

IBC Meeting Minutes Cleveland Clinic Main Campus

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| Date: March 25 th , 2026 | Location: Zoom |
| IBC Member Attendance: | |
| <input type="checkbox"/> Ahern, Philip <input checked="" type="checkbox"/> DiDonato, Joseph <input checked="" type="checkbox"/> Dragan, Amanda (BSO) <input type="checkbox"/> Hajjar, Adeline <input checked="" type="checkbox"/> Heemers, Hannelore <input checked="" type="checkbox"/> Kerr, Travis <input checked="" type="checkbox"/> Lindner, Daniel <input type="checkbox"/> McDonald, Christine (IBC Chair) <input type="checkbox"/> Mortimer, Joanne <input checked="" type="checkbox"/> Speranza, Emily <input checked="" type="checkbox"/> Such, Kimberly | |
| <p><i>Guests: Anthony Santilli*, Nikki Meyer*, Jennifer, Veillette*, Sara Tavakoli**, Dylan Champer**, Molly Urban***, Karsyn McClain****</i></p> <p><i>* Cleveland Clinic Main Campus</i> <i>** Cleveland Clinic Florida Research & Innovations Center</i> <i>*** Pending Cleveland Clinic Main Campus IBC Community Member</i> <i>**** Ohio State University Veterinary Student</i></p> | |
| Call To Order: 2:34 PM | Adjourn: 3:24 PM |

I. Review of Feb. 25th, 2026 Meeting Minutes

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| Committee Comments: N/A | | | |
| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 |

II. Administrative Business

- a. Pending IBC Community Member, Molly Urban, was introduced to the Committee.
- b. Committee presented with Expedited 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 March 2026. No major deficiencies identified.

III. Non-Clinical Research:

- a. Renewals:

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| Basic Research Renewal #1 | Protocol ID: IBC2210 | PI: Melenhorst | Biosafety Level: BSL-1, BSL-2, ABSL-2 | NIH Cat.: |
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| | | | | III-D-1-a, III-D-3-a, III-D-4-b, III-E, III-E-1 | |
| Project Title: Development, investigation, and evaluation of gene-modified cell therapies for efficacy against solid tumors and hematological malignancies | | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | | |
| Protocol Summary: <ul style="list-style-type: none"> • Generation of replication-defective lentiviral and retroviral particles, • Transduction and plasmid transfection of tissue culture cells • Administration of recombinant and wild type cells <i>in vivo</i> • Processing of potentially infectious or Hepatitis B/C positive human material • Human-derived samples. <p><u>Function/Nature of Recombinant Genes to be Expressed:</u></p> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Oncogene <input checked="" type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input checked="" type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input checked="" type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | |
| <p><u>Species of Recombinant Genes to be Expressed:</u></p> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> • Confirm core locations for downstream assays of un-inactivated samples • Add statement that cores will be made aware when given un-inactivated recombinant, infectious, or otherwise hazardous materials • Clearly identify which samples are positive Hepatitis B/C. • Update CAR-T manufacturing waste to differentiate between steps for biohazardous and non-biohazardous waste. • Clarify that all biohazardous agents are transported within secondary containment. • Update list of <i>in vivo</i> locations to match steps wise procedures. • Specify that cell lines with known infections will not be used <i>in vivo</i>. • Clarify timeline for sample collection from rDNA <i>in vivo</i> experiments • Update PPE for <i>in vivo</i> experiments performed outside of BSC to include the following at minimum: Lab coat, eye protection, surgical mask, gloves | | | | | |
| Motion Approval: | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: |

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| Approved w/ Administrative Revisions | | | | | 0 |
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| Clinical Application #2 | Protocol ID: IBC 2216 | PI: Nikhil Panicker | Biosafety Level: BSL-1, ABSL-1, ABSL-2 | NIH Cat.: III-D-1-a, III-D-4-b, III-E-1, III-E-3 |
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Project Title:

Innate immune mechanisms in neurodegeneration; Molecular mechanisms of neuroinflammation and neurotoxicity

Associated Grant Numbers:

Non-NIH Funding

Protocol Summary:

- Acquisition of replication defective adeno-associated virus particles and mouse α -Syn pre-formed fibrils, 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:

