



University of Colorado
Anschutz Medical Campus

Institutional Biosafety Committee (IBC)

Zoom Meeting Minutes

27 July 2026

9:00-11:00am (Mountain Time)

Attendance:

Voting IBC Members:

Dr. [REDACTED] (HD)
Dr. [REDACTED] (MF)
Dr. [REDACTED] (LH)
Dr. [REDACTED] (BH)
[REDACTED] (EK)
Dr. [REDACTED] (SK)
Dr. [REDACTED] (SM)*
Dr. [REDACTED] (Co-chair) (BM)
[REDACTED] (JR)
Dr. [REDACTED] (MV)
[REDACTED] (ZJW)
[REDACTED] (ZW)

Non-voting IBC Members/Guests:

[REDACTED] (AA)
[REDACTED] (JA)
[REDACTED] (QB)
[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: 22 June 2026

The minutes were reviewed and approved by the IBC.

Approved = 10

Opposed = 0

Abstained = 1 (EK)

IV. IBC Administrative Business:

A. IBC Administrative Changes: None

B. Protocol Closures:

i. [REDACTED] - # 1527

ii. [REDACTED] - # 1335

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:

- i. BH provided introduction for new community member that will be joining the IBC (JA).
- ii. BH reminded the IBC that the meeting can proceed with quorum even if no community members are present.

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

1. Gutman, Jonathan - # 23-0111 x2: *Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucel (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma*
2. Benke, Tim - # 23-0323 x2: *A Phase 1 / 2, Open-Label Clinical Study to Evaluate Safety, Tolerability, and Efficacy of NGN-401 in Pediatric Subjects with Rett Syndrome.*
3. Taylor, Matthew - # 25-0602: *A Phase 3 Safety and Efficacy Trial of FLT201 Gene Therapy in Patients with Gaucher Disease Type 1*
4. 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)*
5. Monge Urrea, Jorge - # 24-2523: *A Phase 1b/2 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects With Relapsed/Refractory Multiple Myeloma*
6. Patel, Sapna - # 25-0004: *A Randomized, Phase 2/3, Open-Label Study to Investigate the Efficacy and Safety of RP2 in Combination with Nivolumab versus Ipilimumab in Combination with Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients with Metastatic Uveal Melanoma*
7. 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*
8. Knupp, Kelly - # 25-2098: *A phase 1 study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis*
9. Schenk, Erin - # 24-2314: *A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)*

*SM joined the meeting at 9:10am.

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

1. **Subramanian, Prem - # 26-1157: An Adaptive Phase 1/2 Multicenter Study Evaluating the Safety, Tolerability, Pharmacokinetics and Efficacy of VV-14305 Delivered via Peribulbar Injection in Patients with Moderate to Severe Thyroid Eye Disease (the RECLAIM Study)**

Biosafety level: BSL-1

NIH Section(s): III-C

Approved = 12

Opposed = 0

Abstained = 0

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



2. **Robinson Diamond, Jennifer - # 26-1182: A Phase 1, Multicenter, Open-label, First-in-Human Study of ITI-5000 (Self-Amplifying RNA Vaccine) Alone and in Combination with Pembrolizumab in Participants with Stage II–III Triple-Negative Breast Cancer (TNBC) Who Have Completed Standard Curative-Intent Therapy (VITAL-TNBC Study)**

Biosafety level: BSL-1

NIH Section(s): III-C

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating drug receipt and storage details, protocol checkboxes, and providing the PI signature and date.

3. **Kamdar, Manali - # 26-1213: A PHASE 1/2, OPEN-LABEL, MULTICENTER STUDY OF UB-VV400 WITH RAPAMYCIN IN RELAPSED OR REFRACTORY B-CELL MALIGNANCIES**

Biosafety level: BSL-2

NIH Section(s): III-C

Approved = 12

Opposed = 0

Abstained = 0

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

**JH and CW left the meeting at 9:33am.

VIII. New Laboratory Protocol Reviews:

1. **[REDACTED] - # 1758: Overcoming therapeutic resistance in lung cancer (Previously deferred)**

Biosafety level: BSL-2

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address adding animal use details, clarifying biological safety level details, adding necessary procedures, and adding vector details as needed.

2. **[REDACTED] - # 1772: Translational antimicrobial research targeting urgent multidrug-resistant infections**

Biosafety level: BSL-2

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address selecting appropriate BSC checkboxes, clarifying disinfection and procedural practices, and providing consistent PPE use. BSO to perform site visit with laboratory.

3. **[REDACTED] - # 1778: Research on viral glycoproteins, antibodies, virus-like particles,**



and paramyxo/pneumoviruses for structural and functional studies in vitro and in vivo

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

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address clarifying animal use and vector generation/use details, providing insertion and target cell details, adding rDNA procedures, updating biomaterial use details, and ensuring the proper research narrative is in-place.

