevacizumab, and Tumor Treatment Fields With or Without PD-L1 t-haNK in Participants With Recurrent or Progressive Glioblastoma

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of plasmid transfected 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:	**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:

- Approved with no modifications

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved	9	0	0	0	1

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

Project Title: A Phase 1/2, First-in-Human Study of VNX-202 Gene Therapy in Patients with HER2-Positive Cancer

Associated Grant Numbers:
Non-NIH Funding

Protocol Summary:

- Administration of replication-incompetent, adeno-associated viral vector 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: • Minor administrative edits					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

IV. Non-Clinical Research:

a. Renewals:

Basic Research Renewal #1	**Protocol ID:** IBC 1810	**PI:** Clasen	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b
Project Title: Identification and in vitro & in vivo characterization of bacterial biosynthetic gene clusters				
Associated Grant Numbers: R01AI153173				
Protocol Summary: • Acquisition of various human and rodent-derived material, microbial isolates • Generation and culturing of recombinant *Citrobacter, Clostridium, Esherichia, Lactobacillus,* and *Staphylococcus spp.* and non-recombinant *Acidaminococcus, Acutalibacter, Akkermansia, Aldercreutza, Alistipes, ASF, Anaerobutyricum, Anaerococcus, Anaerofustis, Anaerostipes, Anaerotruncus, Bacteroides, Bifidobacterium, Blautia, Bilophilia, Burkholderiales, Butryicimonas, Butyrivibro, Catenibacterium, Cellulosimicrobium, Citrobacter, Clostridium, Collinsella, Coprococcus, Corynebacterium, Desulfovibrio, Dietzia, Dorea, Eggerthella, Enterococcus, Escherichia, Ethanoligenens, Eubacterium, Faecalibacterium, Flavinofracter, Fusobacteria, Gordonia, Granulicatella, Holdemania, Hungatella, Intestinibacter, Intestinimonas, Kocuria, Lachnospiraceae, Lactobacillus, Lactococcus, Marvinbryantia, Megasphaera, Microbacterium, Mitsuokella, Muribaculum, Odoribacter, Olsenella, Oscillibacter, Pantoea, Parabacteroides, Peptostreptococcaceae, Prevotella, Propionibacterium, Proteus, Pseudomonas, Roseburia, Ruminococcus, Serratia, Slackia, Solobacterium, Staphylococcus, Stenontrophomonas Streptococcus, Streptomyces, Subdoligranulum, Turicibacter,* and *Turicimonas spp.* • Co-culture of recombinant and non-recombinant bacteria in tissue culture cells				

- Administration of agents *in-vivo*
- 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 agent description for *Clostridium spp.*
- Include a statement for *C. difficile* in "Special Hazards" section.
- Update disinfectant list
- Clarify waste disposal for *in vivo* experiments
- Clarify sample processing and inactivation steps
- Minor administrative edits

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

Basic Research Renewal #2	**Protocol ID:** IBC 1410	**PI:** Zhang	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-a

Project Title:
Mechanism of secretory defects in human diseases

Associated Grant Numbers:
HL169427

Protocol Summary:
- Generation of replication defective lentiviral and retroviral particles and transduction of tissue culture cells
- Acquisition of Adeno-Associated Virus (AAV) and administration *in vivo* Administration of plasmid DNA *in vivo*
- K12 *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:

- Indicate replication competency will be assessed whenever new viral stocks are generated.
- Include an additional replication competency test
- Minor administrative edits

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	9	0	0	0	1

Basic Research Renewal #3	**Protocol ID:** IBC 1803	**PI:** Maciejewski	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a

Project Title:
Roles of bone marrow failure genes in hematologic malignancies

Associated Grant Numbers:
R01CA257544

Protocol Summary:

- Generation of replication-defective lentiviral particles and transduction 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):	**Handler Training (Y/N):**

☒ Yes ☐ No	☒ Yes ☐ No

Discussion/Required Modifications:

- Confirm all plasmids are listed in inventory
- Clarify which genes will be overexpressed
- Update centrifuge procedures to include use of biocontainment covers and that buckets will be loaded and unloaded within BSC
- Clarify what type of tubes will be used for centrifugation
- Add a statement that core personnel will be made aware if they are processing unfixed samples and be provided with relevant safety information.
- Minor administrative edits

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	9	0	0	0	1

Basic Research Renewal #4	**Protocol ID:** IBC 1909	**PI:** Wang	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b

Project Title:
Novel immuno-prevention strategies for controlling lung cancer and pancreatic cancer

Associated Grant Numbers:
R01CA278633, R21CA286304, R01CA297621

Protocol Summary:

- Generation of replication-defective lentiviral and retroviral particles, transduction of tissue culture cells, plasmid transfection of tissue culture cells, and administration of cells to animals; Propagation of recombinant modified *Listeria monocytogenes* and administration to mice; 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:	**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 room location for indicated equipment
- Update disinfectant list

• Suggestion to add additional *in vivo* equipment if needed • Minor administrative edits					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 8	**Against:** 0	**Abstain:** 0	**Recuse:** 1	**Not Present:** 1

Basic Research Renewal #5	**Protocol ID:** IBC 1801	**PI:** Ivanov	**Biosafety Level:** BSL-1, BSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-E

