



University of Colorado
Anschutz Medical Campus

Institutional Biosafety Committee (IBC)

Zoom Meeting Minutes

23 June 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)
Dr. [REDACTED] (AL)
Dr. [REDACTED] (JL)
Dr. [REDACTED] (CM) (SM)*
Dr. [REDACTED] (Co-chair) (BM)
Dr. [REDACTED] (Co-chair) (TM)
[REDACTED] (JR)
Dr. [REDACTED] (CM) (ET)
[REDACTED] (ZW)

Non-voting IBC Members/Guests:

[REDACTED] (AA)
[REDACTED] (EJ)
[REDACTED] (LR)
[REDACTED] (JW)

*SM joined the meeting at 09:45am (Mountain Time)

I. Call to Order: 09:00am (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: 19 May 2025

The minutes were reviewed and approved by the IBC.

Approved = 13

Opposed = 0

Abstained = 0

IV. IBC Administrative Business:

A. IBC Administrative Changes: None

B. Protocol Closures:

- [REDACTED] - # 1650: PI left university.
- [REDACTED] - # 1623: PI confirmed closure.
- [REDACTED] - # 1208: PI left university.
- [REDACTED] - # 1383: PI confirmed closure.
- [REDACTED] - # 1433: PI confirmed closure.
- [REDACTED] - # 1301: PI left university.
- [REDACTED] - # 1333: PI confirmed closure.
- [REDACTED] - # 24-0668: Final IP dose administered.

C. Protocol Transfers:

- Core IBC protocol # 1558: [REDACTED] updated to [REDACTED].



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 reminded the IBC of the upcoming IRE meeting.

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

1. 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*
2. Wilky, Breelyn - # 19-0967 x2: *A Phase 2 Single Arm Open-Label Clinical Trial of ADP-A2M4 SPEAR™ T cells in subjects with Advanced Synovial Sarcoma or Myxoid/Round Cell Liposarcoma (MRCLS)*
3. Lentz, Robert - # 23-2048: *Phase I open-label, dose escalation trial of BI 1831169 monotherapy and in combination with ezabenlimab in patients with advanced or metastatic solid tumors.*
4. Schwartz, Marc - # 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)*
5. 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*
6. Gutman, Jonathan - # 21-5082: *Expanded Access Protocol (EAP) For Subjects Receiving Idecabtagene Vicleucel That is Nonconforming for Commercial Release*

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

1. **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**

Biosafety level: BSL-1 with standard precautions

NIH Section(s): III-C

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including providing more plasmid detail, completing section III-C of the application, updating contact time within the biosafety SOP, resubmitting the application in proper formatting for legibility, and updating the BSC certification details for accuracy.

VIII. New Laboratory Protocol Reviews:



1. [REDACTED] - # 1733: Biophysics of voltage-gated ion channels
Biosafety level: BSL-2
NIH Section(s): III-E-1 and III-F
Approved = 14
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation modifications required to address minor administrative items including providing more details to the research narrative and updating laboratory cleaning details.
2. [REDACTED] - # 1736: The immunologic and biologic study of tumors of the central nervous system.
Biosafety level: BSL-2, ABSL-1
NIH Section(s): III-D-4 and III-F
Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation for modifications required to address minor administrative items including adding additional procedures, adding additional biomaterial details, updating protocol checkboxes, updated NIH recommendations, and updating disinfection details.
3. [REDACTED] - # 1738: Uncovering the molecular mechanisms governing genome integrity
Biosafety level: BSL-1, BSL-2
NIH Section(s): III-D-1, III-D-2, III-E-1, and III-F
Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor administrative items including clarifying cell culture work, updating protocol checkboxes, and updating engineering control details.

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1359: The role of the gut microbiome in immune activation, inflammation and metabolic syndrome in people living with HIV.
Biosafety level: BSL-2, BSL-2+, BSL-3, ABSL-2+
NIH Section(s): III-D-1
Approved = 14
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation for modifications required to address minor administrative items including updating IACUC protocol, research narrative, progress report, and BSC certification details as well as improving congruency throughout the IBC protocol.
2. [REDACTED] - # 1367: Skin Cancer Research Laboratory
Biosafety level: BSL-1, BSL-2, ABSL-2
NIH Section(s): III-D-1, III-D-2, III-D-4, and III-F
Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor



administrative items including updating IBC protocol checkboxes, adding animal work details, and marking the appropriate NIH Guideline checkboxes.

3. [REDACTED] - # 1136: Immune responses to bacterial and viral infections

Biosafety level: BSL-2, ABSL-2+

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation to address minor administrative items including updating research goals, laboratory cleaning, progress report, PPE, infectious agents signs/symptoms, and BSC details for accuracy.

4. [REDACTED] - # 1399: Chromatin Structure and Dynamics

Biosafety level: BSL-1, BSL-2

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

Approved = 14

Opposed = 0

Abstained = 0

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

5. [REDACTED] - # 1382: Mechanisms of cholestatic and pancreatic injury

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

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address minor administrative items including updating collaborator, transportation, established islet, and biomaterial biohazard procedure details.

X. Significant Amendment Reviews for Laboratory Protocols:

1. [REDACTED] - # 1725: Dynamics of brain perivascular cells

Biosafety level: BSL-1, ABSL-1

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address minor administrative items including providing an overview description of procedures as well as updating procedure types and checkboxes.

XI. Exempt Protocols (Initial and Renewals):

1. [REDACTED] - # 1735: Hemostasis Research to Study Bleeding, Clotting, and Stroke Disorders

2. [REDACTED] - # 1629: Study of human milk and the use of mouse models to study milk secretion regulation and mechanism.

XII. Exempt Protocol Amendments

1. [REDACTED] - # 1037: Molecular, genetic and neurological study of genes for schizophrenia and their impact on brain development in both humans and animal model systems.



University of Colorado
Anschutz Medical Campus

2. [REDACTED] - # 1687: *The impact of malignancies and their targeted treatments on smooth muscle cell transcriptional programs, epigenetics, and mechanical properties.*
3. [REDACTED] - # 1149: *Developmental Biology of the Placenta and In Utero Base Editing for Ornithine Transcarbamylase Deficiency*
4. [REDACTED] - # 1493: *Intercellular communication and protein spatiotemporal dynamics in human induced pluripotent stem cell models*
5. [REDACTED] - # 1626: *Mechanisms of cellular self-renewal*
6. [REDACTED] - # 1533: *Neo-Epitope Discovery in Tissues*
7. [REDACTED] - # 1165: *Investigation of novel cell-surface immune checkpoints in regards to cancer immunotherapy treatment*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 28 July 2025, 09:00am (Mountain Time)

XV. Adjournment: 10:05am (Mountain Time)