- No modifications requested

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| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |
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| Clinical Application #3 | Protocol ID: IBC 2207 | PI: Jung | Biosafety Level: BSL-2 | NIH Cat.: III-D-1-a, III-D-3-a |
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Project Title:

Identifying viral mechanisms of osteo-immunopathogenesis using infectious clones

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| Associated Grant Numbers: K99DE028573, R00DE028573 | | | | | | |
| Protocol Summary: | | | | | | |
| <ul style="list-style-type: none"> • Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab <ul style="list-style-type: none"> ○ Recombinant Zika Virus, Dengue Fever virus, and attenuated Chikungunya virus (181/25) ○ Ross River and Mayaro Virus infectious cDNA clones ○ Transduced tissue culture cell lines | | | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | | | |
| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input checked="" type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> | | | | | | |
| <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input checked="" type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: | | | Facilities, Procedures, and Safety Practices | | | |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): | | | Handler Training (Y/N): | | | |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: | | | | | | |
| <ul style="list-style-type: none"> • Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore. | | | | | | |
| Motion Approval: | | For: | Against: | Abstain: | Recuse: | Not Present: |
| Approved | | 7 | 0 | 0 | 0 | 0 |

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| Clinical Application #4 | Protocol ID: IBC 2208 | PI: Jae | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b |
| Project Title: | | | | |
| Identifying viral determinants involve in osteo-immunopathogenesis; Molecular regulatory mechanisms during vector-borne virus infection and pathogenesis | | | | |
| Associated Grant Numbers: K99DE028573, R00DE028573 | | | | |
| Protocol Summary: | | | | |

- Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab
 - Replication defective lentiviral and Adeno-associated viral particles
 - Transduced 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:

- Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore.

Motion Approval:
Approved

For:
7

Against:
0

Abstain:
0

Recuse:
0

Not Present:
0

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| Clinical Application #5 | Protocol ID: IBC 2213 | PI: Jung | Biosafety Level: BSL-2 | NIH Cat.: III-D-1-a, III-D-3-a |
| Project Title: Role of ZIKV viral determinants on immune rewiring of prenatal immunity | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | |
| Protocol Summary: <ul style="list-style-type: none"> • Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab <ul style="list-style-type: none"> ○ Recombinant Zika, Oropouche, and West Nile viruses ○ Transduced tissue culture cell lines | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | |

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|---|--|------------------|---|----------------------|---------------------|--------------------------|
| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input checked="" type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input checked="" type="checkbox"/> Viral <input type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore. | | | | | | |
| Motion Approval: Approved | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Clinical Application #6 | Protocol ID: IBC 2214 | PI: Jung | Biosafety Level: BSL-2 | NIH Cat.: III-D-1-a, III-D-3-a |
| Project Title: Identifying viral determinants involve in ZIKV-induced immune rewiring | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | |
| Protocol Summary: <ul style="list-style-type: none"> Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab <ul style="list-style-type: none"> Replication defective lentiviral particles Transduced tissue culture cell lines | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input checked="" type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input checked="" type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | |

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| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore. | | | | | |
| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

b. Renewals Not Applicable to NIH Guidelines:

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| Basic Research Renewal #7 | Protocol ID: IBC 2212 | PI: Jae | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: N/A |
| Project Title: Immune reperussion of ZIKV infection on mother and child | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | |
| Protocol Summary: <ul style="list-style-type: none"> Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab <ul style="list-style-type: none"> Zika, Dengue, and Yellow Fever (vaccine strain) viruses | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore. | | | | |

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| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |
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| Clinical Application #8 | Protocol ID: IBC 2206 | PI: Jae | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: N/A |
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Project Title:
Molecular regulatory mechanisms during vector-borne virus infection and pathogenesis

Associated Grant Numbers:
K99DE028573, R00DE028573

Protocol Summary:

- Temporary storage of following agents while transport permits are being obtained by departing PIs. Outside of storage and shipping, no work with these agents is or will be carried out by the lab
 - Zika, Dengue, Una, Mayaro, Chikungunya (vaccine strain), Sindbis, and Ross River viruses.
 - Tissues derived from septic patients

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:

- Note to PI: For some agents, safety and shipping regulations may differ between USA and Singapore.