Project Title:
Regulation of the intestinal epithelial barrier during mucosal inflammation

Associated Grant Numbers:
R01DK132038, R01DK137822

Protocol Summary:

- Generation of replication defective lentiviral and retroviral particles
- Transduction of tissue culture cells
- *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:

- Minor administrative edits

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 9	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 1

Basic Research Renewal #6	**Protocol ID:** IBC 1413	**PI:** Bonilha	**Biosafety Level:** BSL-2	**NIH Cat.:** III-D-1-a

Project Title:

Transduction of cell cultures with replication-deficient adenoviruses for the study of eye diseases
Associated Grant Numbers: Non-NIH Funding
Protocol Summary: • Acquisition of replication defective AAV and adenoviral particles • K12 *E. coli* • Transduction of tissue culture cells Function/Nature of Recombinant Genes to be Expressed: ☐ N/A ☒ Oncogene ☐ Tumor Suppressor Gene ☐ Structural ☐ Signaling ☐ Antimicrobial ☒ Immunomodulatory ☐ Toxin ☒ Antibiotic Resistance ☒ Reporters ☐ Cell Metabolism ☒ Other Species of Recombinant Genes to be Expressed: ☐ N/A ☒ Human ☒ Murine ☐ Bacterial ☐ Viral ☒ Other

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

Motion Approval:	**For:**	**Against:**	**Abstain:**	**Recuse:**	**Not Present:**
Approved w/ Administrative Revisions	7	0	0	0	3

b. Amendments:

Basic Research Amendment #1	**Protocol ID:** IBC 2312	**PI:** Stolley	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-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 to mice; Acquisition of saporin toxin and administration *in vivo*.				
Requested Additions/Changes: • Acquisition of bacteria community from human dental plaques • Generation of heat killed bacteria				

- Administration *in vivo*
- New rooms

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

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

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

Discussion/Required Modifications:

- Please update "New Hazards" and "Special Hazards" sections to reflect use on new BSL-2 agents
- Clarify equipment used for sample processing
- For new *in vivo* procedures
    - Add statement detailing required signage while procedures are being performed
    - Clarify sharps usage for sample collection
    - Clarify sample processing and inactivation steps
    - If unfixed samples may be given to core personnel, add a statement that core personnel will be made aware if they are processing unfixed samples and be provided with relevant safety information
    - Clarify disinfection steps for equipment
    - Describe how space will be disinfected at conclusion of procedure.

Motion Approval: Approved w/ Contingency	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 3

Basic Research Amendment #2	**Protocol ID:** IBC 2410	**PI:** Cameron	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-4-b, III-E, III-E-1

Project Titles:
Exploring the cellular, molecular, and transcriptional effects of cyclic adenosine monophosphate signaling in reactive astrocytes

Associated Grant Numbers:
N/A

Summary of Approved Items:

Acquisition of Adeno-Associated Virus (AAV) particles, transduction of tissue culture cells, administration of AAV particles *in vivo*; Transfection of tissue culture cells; Human-derived materials.

Requested Additions/Changes:

- 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:

- Approved with no modifications

Motion Approval: **Approved**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 3

Basic Research Amendment #3	**Protocol ID:** IBC 1926	**PI:** Stappenbeck	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-b

Project Titles:

Microbes in the gut and control of Inflammatory Bowel Disease

Associated Grant Numbers:

Non-NIH Funding

Summary of Approved Items:

Isolation and growth of wt and recombinant bacterial strains, co-culture with tissue culture cells; administration of bacteria *in vivo*, treatment of tissue culture cells with bacterial isolate; Acquisition of cholera, diphtheria and Clostridium Difficile A & B toxin and administration *in vivo*; Human-derived materials.

Requested Additions/Changes:

- Recombinant *E. coli* and non-recombinant *E. coli* and *T. bilis.*
- Update to procedures
- New source for accusation of human fecal matter

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:

- Confirm whether a BSC or anaerobic chamber is being used for updated procedures, and update PPE accordingly.

Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 3

Basic Research Amendment #4	**Protocol ID:** IBC 2110	**PI:** Wu	**Biosafety Level:** BSL-2, ABSL-2	**NIH Cat.:** III-D-1-a, III-D-3-a, III-D-4-b, III-E

Project Titles:
Innate immune response in infection, autoimmune disease and cancer

Associated Grant Numbers:
R37CA288747, Non-NIH Funding

Summary of Approved Items:
Generation of replication defective lentiviral and retroviral particles, transduction of tissue culture cells, administration of transduced cells *in vivo*; Generation of adeno-associated viral particles (AAV), transduction of tissue culture cells and administration of AAV *in vivo*; Propagation of Herpes simplex virus 1, Vesicular stomatitis virus, Dengue virus 2, Zika virus, and recombinant Vaccinia virus and Sindbis virus; transduction of tissue culture cells; Administration of Herpes simplex virus 1 and Vesicular stomatitis virus *in vivo*; Plasmid transfection of tissue culture cells and administration of transfected cells *in vivo*; Human-derived materials.

Requested Additions/Changes:

- 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: • Clarify method for gene modification/editing					
Motion Approval: **Approved w/ Administrative Revisions**	**For:** 7	**Against:** 0	**Abstain:** 0	**Recuse:** 0	**Not Present:** 3

V. Other Business

None