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1065: Development and Homeostasis of innate T cells.

Biosafety level: BSL-2, ABSL-1

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including adding procedures, updating research narrative details, and updating BSC certification details as needed.

2. [REDACTED] - # 1156: Examine the role of complement inhibition on arthritis and lupus

Biosafety level: BSL-2, ABSL-2

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating protocol checkboxes, clarifying procedure details, and removing out of date protocol attachments.

3. [REDACTED] - # 1167: Understanding development and progression of pediatric sarcomas.

Biosafety level: BSL-1, ABSL-1

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including unchecking vertebrate animal checkboxes where appropriate, adding procedures, clarifying use of human biomaterial and purchasing/use of vectors, and providing overall protocol congruency between multiple sections.

4. [REDACTED] - # 1246: skin and melanoma related studies

Biosafety level: BSL-2, ABSL-2

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

Approved = 12

Opposed = 0

Abstained = 0



The IBC protocol presented was approved with the recommendation to address minor administrative items including updating BSC checkboxes, listing signs and symptoms for microorganisms, and updating the BSC certification details.

5. [REDACTED] - # 1260: **Fetal insulin secretion and sensitivity and placental function**
Biosafety level: BSL-1, BSL-2, ABSL-1, ABSL-2
NIH Section(s): III-D-4-b, III-F
Approved = 12
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor administrative items including updating protocol checkboxes, adding biomaterial details, and updating procedure details for clarity.
6. [REDACTED] - # 1424: **Pseudomonas aeruginosa, Escherichia coli and Streptococcus mutans pathogenesis.**
Biosafety level: BSL-2, ABSL-2
NIH Section(s): III-D-1, III-D-2, III-D-4-b, III-F
Approved = 12
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor administrative items including updating protocol checkboxes, adding agent details including signs and symptoms, as well as updating research narrative and associated IACUC protocol expiration dates.
7. [REDACTED] - # 1456: **Basic and translational applications of RNA molecular biology**
Biosafety level: BSL-2
NIH Section(s): III-D-2, III-E-1, III-F
Approved = 12
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor administrative items including providing microorganism signs and symptom details and specifying PPE details for all procedures.
8. [REDACTED] - # 1632: **Genetic and Molecular Basis for Hematologic Malignancies**
Biosafety level: BSL-2, ABSL-1
NIH Section(s): III-D-4, III-D-2, III-D-1, 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 protocol checkboxes and providing clarifying details within the IBC protocol application.
9. [REDACTED] - # 1657: **studying protein translation and folding in living cells with high spatiotemporal resolution**
Biosafety level: BSL-2
NIH Section(s): III-D-2, III-D-1, III-E-1, III-F



Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating protocol checkboxes as well as adding plasmid and procedure details.

X. Significant Amendment Reviews for Laboratory Protocols:

1. [REDACTED] - # 1501: Probing and manipulating protein interactions

Biosafety level: BSL-1, BSL-2

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating BSL for human material use and checkboxes for BSC.

2. [REDACTED] - # 1707: Neurodevelopmental mechanisms and Rare Diseases

Biosafety level: BSL-2

NIH Section(s): III-E-1

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was deferred by the IBC. The IBC to review the protocol at a later IBC meeting with recommendations to address items including providing animal work details and listing PPE for procedures as needed.

3. [REDACTED] - # 1720: Research Workflow for patient derived of adult and early development esophageal and gastric in vitro organoid models

Biosafety level: BSL-1, BSL-2

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating protocol procedures, checkboxes, and BSC certification details.

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1779: Structural and Biochemical Characterization of Macromolecular Complexes Regulating Autophagy and Lysosomal Dynamics.

2. [REDACTED] - # 1770: The role of unconventional lymphocytes during homeostasis and chronic inflammation.

3. [REDACTED] - # 1780: Nutrition and multi-omics integration for improvement of lifestyle behaviors and health across the life course

4. [REDACTED] - # 1045: The role of inflammation in disease.

5. [REDACTED] - # 1105: Study of autoimmune and acute inflammation

6. [REDACTED] - # 1571: Regulation of Extracellular Matrix and Smooth Muscle Cell Remodeling in Pelvic Support Structures in Understanding Pelvic Organ Prolapse



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XII. Exempt Protocol Amendments:

1. [REDACTED] - # 1764: *Mechanisms underlying the biogenesis and function of ion channels*
2. [REDACTED] - # 1136: *Immune responses to bacterial and viral infections*
3. [REDACTED] - # 1154: *The effects of advanced age and alcohol intoxication on inflammatory responses after injury and/or infection*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 24 August 2026, 9:00am (Mountain Time)

XV. Adjournment: 10:55am (Mountain Time)