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| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |
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| Clinical Application #9 | Protocol ID: IBC 1816 | PI: Gupta | Biosafety Level: BSL-2, ABSL-1 | NIH Cat.: N/A |
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| Project Title: B cell immune response to influenza; Regulation of B cell function; Role of unconventional myosin Myo18A and ERM family proteins in B cell function | | | | | | |
| Associated Grant Numbers: R01AI172916 | | | | | | |
| Protocol Summary: <ul style="list-style-type: none"> • Acquisition of Influenza A viral particles • UV-inactivation of viral particles • Administration of inactivated viral particles <i>in vivo</i>. <p><u>Function/Nature of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other</p> <p><u>Species of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other</p> | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> • Add steps for samples aliquoting upon receipt of viral stocks if needed. • Recommendation from Committee: Periodically assess UV output. | | | | | | |
| Motion Approval: Approved w/ Administrative Revisions | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

c. Amendments:

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| Basic Research Amendment #1 | Protocol ID: IBC 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 | | | | |

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| Summary of Approved Items: Generation of replication defective lentivirus particles, transduction of tissue culture cells. Reprogramming of iPSCs for transduction; Human-derived materials. | | | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> • Replication defective lentiviral particles • Genes for editing, gene targets | | | | | | |
| Function/Nature of Recombinant Genes to be Expressed: <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| Species of Recombinant Genes to be Expressed: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> • No modifications requested | | | | | | |
| Motion Approval: Approved | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Basic Research Amendment #2 | Protocol ID: IBC 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 | | | | |
| 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 <i>in vivo</i> ; Human-derived material | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> • Recombinant modified cell lines generated on IBC 1602 | | | | |
| Function/Nature of Recombinant Genes to be Expressed: | | | | |

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| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Administrative edits | | | | | | |
| Motion Approval: Approved w/ Administrative Revisions | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Basic Research Amendment #3 | 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: Acquisition of replication defective lentiviral particles, transduction of tissue culture cells. Human-derived material | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> Generation of replication-deficient lentiviral particles Gene targets and genes for editing Mammalian expression plasmids Updated experimental procedures Room additions | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> | | | | |

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|--|--|------------------|---|----------------------|---------------------|--------------------------|
| <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input checked="" type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> No modifications requested | | | | | | |
| Motion Approval: Approved | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Basic Research Amendment #4 | Protocol ID: IBC 2218 | PI: Kim | Biosafety Level: BSL-1, BSL-2 | NIH Cat.: III-E, III-D-3-a |
| Project Titles: Microfluidic culture of human cells and bacteria | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | |
| Summary of Approved Items: Culturing of bacteria; co-culture of human and mammalian tissue culture cells with bacteria; human-derived materials | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> Generation of replication-deficient lentiviral particles Gene targets and genes for editing Transduction of tissue culture cells Mammalian expression plasmids Human-derived materials Updates to experimental procedures Room additions | | | | |
| Function/Nature of Recombinant Genes to be Expressed: <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input checked="" type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | |
| Species of Recombinant Genes to be Expressed: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | |

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|---|--|---|----------------------|----------------------|---------------------|--------------------------|
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Approval contingent on final walkthrough and approval of new spaces from safety and regulatory teams. | | | | | | |
| Motion Approval: Approved w/ Contingency | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Basic Research Amendment #5 | Protocol ID: IBC 1810 | PI: Claesen | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: III-D-1-a, III-D-4-b | | |
| Project Titles: Identification and <i>in vitro</i> & <i>in vivo</i> characterization of bacterial biosynthetic gene clusters | | | | | | |
| Associated Grant Numbers: R01AI153173 | | | | | | |
| Summary of Approved Items: Acquisition of various human and rodent-derived material, microbial isolates; generation and culturing of various recombinant and non-recombinant modified bacteria; co-culture in tissue culture cells; and administration <i>in vivo</i> ; Human-derived material | | | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> <i>R. ilealis</i> and <i>E. coprostanoligenes</i> | | | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Administrative edits | | | | | | |
| Motion Approval: | | For: | Against: | Abstain: | Recuse: | Not Present: |

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| Approved w/ Administrative Revisions | 7 | 0 | 0 | 0 | 0 |
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| Basic Research Amendment #6 | Protocol ID: IBC 1525 | PI: Zhao | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: III-D-1-a, III-D-3-a, III-D-4-b |
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Project Titles:
Elucidating the Role of Deregulated Genes in Cancer

