



Institutional Biosafety Committee (IBC)
Zoom Meeting Minutes
26 January 2026
9:00-11:00am (Mountain Time)

Attendance:

Voting IBC Members:

Dr. [REDACTED] (EC)
 Dr. [REDACTED] (HD)
 Dr. [REDACTED] (LH)
 Dr. [REDACTED] (BH)
 [REDACTED] (MJ)*
 [REDACTED] (EK)
 Dr. [REDACTED] (SK)
 Dr. [REDACTED] (AL)**
 Dr. [REDACTED] (JL)
 Dr. [REDACTED] (CM)
 Dr. [REDACTED] (Co-chair) (BM)
 Dr. [REDACTED] (Co-chair) (TM)
 [REDACTED] (JR)
 Dr. [REDACTED] (MV)
 Dr. [REDACTED] (ZJW)

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: 15 December 2025

The minutes were reviewed and approved by the IBC.

Approved = 14

Opposed = 0

Abstained = 0

IV. IBC Administrative Business:

A. IBC Administrative Changes:

- JW announced the voting status for the new IBC members.

B. Protocol Closures: None

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:

- i. BSL-3 spill 12/15/2025: BH announced a spill that was properly contained without injury/exposure and did not require reporting to NIH.
- ii. Status update of ABSL-3: BH announced that ABSL-3 is currently down due to fan failure. Fan replacement project will take 3-6 months.

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

1. 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)*
2. Bruckner, Anna - # 25-1076: *Phase 4 Master Protocol for Patients Prescribed Prademagene Zamikeracel for the Treatment of Wounds*
3. Moreland, Larry - # 22-1353: *A phase 1 study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis*
4. Medina, Theresa - # 24-1672: *Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician's Choice in Patients with Advanced Melanoma That Has Progressed on an Anti- PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]*
5. 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)*
6. 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*

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

1. Alvarez, Enrique - # 25-2553: A PHASE I, MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE SAFETY, TOLERABILITY, CELLULAR KINETICS, AND PHARMACODYNAMICS OF P-CD19CD20-ALLO1 IN PATIENTS WITH MULTIPLE SCLEROSIS

Biosafety level: BSL-2 with standard precautions

NIH Section(s): III-C

Approved = 15

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for administrative changes to update language references within the site-specific SOP document.

*MJ joined the meeting at 9:10am.

**AL, CW, and JH left the meeting at 9:14am.

VIII. New Laboratory Protocol Reviews:

1. [REDACTED] - # 1760: In Vivo Genetic Modulation Studies Using AAV Vectors in



ADPKD Mouse Models

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

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

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including checking appropriate IBC protocol form checkboxes, clarifying procedure location details, and adding procedure details throughout the protocol as needed.

2. [REDACTED] - # 1721: Role of Kidney Endothelium in Renal Disease

Biosafety level: BSL-1, BSL-2

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

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including updating recombinant product and procedure details, IBC protocol form checkboxes, procedure location details, and BSC certification details.

IX. De Novo Laboratory Protocol Reviews:

1. [REDACTED] - # 1221: Investigating therapy resistance, metastasis, and novel therapies in gynecologic malignancies.

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

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

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for administrative changes to address items including updating typographical errors, animal work details, research narrative details, biomaterial details, IACUC protocol expiration dates, IBC protocol form checkboxes, in addition to ensuring that the laboratory has the appropriate engineering controls selected, MTA documentation, and personnel listed in the IBC protocol form.

2. [REDACTED] - # 1100: Investigations into host/pathogen interactions and innate immunity in retroviral and RNA virus infections.

Biosafety level: BSL-1, BSL-2, BSL-3, ABSL-1, ABSL-2, ABSL-3

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

Approved = 14

Opposed = 0

Abstained = 0

The IBC protocol presented was approved with the recommendation for modifications required to address items including resolving IBC protocol form inconsistencies, updating animal work details, updating research narrative details, adding procedure details, attaching appropriate SOPs as needed, and updating IBC protocol form checkboxes.

X. Significant Amendment Reviews for Laboratory Protocols:

1. [REDACTED] - # 1429: Regulation of immune response, metabolism and cancer

Biosafety level: BSL-2, ABSL-2

NIH Section(s): III-D-4



Approved = 14

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, updating BSC certification dates, clarifying research narrative and associated protocol section details, and clarifying tissue fixation details.

XI. Exempt Protocols – New/Renewal:

1. [REDACTED] - # 1761: *University of Colorado Skin Cancer Biorepository Core Protocol*
2. [REDACTED] - # 1588: *Laboratory Activities Investigating Mechanisms of Mammalian Ovarian Aging*
3. [REDACTED] - # 1649: *Mechanistic understanding of DNA synthesis during mitosis.*
4. [REDACTED] - # 1643: *Regulation of Uterine Remodeling*

XII. Exempt Protocol Amendments

1. [REDACTED] - # 1370: *Pre-clinical studies in rodent and miniature swine models to improve transplant outcomes*
2. [REDACTED] - # 1060: *Role of intestinal microbiota in influencing host physiology (x2)*
3. [REDACTED] - # 1701: *Glial epigenetic control of sensory processing*

XIII. Additional Business: None

XIV. Next Meeting Scheduled: 23 February 2026, 9:00am (Mountain Time)

XV. Adjournment: 09:54am (Mountain Time)