



Institutional Biosafety Committee (IBC)
Zoom Meeting Minutes
15 December 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] (EK)
Dr. [REDACTED] (AL)*
Dr. [REDACTED] (JL)
Dr. [REDACTED] (SM)
Dr. [REDACTED] (Co-chair) (BM)
Dr. [REDACTED] (Co-chair) (TM)
Dr. [REDACTED] (JR)
Dr. [REDACTED] (ZW)

Non-voting IBC Members/Guests:

[REDACTED] (AA)
[REDACTED] (QB)
[REDACTED] (EJ)
[REDACTED] (SK)*
[REDACTED] (CM)
[REDACTED] (MV)
[REDACTED] (JW)
[REDACTED] (ZJW)
[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: 17 November 2025

The minutes were reviewed and approved by the IBC.

Approved = 13

Opposed = 0

Abstained = 1 (EC)

IV. IBC Administrative Business:

A. IBC Administrative Changes:

- JW gave thanks and announced departure of Dr. Thomas Ragole from the IBC.
- CM introduced themselves as a new potential community member for the IBC.

B. Protocol Closures:

- Wilky, Breelyn - # 19-0967
- Podoll, Amber - # 23-2341

C. Protocol Transfers:

- # 25-0137: Thomas Ragole transferred to Varun Sreenivasan
- # 21-5117: Thomas Ragole transferred to Varun Sreenivasan
- # 24-0669: Thomas Ragole transferred to Amanda Piquet



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 informed confirmed the date for region 5's listening session and called for questions from the committee members to provide on their behalf. BH to check if open registration is available.

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

1. **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*
2. **Fabrizio, Vanessa** - #22-0998: *Phase I Dose Escalation and Preliminary Efficacy Study of Bispecific CD19 and CD22 Chimeric Antigen Receptor Co-Expressing T Cells (CD19x22 CAR T) in Pediatric Patients with Relapsed and/or Refractory B-Cell Acute Lymphoblastic Leukemia (B-ALL)*
3. **Benke, Tim** - # 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.*
4. **Kamdar, Manali** - #21-2578: *Phase 1 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)*
5. **Macy, Margret**.- #24-1222: *NANT2021-01: Phase II Study of Ex-Vivo Expanded Allogeneic Universal Donor Tgf β 1 Nk Cell Infusions in Combination with Temozolomide, Irinotecan, Dinutuximab, And Sargramostim in Patients with Relapsed or Refractory Neuroblastoma*
6. **Schwartz, Marc** - #22-0054: *Phase 1/1b 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*

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

1. **Schwartz, Marc** - # 25-0237: **Expanded Access Program (EAP) for Obecabtagene Autoleucel (obe-cel) Out-of-specification (OOS) in Adult Patients with Acute Lymphoblastic Leukemia**

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 the recommendation for modifications required to address items including clarifying IP out of spec parameters, receipt and storage procedures, language regarding standard of care, and selecting appropriate protocol checkboxes.



2. **Haverkos, Bradley - # 25-1099: The CAROLYN Trial: Lisocabtagene Maraleucel as First-Line Therapy for Primary Central Nervous System Lymphoma (PCNSL) in Transplant-Ineligible Patients**
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 the recommendation for administrative changes to address items including clarifying IP receipt and storage procedures.
3. **Alvarez, Enrique - # 25-2313: A Phase 1B, Open-label, Multi-center, Randomized Study Evaluating the Safety and Tolerability of AZD0120, an Autologous CD19/BCMA Targeting Chimeric Antigen Receptor T-cells, in Adults with Refractory Relapsing, or Progressing Multiple Sclerosis**
Biosafety level: BSL-2 with droplet precautions
NIH Section(s): III-C
Approved = 13
Opposed = 0
Abstained = 1 (HD)
The IBC protocol presented was approved by the IBC with no further concerns.
4. **Kamdar, Manali - # 25-2042: A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting Cd19/Cd20 Car T-Cell Product Candidate, Versus Investigator's Choice of Cd19 Car T-Cell Therapy In Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (Pinacle-H2H)**
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 the recommendation for administrative changes to address items including clarifying IP receipt, storage, preparation, transport, and administration locations, clarifying IP handling procedures, and selecting appropriate PPE checkboxes.

*AL and CW left the meeting at 9:38am.

VIII. New Laboratory Protocol Reviews:

1. [REDACTED] - # 1749: Investigating Stem Cells and Tumors in the Brain
Biosafety level: BSL-1, BSL-2
NIH Section(s): III-D-1, III-D-2, III-E-1, III-F
Approved = 13
Opposed = 0
The IBC protocol presented was approved with the recommendation for administrative changes to address items including clarifying active use of agents, updating the research narrative details, and updating the rDNA section details.

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1020: B cells and immune responses in health and during



infections, cancer, and autoimmunity

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

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 for modifications required to address items including clarifying administration of agents to animals, active use/storage of agents, details regarding the shipping/receipt of agents and associated permits, research narrative details, and procedure location details.

2. [REDACTED] - # 1389: Optical imaging and photostimulation of brain and peripheral nerve

Biosafety level: BSL-2, ABSL-1

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

Approved = 13

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for administrative changes to address items including selecting appropriate protocol and PPE checkboxes.

*SK left the meeting at 9:58am.

3. [REDACTED] - # 1640: Role of lung tissue stem/progenitor cells in exposure mediated lung diseases

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

NIH Section(s): III-D-1, III-D-2, III-D-4, III-E-1, III-E-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 appropriate protocol checkboxes and clarifying the use of human materials.

4. [REDACTED] - # 1051: Molecular Pathogenesis and Immunity of Arthropod-Borne Pathogens and other Virus Infections

Biosafety level: BSL-2, BSL-3, ABSL-2, ABSL-3

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

Approved = 12

Opposed = 0

Abstained = 1 (TM)

The IBC protocol presented was approved with the recommendation for administrative changes to address items including selecting appropriate protocol and PPE checkboxes as well as updating research narrative details.

*PD left the meeting at 10:20am.

5. [REDACTED] - # 1074: Regulation of Retinal Development

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 administrative changes to address items including updating research narrative details, adding signs and symptoms for infectious agents, updating BSC certifications, adding room numbers for procedures, and selecting appropriate protocol checkboxes.

6. [REDACTED] - # 1068: Neuron-glia interactions in the adult CNS

Biosafety level: BSL-2, BSL-1, 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 administrative changes to address items including updating IACUC protocol expiration dates, removing outdated attachments, and selecting appropriate protocol checkboxes.

X. Significant Amendment Reviews for Laboratory Protocols: None

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1417: *Islet Death and Dysfunction in Type 1 Diabetes*
2. [REDACTED] - # 1759: *Evaluation of complement activity in neonatal human cerebrospinal fluid*

XII. Exempt Protocol Amendments

1. [REDACTED] - # 1605: *Metabolic Response to Acute Stressors in Aging: Animal Models and Human Studies*
2. [REDACTED] - # 1063: *Gastrointestinal Stem Cell Biology, Inflammation and Cancer*
3. [REDACTED] - # 1628: *Cancer- and chemotherapy-induced musculoskeletal defects*
4. [REDACTED] - # 1359: *The role of the gut microbiome in immune activation, inflammation, and metabolic syndrome (MS) in people living with HIV.*
5. [REDACTED] - # 1165: *Investigation of novel cell-surface immune checkpoints in regards to cancer immunotherapy treatment*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 26 January 2026, 9:00am (Mountain Time)

XV. Adjournment: 10:37am (Mountain Time)