Associated Grant Numbers:
R00CA172292

Summary of Approved Items:
Generation of replication defective lentivirus, transduction of tissue culture cells, and administration of transduced cells *in vivo*; Administration of plasmid transfected cells *in vivo*; Administration of adenovirus *in vivo*; Human-derived materials

Requested Additions/Changes:

- Gene targets and mutations to gene targets
- Human-derived materials

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

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| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
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| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
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Discussion/Required Modifications:

- No modifications requested

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| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |
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| Basic Research Amendment #7 | 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 |
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| Project Titles: Novel immuno-prevention strategies for controlling lung cancer and pancreatic cancer | | | | | |
| Associated Grant Numbers: | | | | | |
| Summary of Approved Items: Generation of replication-defective lentiviral and retroviral particles, transduction of tissue culture cells, plasmid transfection of tissue culture cells, and administration of cells <i>in vivo</i> ; Propagation of recombinant modified Listeria monocytogenes and administration <i>in vivo</i> ; Human-derived material | | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> • Replication defective retroviral and lentiviral particles • Gene targets | | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> • No modifications requested | | | | | |
| Motion Approval: Approved | For: 6 | Against: 0 | Abstain: 0 | Recuse: 1 | Not Present: 0 |

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| Basic Research Amendment #8 | Protocol ID: Brown | PI: IBC 1829 | Biosafety Level: BSL-2, ABSL-2 | NIH Cat.: III-D-1-a, III-D-4-b, III-F-2, III-F-8 |
| Project Titles: The Role of Bacterial Choline Metabolism in Host Stress Response | | | | |
| Associated Grant Numbers: R01DK120679, P01HL147823 | | | | |
| Summary of Approved Items: Growth of recombinant and non-recombinant bacteria and fungi and administration <i>in vivo</i> | | | | |

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| Requested Additions/Changes: | | | | | | |
| <ul style="list-style-type: none"> • <i>H. hepaticus</i> and defined microbial community | | | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | | | |
| <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> | | | | | | |
| <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: | | | Facilities, Procedures, and Safety Practices Reviewed: | | | |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): | | | Handler Training (Y/N): | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: | | | | | | |
| <ul style="list-style-type: none"> • No modifications requested | | | | | | |
| Motion Approval: | | For: | Against: | Abstain: | Recuse: | Not Present: |
| Approved | | 7 | 0 | 0 | 0 | 0 |

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| Basic Research Amendment #9 | Protocol ID: IBC 2040 | PI: Stappenbeck | Biosafety Level: BSL-1, BSL-2, ABSL-2 | NIH Cat.: III-D-1-a, III-D-4-b |
| Project Titles: Shaping immune response by select members of the mycobiome | | | | |
| Associated Grant Numbers: R01AI168411 | | | | |
| Summary of Approved Items: Acquisition and propagation of WT bacteria and yeast, generation of recombinant modified yeast strains, infection of cell lines, and administration <i>in vivo</i> ; Generation of replication defective lentiviral particles, transduction of tissue culture cells, administration <i>in vivo</i> ; Human-derived material | | | | |
| Requested Additions/Changes: | | | | |
| <ul style="list-style-type: none"> • New <i>in vivo</i> administration route for yeast • Recombinant <i>S. cerevisiae</i> • Wild type <i>C. albicans</i> | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | |

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|---|--|------------------|---|----------------------|---------------------|--------------------------|
| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input checked="" type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> Administrative edits | | | | | | |
| Motion Approval: Approved w/ Administrative Revisions | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| 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: Towards precision immuno-oncology | | | | |
| Associated Grant Numbers: | | | | |
| Summary of Approved Items: Generation of replication defective lentiviral and retroviral particles; transduction of tissue culture cells, and administration <i>in vivo</i> ; acquisition of and adeno-associated viral (AAV) particles and transduction of tissue culture cells; administration of plasmid DNA via electroporation <i>in vivo</i> ; generation and propagation of phage; administration of AAV and lentiviral particles <i>in vivo</i> ; administration of wt bacteria <i>in vivo</i> ; Generation and administration of mRNA vaccines <i>in vivo</i> ; generation of humanized <i>in vivo</i> model; Human-derived materials | | | | |
| Requested Additions/Changes: <ul style="list-style-type: none"> Replication defective lentiviral and retroviral particles Packaging, mammalian expression and CRISPR expression plasmids Gene targets Tissue culture cell lines Human-derived materials | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | |

