



**Institutional Biosafety Committee (IBC)**  
**Zoom Meeting Minutes**  
27 April 2026  
9:00-11:00am (Mountain Time)

**Attendance:**

**Voting IBC Members:**

- Dr. [REDACTED] (EC)
- Dr. [REDACTED] (PD)
- Dr. [REDACTED] (MF)
- Dr. [REDACTED] (BH)
- Dr. [REDACTED] (MJ)
- [REDACTED] (EK)
- Dr. [REDACTED] (SK)
- Dr. [REDACTED] (AL)\*
- Dr. [REDACTED] (JL)
- Dr. [REDACTED] (CM)
- Dr. [REDACTED] (Co-chair) (BM)
- Dr. [REDACTED] (Co-chair) (TM)
- [REDACTED] (JR)
- [REDACTED] (ZJW)
- [REDACTED] (ZW)

**Non-voting IBC Members/Guests:**

- [REDACTED] (AA)
- [REDACTED] (JH)\*
- [REDACTED] (JW)
- [REDACTED] (CW)\*

**I. Call to Order:** 9:01am (Mountain Time)

**II. Conflict of Interest:**

- All present IBC members were reminded that no member of an IBC may be involved (except to provide information requested by the IBC) in the review of approval of a project in which he/she/they have been or expect(s) to have a conflict of interest—including financial interests, personal relationships, or involvement in the research. Any committee member with a conflict of interest shall abstain from the vote.

**III. Review and Approval of Previous Minutes:** 23 March 2026

The minutes were reviewed and approved by the IBC.

Approved = 15

Opposed = 0

Abstained = 0

**IV. IBC Administrative Business:**

**A. IBC Administrative Changes:** None

**B. Protocol Closures:**

- i. [REDACTED] - # 1250
- ii. [REDACTED] - # 1479
- iii. [REDACTED] - # 1340
- iv. [REDACTED] - # 19-2405
- v. [REDACTED] - # 21-5117

**C. Protocol Transfers:** None

**Recombinant and/or Synthetic Nucleic Acid Molecules Research Applications Review:**

During the review, the IBC assessed the containment levels in addition to the facilities,



procedures, practices, training, and expertise of the laboratory personnel involved in recombinant and/or synthetic nucleic acid molecules research. Additionally, the IBC reviewed agent characteristics, types of manipulations planned, sources of the inserted nucleic acid sequences, the nature of the inserted nucleic acid sequences, and whether an attempt will be made to obtain expression of a foreign gene, and, if so, the protein that will be produced. The Principal Investigator must determine the applicable section(s) of the *NIH Guidelines*.

**V. New Business:**

1. **Environmental Health and Safety Office Updates:** None
2. **Biosafety Office Updates:** None

**VI. Clinical Trial (Human Gene Transfer) Amendments and Notices:**

1. Patel, Sapna - # 25-0844: *A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator's choice of treatment in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)*
2. Moreland, Larry - # 22-1353: *A phase 1 study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis*
3. Knupp, Kelly - # 25-2098: *ENDEAVOR: A Clinical Study to Evaluate the Safety and Efficacy of ETX101, an AAV9-Delivered Gene Therapy in Infants and Children with SCN1A-positive Dravet Syndrome*
4. Medina, Theresa - # 25-0580: *A MULTICENTER, RANDOMIZED, DOUBLE-BLINDED, PLACEBOCONTROLLED TRIAL OF IFX-HU2.0 FOLLOWED BY PEMBROLIZUMAB IN CHECKPOINT INHIBITOR NAÏVE PATIENTS WITH ADVANCED OR METASTATIC MERKEL CELL CARCINOMA*
5. Fabrizio, Vanessa - # 18-2424: *Phase I/II Dose Escalation and Preliminary Efficacy of CD19 Directed CAR-T Cells Generated Using the Miltenyi CliniMACs Prodigy System (UCD19 CAR-T) in Pediatric Patients with Relapsed and/or Refractory B-Cell Acute Lymphoblastic Leukemia (B-ALL) and B-Cell Non-Hodgkin Lymphoma (B-NHL)*
6. Yang, Michele - # 24-1082 - x2: *A Phase 1/2/3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD)*
7. Walleigh, Diana - # 25-2216: *Phase 1/2 First-in-Human Study to Evaluate the Safety, Tolerability, and Efficacy of MZ-1866, an AAV-9 Gene Therapy Delivered by Intracerebroventricular Injection to Participants with Pitt Hopkins Syndrome*
8. Angelos, Mathew - # 22-1502: *Open label, dose-escalation, and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogenic engineered T-cells expressing anti CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL)*
9. Benke, Timothy - # 23-0323: *A Phase 1 / 2, Open-Label Clinical Study to Evaluate Safety, Tolerability, and Efficacy of NGN-401 in Pediatric Subjects with Rett Syndrome.*
10. Angelos, Mathew - # 25-0718: *Phase 1, Open Label, Dose Escalation Study to Evaluate the Safety, Expansion, Persistence, and Preliminary Clinical Activity of Autologous CD64 CAR T Cells in Patients with Relapsed and/or Refractory Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndromes (HR-MDS)*
11. Sreenivasan, Varun - # 25-0137: *A Randomized Double-blind, Placebo-Controlled Phase 3 Trial of Descartes-08 in Patients with Acetylcholine Receptor Antibody-Positive Generalized Myasthenia Gravis (MG)*



**VII. Clinical Trial (Human Gene Transfer) Protocol Reviews:**

- 1. Griffith, Melissa - # 26-0156: 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)**

Biosafety level: BSL-2 with standard precautions

NIH Section(s): III-C

Approved = 15

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with no further committee concerns.

