University of Colorado
Anschutz Medical Campus

Institutional Biosafety Committee (IBC)
Zoom Meeting Minutes
22 September 2025
9:00-11:00am (Mountain Time)

Attendance:

Voting IBC Members:

Dr. [redacted] (EC)
Dr. [redacted] (PD) (CM)
Dr. [redacted] (MF)
Dr. [redacted] (LH)
Dr. [redacted] (BH)
[redacted] (EK)
Dr. [redacted] (AL)
Dr. [redacted] (JL)
Dr. [redacted] (SM) (CM)
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)
[redacted] (JW)
[redacted] (MW)
[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: 25 August 2025
The minutes were reviewed and approved by the IBC.
Approved = 13
Opposed = 0
Abstained = 0

IV. IBC Administrative Business:

A. IBC Administrative Changes:

i. TM provided an update on the IBC member recruitment process.

B. Protocol Closures:

i. [redacted] - # 23-0956
ii. [redacted] - # 20-2626

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 announced NIH's "Strengthening and Modernizing Biosafety Oversight" initiative including listening sessions to begin this month and to span over the next year.

ii. BH confirmed that the updated IBC policy is now displayed on the IBC website.

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

1. Piquet, Amanda - # 24-1330: *A Phase 2 Open-Label, Single-Arm, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, in Subjects with Treatment Refractory Stiff Person Syndrome (KYSA-8)*
2. 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*
3. Kim, Sunnie - # 23-1329: *A Phase 1b Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in Patients with KRAS G12D/G12V Mutated Pancreatic Ductal Adenocarcinoma*
4. 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)*
5. 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.*
6. 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)*
7. 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. Jimeno, Antonio - # 25-1567: A Phase 1/2 Open-label, Single-arm, Multicenter Study to Evaluate the Safety and Preliminary Efficacy of Autologous SCG142 T Cell Receptor (TCR) T Cells in Patients with Advanced or Metastatic HPV16- or HPV52-positive Carcinomas

Biosafety level: BSL-2 with droplet 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 the clarification of drug preparation location, drug storage location, and participants' activity post-treatment.

*JH and CW left the meeting at 9:18am.

VIII. New Laboratory Protocol Reviews:

1. [redacted] **- # 1743: Analysis of Pathways Relevant to Tumorigenesis, Inflammation, and Development of Human Skin**
   Biosafety level: BSL-2, ABSL-1
   NIH Section(s): III-D-1, III-D-2, III-D-4, 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, adding nanoparticle use, adding IACUC protocol expiration dates, and completing protocol checkboxes.

2. [redacted] **- # 1740: Modeling placental villous development in vitro – Previously deferred by IBC**
   Biosafety level: BSL-2
   NIH Section(s): N/A
   Approved = 13
   Opposed = 0
   Abstained = 0
   The IBC protocol presented was approved with the recommendation for modifications required to address items including update BSC certification details, adding details to the research narrative, and updating laboratory cleaning details.

3. [redacted] **- # 1746: Genetic Manipulation of Human Primary and Cancer Cell Lines Using Lentiviral Vectors, CRISPR/Cas9, shRNA, and siRNA Technologies**
   Biosafety level: BSL-2
   NIH Section(s): III-D-1, III-D-2, 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 template language for *E. coli*, checking the appropriate protocol checkboxes, adding procedures in protocol to match language in the Research Narrative, and adjusting cleaning agent details as needed.

4. [redacted] **- # 1747: Characterizing genetic regulators of cutaneous tumor development**
   Biosafety level: BSL-2
   NIH Section(s): III-D-1, III-D-2, III-F
   Approved = 13
   Opposed = 0
   Abstained = 0
   The IBC protocol presented was approved with the recommendation for modifications required to address items including updating research narrative details, updating recombinant products and biomaterials sections, adding map attachments as needed, and updating PPE details.

5. [redacted] **- # 1745: Investigation of copy number landscape and metabolic reprogramming in breast cancer evolution.**
   Biosafety level: BSL-2, ABSL-1
   NIH Section(s): III-D-1, III-D-2, III-D-4, III-F

Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation for modifications required to address items including removing reference to animal use references and updating research narrative details.

IX. De Novo Laboratory Protocol Reviews:

1. [redacted] **- # 1362: Identification of genes causing cardiomyopathies and heart failure using established assays in molecular genetics.**
Biosafety level: BSL-2, ABSL-1
NIH Section(s): III-D-1, III-D-2, 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 correct IBC protocol checkboxes, updated the listed IACUC protocol expiration date, and ensuring the proper engineering controls are selected for procedures.

2. [redacted] **- # 1069: Functional Analysis of Genes Involved in Central Nervous System Development**
Biosafety level: BSL-2, ABSL-1
NIH Section(s): III-D-2, III-D-4-a, III-E-3, III-F
Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation to address minor administrative items including updating the listed expiration date for the associated IACUC protocol and adding language regarding exposure signs and symptoms.

3. [redacted] **- # 1415: Investigations into the impact of microbes, including enteric bacteria and HIV-1, on immune cell phenotype and function**
Biosafety level: BSL-2, BSL-2+, BSL-3
NIH Section(s): III-D-1, III-D-2, III-D-3, III-F
Approved = 13
Opposed = 0
Abstained = 0
The IBC protocol presented was approved with the recommendation for modifications required to address items including selecting IBC protocol checkboxes, adding rDNA details, adding biomaterial details, and adding micro/infectious procedure details.

4. [redacted] **- # 1057: Novel therapies for solid tumors**
Biosafety level: BSL-2, ABSL-1
NIH Section(s): III-D-1, III-D-4, 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 line details in the research narrative and appropriate sections as needed.

5. [redacted] **- # 1552: An expanded view of telomeres and their roles in safeguarding genome stability**
   Biosafety level: BSL-2
   NIH Section(s): III-D-1, III-D-2, 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 adding research narrative details, selecting appropriate IBC protocol checkboxes, and ensuring proper engineering controls.

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

XI. **Exempt Protocols – New/Renewal:** None

XII. **Exempt Protocol Amendments**

1. [redacted] - # 1705: *Defining the molecular determinants of viral infection competence of the intestine*
2. [redacted] - # 1164: *Translational investigation of pediatric high-grade glioma*
3. [redacted] - # 1611: *B cells, loss of tolerance, and development of autoimmunity*
4. [redacted] - # 1429: *Regulation of immune response, metabolism and cancer*
5. [redacted] - # 1566: *Natural history and pathogenesis of rheumatoid arthritis*
6. [redacted] - # 1264: *Investigations of bacterial species of interest and the further characterization of their genomes*
7. [redacted] - # 1165: *Investigation of novel cell-surface immune checkpoints in regards to cancer immunotherapy treatment*

XIII. **Additional Business:** None

XIV. **Next Meeting Scheduled:** 27 October 2025, 9:00am (Mountain Time)

XV. **Adjournment:** 10:15am (Mountain Time)