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|---|--|------------------|---|----------------------|---------------------|--------------------------|
| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input checked="" type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input checked="" type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> No modifications requested | | | | | | |
| Motion Approval: Approved | | For: 6 | Against: 0 | Abstain: 0 | Recuse: 1 | Not Present: 0 |

IV. Clinical Research:

a. Applications:

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|---|---------------------------------------|-------------------------|---|------------------------------------|
| Clinical Application #1 | Protocol ID: Application #1 | PI: Brunstein | Biosafety Level: BSL-2 | NIH Cat.: III-C-1, III-E |
| Project Title: 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 | | | | |
| Protocol Summary: <ul style="list-style-type: none"> Administration of replication defective lentiviral transduced cells to humans | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input checked="" type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input checked="" type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| PI/Supervisor Training (Y/N): | | | Handler Training (Y/N): | |

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| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| Discussion/Required Modifications: | | | | | |
| <ul style="list-style-type: none"> No modifications requested | | | | | |
| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Clinical Application #2 | Protocol ID: Application #2 | PI: Caimi | Biosafety Level: BSL-2 | NIH Cat.: III-C-1, III-E | |
| Project Title: | | | | | |
| A Phase 3, Randomized, Open-label, Multicenter Study to Compare the Efficacy and Safety of BMS-986353, CD19-targeted NEX-T CAR T Cells, Versus Standard of Care in Participants with Active Systemic Sclerosis (Breakfree-SSc) | | | | | |
| Associated Grant Numbers: | | | | | |
| Non-NIH Funding | | | | | |
| Protocol Summary: | | | | | |
| <ul style="list-style-type: none"> Administration of replication defective lentiviral transduced cells to humans | | | | | |
| <u>Function/Nature of Recombinant Genes to be Expressed:</u> | | | | | |
| <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input checked="" type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input checked="" type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input type="checkbox"/> Other | | | | | |
| <u>Species of Recombinant Genes to be Expressed:</u> | | | | | |
| <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input checked="" type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input type="checkbox"/> Other | | | | | |
| Risk Assessment Discussion: | | | Facilities, Procedures, and Safety Practices Reviewed: | | |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| PI/Supervisor Training (Y/N): | | | Handler Training (Y/N): | | |
| <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | |
| Discussion/Required Modifications: | | | | | |
| <ul style="list-style-type: none"> No modifications requested | | | | | |
| Motion Approval: Approved | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

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| Clinical Application #3 | Protocol ID: Application #3 | PI: Rotz | Biosafety Level: | NIH Cat.: III-C-1, III-E | |
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| | | | BSL-2 | | | |
| Project Title: Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL) | | | | | | |
| Associated Grant Numbers: Non-NIH Funding | | | | | | |
| Protocol Summary: <ul style="list-style-type: none"> Administration of replication defective lentiviral transduced and TALEN® edited cells to humans <p><u>Function/Nature of Recombinant Genes to be Expressed:</u></p> <input type="checkbox"/> N/A <input type="checkbox"/> Oncogene <input type="checkbox"/> Tumor Suppressor Gene <input type="checkbox"/> Structural <input type="checkbox"/> Signaling <input type="checkbox"/> Antimicrobial <input checked="" type="checkbox"/> Immunomodulatory <input type="checkbox"/> Toxin <input type="checkbox"/> Antibiotic Resistance <input type="checkbox"/> Reporters <input type="checkbox"/> Cell Metabolism <input checked="" type="checkbox"/> Other | | | | | | |
| <p><u>Species of Recombinant Genes to be Expressed:</u></p> <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Human <input type="checkbox"/> Murine <input type="checkbox"/> Bacterial <input type="checkbox"/> Viral <input checked="" type="checkbox"/> Other | | | | | | |
| Risk Assessment Discussion: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Facilities, Procedures, and Safety Practices Reviewed: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| PI/Supervisor Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Handler Training (Y/N): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | | | |
| Discussion/Required Modifications: <ul style="list-style-type: none"> No modifications requested | | | | | | |
| Motion Approval: Approved | | For: 7 | Against: 0 | Abstain: 0 | Recuse: 0 | Not Present: 0 |

V. Other Business

None