



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

Attendance:

Voting IBC Members:

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)
[REDACTED] (JR)
[REDACTED] (ZW)

Non-voting IBC Members/Guests:

[REDACTED] (AA)
[REDACTED] (JH)
[REDACTED] (EJ)
Dr. [REDACTED] (MJ)
Dr. [REDACTED] (SK)
Dr. [REDACTED] (CM)
Dr. [REDACTED] (MV)
[REDACTED] (JW)
Dr. [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: 27 October 2025

The minutes were reviewed and approved by the IBC.

Approved = 13

Opposed = 0

Abstained = 0

IV. IBC Administrative Business:

A. IBC Administrative Changes:

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

B. Protocol Closures:

- [REDACTED] - # 1188
- Thomas, Janet - # 23-1000

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:

1. **Environmental Health and Safety Office Updates:** None
2. **Biosafety Office Updates:** None

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. Schenk, Erin - # 24-2314 x2: *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)*
3. Thomas, Janet - # 23-1000: *A Phase 1/Phase 2, open-label, dose-escalation, and dose expansion study to evaluate the safety, tolerability, and efficacy of SAR444836, an adeno associated viral vector- mediated gene transfer of human phenylalanine hydroxylase, in adult participants with phenylketonuria.*
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. Sherbenou, Daniel - # 23-0376: *A Phase 1, Multicenter, Open-Label Study of CB-011, a CRISPR-Edited Allogeneic Anti-BCMA CAR-T Cell Therapy in Patients with Relapsed/ Refractory Multiple Myeloma (CaMMouflage Trial)*
6. Urrea, Jorge - # 24-2523: *A Phase 1b/2 Study of GC012F (AZD0120), a Chimeric Antigen Receptor T-cell (CAR T) Therapy Targeting CD19 and B-cell Maturation Antigen (BCMA) in Subjects With Relapsed/Refractory Multiple Myeloma*
7. Mathias, Marc - # 24-2596: *A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-1)*
8. Jimeno, Antonio - # 22-1490: *A Phase 1/2 study of mRNA-4359 administered alone and in combination with immune checkpoint blockade in participants with advanced solid tumors*
9. 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.*
10. Kukreja, Janet - # 24-1264: *A Phase 2, Open-Label Study to Evaluate the Safety and Anti-Tumor Activity of Intravesical Instillation of TARA-002 in Adults with High-Grade Non-Muscle Invasive Bladder Cancer*
11. 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*

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

1. [REDACTED] - # 25-2098: **ENDEAVOR: A clinical study to evaluate the safety and efficacy of ETX101, an AAV9 delivered gene therapy in infants and children with SCN1A-positive Dravet Syndrome**
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 for modifications required to address items including checking the appropriate PPE checkboxes in the biosafety site-specific SOP, clarifying the disinfection solution and procedure to be used, and consideration of a recommended single scoop recapping method.

2. [REDACTED] - # 25-2216: Phase 1/2 First-in-Human Study to Evaluate the Safety, Tolerability, and Efficacy of MZ-1866, an AAV-9 Gene Therapy Delivered by Intracerebroventricular Injection to Participants with Pitt Hopkins Syndrome

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 for administrative changes to clarify the disinfection solution and procedure to be used.

3. [REDACTED] - # 25-2206: Phase 1/2 study evaluating genetically modified autologous T cells expressing a T cell receptor recognizing a cancer/germline antigen as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors (ACTengine® IMA203-101)

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 for modifications required to clarify use of two IP and associated details.

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

VIII. New Laboratory Protocol Reviews: None

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1622: Regulation of Methylation-Controlled J Protein in mitochondrial stress (Obesity, Burn injury and Ischemia-Reperfusion)

Biosafety level: BSL-2, ABSL-2

NIH Section(s): III-D-4, III-D-2, III-D-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 details regarding the research narrative, use of vectors, and recombinant product procedures.

2. [REDACTED] - # 1175: Mechanistic and translational studies on head and neck cancers

Biosafety level: BSL-2, ABSL-1

NIH Section(s): III-D-4, III-D-2, III-D-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 details regarding the research narrative, animal strains/lines, agents in-storage versus in-use, and BSC certification dates.

3. [REDACTED] - # 1049: Infection of immunodeficient (Tg, Spontaneous, and humanized) mice with the bacterium *Corynebacterium bovis* and other commensal bacteria and their impact on human and murine immortalized tumor xenografts and allografts.

Biosafety level: BSL-2, ABSL-2

NIH Section(s): 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 clarifying details regarding the research narrative, animal breeding, pre- and post-infection procedures, downstream analysis, antibiotic administration, infectious agent use, and checkboxes throughout the IBC protocol form.

4. [REDACTED] - # 1455: Identifying protective immune responses against infections

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 clarifying details regarding the research narrative, biomaterials, procedure for RAM use, procedure locations, import permits, select agent chair letter, and checkboxes throughout the IBC protocol form.

5. [REDACTED] - # 1071: The role of voltage-gated calcium channels in anesthesia and analgesia

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 for modifications required to address items including clarifying details regarding drug administration, plasmids, animals, and cells.

6. [REDACTED] - # 1238: Understanding the biology and function of immune cells to improve outcomes after cancer and cellular therapy.

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

NIH Section(s): III-D-1, III-D-2, III-D-4, 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 clarifying details regarding the research narrative, vector use,



downstream procedures, signs and symptoms for infectious agents, and checkboxes throughout the IBC protocol form.

X. Significant Amendment Reviews for Laboratory Protocols: None

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1153: *Constitutive and injury induced postnatal intestinal neurogenesis*
2. [REDACTED] - # 1750: *Single Cell Systems Biology in the Immune System and Cancer*

XII. Exempt Protocol Amendments

1. [REDACTED] - # 1601: *B cell heterogeneity and Immunity against influenza viruses*
2. [REDACTED] - # 1340: *Phenotypic characterization of primary immunodeficiency disorders and autoimmune disease.*
3. [REDACTED] - # 1662: *Models for understanding human craniofacial disease and treatments*
4. [REDACTED] - # 1599: *Functional Genomics Facility Biosafety Protocol*
5. [REDACTED] - # 1671: *Mucosal eosinophil specialization and activation.*
6. [REDACTED] - # 1388: *hiPSC-derived retinal tissues for disease modeling and therapy development*
7. [REDACTED] - # 1435: *Phenotypic characterization of middle ears of A2ml1- and Muc5b-mutant mice*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 15 December 2025, 9:00am (Mountain Time)

XV. Adjournment: 10:26am (Mountain Time)