- 2. Wolf, Andrew - # 25-2749: 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**

Biosafety level: BSL-2 with standard precautions

NIH Section(s): III-C

Approved = 15

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with no further committee concerns.

- 3. Abbott, Kaleb - # 26-0186: A Phase 1/2, Multicenter, Double-Masked, Placebo-Controlled Study of KB801 in Subjects with Stage 2 or 3 Neurotrophic Keratitis (Previously deferred)**

Biosafety level: BSL-2 with standard precautions

NIH Section(s): III-C

Approved = 15

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with no further committee concerns.

\*JH, CW, and AL left the meeting at 9:20am.

**VIII. New Laboratory Protocol Reviews: None**

**IX. De Novo Laboratory Protocol Reviews:**

- 1. ██████████ - # 1056: Biological investigations and developing therapeutics for solid tumors.**

Biosafety level: BSL-2, ABSL-1

NIH Section(s): III-D-1, III-D-2, III-D-3, III-D-4, III-E-1, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating the listed IACUC protocol expiration date, clarifying research narrative details, and correcting typographical errors.

- 2. ██████████ - # 1021: Genetic manipulation to understand pancreas development and disease**

Biosafety level: BSL-2, ABSL-1



NIH Section(s): III-D-2, III-D-1, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating listed IACUC protocol expiration dates, clarifying use of rDNA, updating the research narrative and protocol procedure sections, updating PPE details, adding details for micro/infectious agents, and adding BSC details were appropriate.

3. [REDACTED] - # 1233: **Neurophysiology of the retina in health and disease**

Biosafety level: BSL-1, BSL-2, ABSL-1

NIH Section(s): III-D-4, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including providing clarity throughout the IBC protocol form, updating research narrative details, providing BSC recertification dates, selecting appropriate IBC protocol checkboxes, and ensuring appropriate BSL designations are selected.

4. [REDACTED] - # 1439: **Genetic regulation of bone quality and formation**

Biosafety level: BSL-2, ABSL-1

NIH Section(s): III-D-1, III-D-2, III-D-4-a, III-E-3

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address updating research narrative details, select appropriate IBC protocol checkboxes, add details to procedure entries, and update PPE checkboxes as needed.

5. [REDACTED] - # 1050: **Analysis of craniofacial development**

Biosafety level: BSL-2, ABSL-1

NIH Section(s): III-D-1, III-D-2, III-D-4-a, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including adding more details to the research narrative.

6. [REDACTED] - # 1481: **Molecular mechanisms of pediatric dilated cardiomyopathy**

Biosafety level: BSL-1, BSL-2, ABSL-1

NIH Section(s): III-D-1, III-D-2, III-D-4, III-E-1, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address inconsistencies throughout the IBC protocol form, add more details to the rDNA and biomaterial sections, update BSL designations as needed, and add procedure entry details.



7. [REDACTED] - # 1032: **Pancreatic islet function and dysfunction in diabetes**

Biosafety level: BSL-1, BSL-2, ABSL-1

NIH Section(s): III-D-1, III-D-2, III-D-4, III-F

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including selecting appropriate checkboxes in the biomaterials section, updating research narrative details, and adding information regarding international shipment.

X. **Significant Amendment Reviews for Laboratory Protocols:** None

XI. **Exempt Protocols – New/Renewal:**

1. [REDACTED] - # 1730: *Our lab uses intraamniotic injections of molecules (lipopolysaccharide, recombinant human sFlt-1, and recombinant endoglin), to model antenatal exposures and study the impact on vascular development in fetal and postnatal rat organs.*
2. [REDACTED] - # 1766: *Studies on protein aggregation in cancer and cancer modeling in 3D*
3. [REDACTED] - # 1459: *Biomarkers and mechanisms underlying progression of polycystic kidney disease.*
4. [REDACTED] - # 1767: *Collection and processing of samples for the AMD registry.*

XII. **Exempt Protocol Amendments:**

1. [REDACTED] - # 1403: *Characterizing the Chemotypic Landscape of Microbiome Communities*
2. [REDACTED] - # 1675: *Therapeutic Targets in Eye Diseases*

XIII. **Additional Business:** None

XIV. **Next Meeting Scheduled:** 18 May 2026, 9:00am (Mountain Time)

XV. **Adjournment:** 10:10am (Mountain Time)