



University of Colorado
Anschutz Medical Campus

Institutional Biosafety Committee (IBC)

Zoom Meeting Minutes

27 October 2025

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

Attendance:

Voting IBC Members:

Dr. [REDACTED] (EC)
Dr. [REDACTED] (HD)
Dr. [REDACTED] (PD)
Dr. [REDACTED] (MF)
Dr. [REDACTED] (LH)
Dr. [REDACTED] (BH)
[REDACTED] (EK)
Dr. [REDACTED] (AL)
Dr. [REDACTED] (JL)
Dr. [REDACTED] (Co-chair) (BM)
Dr. [REDACTED] (Co-chair) (TM)
Dr. [REDACTED] (TR)
[REDACTED] (JR)
[REDACTED] (ZW)

Non-voting IBC Members/Guests:

[REDACTED] (AA)
[REDACTED] (QB)
[REDACTED] (JH)
[REDACTED] (EJ)
Dr. [REDACTED] (MJ)
Dr. [REDACTED] (SK)
Dr. [REDACTED] (MV)
[REDACTED] (JW)
Dr. [REDACTED] (ZJW)
[REDACTED] (MW)
[REDACTED] (CW)

I. Call to Order: 9:00am (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 September 2025

The minutes were reviewed and approved by the IBC.

Approved = 13

Opposed = 0

Abstained = 1 (HD)

IV. IBC Administrative Business:

A. IBC Administrative Changes:

- i. TM announced recruitment of new IBC members and introductions were made.

B. Protocol Closures:

- i. [REDACTED] - # 1564
- ii. [REDACTED] - # 1125
- iii. [REDACTED] - # 1695

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:

A. Environmental Health and Safety Office Updates: None

B. Biosafety Office Updates:

- i. BH updated the IBC regarding the use of EHSAssistant (OnSite Systems, Inc.) to create a protocol form to be used for future clinical trial applications once the testing phase has been completed.

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

1. Podoll, Amber - # 23-2341: *SC291-102: A Phase 1 study evaluating SC291, a hypimmune, allogeneic CD19-directed CAR T cell therapy, in subjects with severe relapsed or refractory autoimmune diseases (GLEAM)*
2. Thomas, Janet - # 21-4252: *A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Adeno-Associated Virus Serotype 8 (AAV8)-Mediated Gene Transfer of Human Ornithine Transcarbamylase (OTC) in Patients with Late-Onset OTC Deficiency*
3. McCandless, Shawn - # 23-2307: *A Phase I/II First-in-Human, Open-Label, Dose-Escalation Study to Evaluate the Safety and Efficacy of a Single Intravenous (IV) Administration of ECUR-506 in Males Less than 9 Months of Age with Genetically Confirmed Neonatal Onset Ornithine Transcarbamylase (OTC) Deficiency*
4. Gutman, Jonathan - # 23-0111: *Intermediate-Size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucel (cilta-cel) Out-of-Specification (OOS) in patients with Multiple Myeloma*
5. Kamdar, Manali - # 19-3011: *JCAR017-FOL-001: A Phase 2, Open-label, Single-arm, Multicohort, Multicenter Trial to Evaluate the Efficacy and Safety of JCAR017 in Adult Subjects with Relapsed or Refractory Indolent B-cell Non-Hodgkin Lymphoma (NHL)*

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

1. **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)**

Biosafety level: BSL-2 with droplet precautions

NIH Section(s): III-C

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with a comment to be sent to the clinical team to address a potential typographical error regarding a dose discrepancy.

*AL left the meeting at 9:16am.

2. **Gate Biomanufacturing Facility (GBF) - 25-018A_CD64: General CAR-T Cell Manufacturing Process Summary**

Biosafety level: BSL-2

NIH Section(s): III-D-1, Appendix K

Approved = 13

Opposed = 0



Abstained = 0

The IBC protocol presented was approved.

3. **Bruckner, Anna - # 25-1076: Phase 4 Master Protocol for Patients Prescribed Prademagene Zamikeracel for the Treatment of Wounds**

Biosafety level: BSL-2 with droplet precautions

NIH Section(s): III-C

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved.

*JH and CW left the meeting at 9:39am.

VIII. New Laboratory Protocol Reviews: None

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1107: **Biotranslational Studies of MRI Contrast Agents, Cancer Cell Isolation, Complement Pathways, and Nanoparticle Delivery.**

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

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including adding details to the research narrative, including IRB details, updating BSC certification details, selecting appropriate protocol checkboxes, and adding/editing procedures.

2. [REDACTED] - # 1022: **Determining how contexts from aging to exposures alters somatic cell evolutionary trajectories and disease**

Biosafety level: BSL-2, ABSL-2

NIH Section(s): III-D-1, III-D-2, III-D-4, III-D-7, III-E-1, III-F

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including selecting the appropriate NIH Guidelines checkboxes, adding transport/shipping permit details, adding signs and symptoms for micro/infectious agents, selecting appropriate engineering controls, and adding/editing procedures.

X. Significant Amendment Reviews for Laboratory Protocols: None

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1741: *Neuroscience of Early Life Brain Injury*
2. [REDACTED] - # 1753: *Immunopathology of autoimmune neurologic diseases*
3. [REDACTED] - # 1232: *Animal Imaging and Irradiation Shared Resources*
4. [REDACTED] - # 1460: *Synthesis of biomaterials for evaluation of cell-matrix, cell-cell, and cell-soluble signal interactions in pulmonary disease and regeneration*

XII. Exempt Protocol Amendments



University of Colorado
Anschutz Medical Campus

1. [REDACTED] - # 1311: *Mechanistic Study of the T cell Antigens in Allergies, Infectious and Autoimmune Diseases*
2. [REDACTED] - # 1051: *Molecular Pathogenesis and Immunity of Arthropod-Borne Pathogens and other Virus Infections*
3. [REDACTED] - # 1260: *Fetal insulin secretion and sensitivity and placental function*
4. [REDACTED] - # 1662: *Models for understanding human craniofacial disease and treatments*
5. [REDACTED] - # 1727: *Investigating Epithelial-Stroma Crosstalk and Spatial Rearrangements in Disease Microenvironments Contributing to Treatment Resistance*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 17 November 2025, 9:00am (Mountain Time)

XV. Adjournment: 9:53am (Mountain Time)