



University of Colorado  
Anschutz Medical Campus

**Institutional Biosafety Committee (IBC)**

**Zoom Meeting Minutes**

28 July 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] (BH)  
Dr. [REDACTED] (AL)  
Dr. [REDACTED] (JL)  
Dr. [REDACTED] (CM) (SM)  
Dr. [REDACTED] (Co-chair) (BM)  
Dr. [REDACTED] (Co-chair) (TM)  
Dr. [REDACTED] (TR)  
[REDACTED] (JR)  
[REDACTED] (ZW)

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

[REDACTED] (QB)  
[REDACTED] (JH)  
[REDACTED] (EJ)  
[REDACTED] (JW)  
[REDACTED] (CW)

**I. Call to Order: 09:01am (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 June 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:**

- i. [REDACTED] - # 1617
- ii. [REDACTED] - # 1362
- iii. [REDACTED] - # 1622
- iv. [REDACTED] - # 1078
- v. [REDACTED] - # 1380

**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. COMIRB representatives invited to IBC meetings: BH welcomed new IRB members joining IBC members to provide insight for new clinical trial applications.
- ii. Update to IBC Policy: BH announced new version of IBC policy for the IBC to review and vote on updates in advance for a later meeting.
- iii. Update to clinical trial application form: BH announced new version of clinical trial application form to be used for future initial submissions.
- iv. Update to animal biosafety level designations: BSO team met with OLAR and veterinary staff to update IBC protocol nomenclature to harmonize better with IACUC protocols regarding biosafety levels.

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

1. Schwartz, Marc - # 22-0054: *Phase I Safety and Tolerability Trial of CD19 Directed CAR T Cells in Adult Patients with B-Cell Acute Lymphoblastic Leukemia (B-ALL) with Minimal Residual Disease (MRD) Positivity at First Complete Remission*
2. Lindsay, Holly - # 24-0756: *Phase 2 Trial of G207 + 5 Gy Radiation for Children with High Grade Gliomas*
3. Patel, Sapna Pradyuman - # 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*
4. Podoll, Amber - # 23-2341: SC291-102: *A Phase 1 study evaluating SC291, a hypoimmune, allogeneic CD19-directed CAR T cell therapy, in subjects with severe relapsed or refractory autoimmune diseases (GLEAM)*
5. Kamdar, Manali - # 21-2578: *Phase 1/1b Study of Bispecific CD19 and CD22 Chimeric Antigen Receptor Co-Expressing T Cells (CD19x22 CAR T) in Adolescent and Adult Patients with Relapsed and/or Refractory B-Non-Hodgkin's Lymphoma (B-NHL)*
6. Podoll, Amber - # 23-2341 x2: SC291-102: *A Phase 1 study evaluating SC291, a hypoimmune, allogeneic CD19-directed CAR T cell therapy, in subjects with severe relapsed or refractory autoimmune diseases (GLEAM)*
7. Macy, Margaret - # 24-1222: NANT 2021-01: *Phase II Study of Ex-vivo Expanded Allogeneic Universal Donor Tgfb NK Cell Infusions in Combination with Temoxolomide, Irinotecan, Dinutuximab, and Sargramostim in Patients with Relapsed or Refractory Neuroblastoma*
8. Lieu, Christopher - # 22-0697: *A Phase 1 Multicenter Study Evaluating the Safety and Tolerability of GCC19CART In Subjects with Relapsed or Refractory Metastatic Colorectal Cancer (CARAPIA-1 Study)*

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

1. **Patel, Sapna Pradyuman - # 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)**  
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 clarifying that standard universal precautions will be used regarding PPE.

\*JH and CW (non-voting attendees) left the meeting at 9:18am.

**VIII. New Laboratory Protocol Reviews:**

**1. [REDACTED] - # 1740: Modeling placental villous development in vitro.**

Biosafety level: BSL-2

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was deferred with changes needed including providing more details for the research narrative, biomaterial procedures, plasmids, import/export of material, associated IRB, and overall clarification.

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

**1. [REDACTED] - # 1142: Study of developmental origins of health and disease**

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

NIH Section(s): 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 correcting protocol discrepancies, selecting appropriate protocol checkboxes for arthropod use, and clarifying propagation agents and use of fume hoods.

**2. [REDACTED] - # 1140: Studies in tumor onset and progression**

Biosafety level: BSL-2, ABSL-1

NIH Section(s): III-D-4, III-D-2, III-D-1, 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 downstream assays and vector use, selecting appropriate checkboxes for breeding and animal use, adding details for procedures, updating the protocol progress report, and updating associated animal protocol expiration dates.

**3. [REDACTED] - # 1144: Developmental genetics of growth factor signaling**

Biosafety level: BSL-1, 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 clarifying use of transgenic animal lines versus existing animals.

\*AL left the meeting at 9:57am and was no longer present for the subsequent votes.

4. [REDACTED] - # 1416: Using Lipoprotein Lipase (LPL) knock down in vivo and in microglial cell cultures to understand the role of LPL in the CNS

Biosafety level: BSL-2, ABSL-1

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including updating the research narrative and procedure sections, adding details for downstream assays and animal use, correcting discrepancies throughout the protocol, updating BSC certification and fume hood details, and adding signs and symptoms for a propagation agent.

5. [REDACTED] - # 1452: Zebrafish transgenesis and vertebrate cell fate studies

Biosafety level: BSL-1, ABSL-1

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

Approved = 12

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including adding details for international shipping and downstream assays, removing outdated laboratory work, and selecting appropriate protocol checkboxes.

X. Significant Amendment Reviews for Laboratory Protocols: None

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1737: Collection and dissemination of human peripheral blood components and cerebral spinal fluid for the purpose of multiple sclerosis research and Autoimmune mediated Encephalitis. Serve as laboratory expert for clinical neurology for the processing and shipping of biological study components
2. [REDACTED] - # 1739: The use of bioengineered arthrospira plantensis (spirulina) in mice and rat weight loss and vaccine studies.
3. [REDACTED] - # 1223: Immune responses to environmental particulates

XII. Exempt Protocol Amendments

1. [REDACTED] - # 1558: Clinical & Translational Research Center (CTRC) - Chemical and immunological assays
2. [REDACTED] - # 1728: Environmental and Genetic factors in Autoimmunity
3. [REDACTED] - # 1018: Transcription Factors and Signaling Molecules in Development
4. [REDACTED] - # 1705: Defining the molecular determinants of viral infection competence of the intestine
5. [REDACTED] - # 1274: Understanding development and progression of pediatric sarcomas.
6. [REDACTED] - # 1429: Regulation of immune response, metabolism and cancer

XIII. Additional Business: None



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**XIV. Next Meeting Scheduled:** 25 August 2025, 9:00am (Mountain Time)

**XV. Adjournment:** 10:12am (Mountain Time)