

Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting June 17, 2026

Present (Voting)

M. Holodniy, MD (Chair)
S. Felt, DVM, MPH, DACLAM, DACVPM
P. Yang, PhD
S. Oliver, PhD
C. Campos
R. Trujillo, PhD
A. Bhatt, PhD
J. Brophy, PhD (arrived 4:08p, left 4:40p)
S. Vleck, PhD (BSO)

Also Present (Not Voting)

D. Berdnik, PhD
J. Yamada
J. Sherrill, DVM
K. Nobrega
S. Chen
C. Inacay (left ~4:18p)

Prior to the meeting, all IBC members should review:

- Confidentiality
 - The Panel proceedings are confidential. No protocols, including proprietary information, reviewed by Biosafety or IBC members and/or presented at Panel meetings should be discussed with anyone other than Panel members.
- Conflict of Interest
 - Any person with a conflicting interest in a protocol must leave the room during discussions and voting on the protocol. Conflicting interest includes participating in or supervising the project, a financial interest, a personal or fiduciary relationship, or some other situation giving rise to a conflicting interest as defined in the Guidelines for IBC Members on Conflicting Interests. A member who leaves the room for any reason will not be counted in the quorum for any vote that takes place during their absence.
- Designated Member Review
 - Please be reminded that all IBC members have agreed in advance, in writing, to use Designated Member Review subsequent to Full Committee Review when a modification is needed to secure approval of any of the protocols being discussed and voted on today. IBC members will have the modified research protocol available to them, and any IBC member may at any time request Full Committee Review of the protocol.

The meeting was called to order at 4:00 PM by M. Holodniy, Chair. A quorum (five or more voting members) was present. The meeting was hybrid.

Agenda Items

1. The first order of business was a reminder that the Panel proceedings are confidential, though

the meeting minutes shall be made publicly available. All protocols reviewed and/or presented, including proprietary information, should not be discussed outside convened meetings.

2. The second order of business was a reminder that any person with a conflicting interest in a protocol must leave the room during discussions and voting on the protocol. "Conflicting interest" includes participating in or supervising the project, an outside interest, a personal or fiduciary relationship, or some other situation giving rise to a conflicting interest as defined in the Guidelines for IBC members on Conflicting Interest. A member who leaves the room for any reason will not be counted in the quorum for any vote that takes place during their absence.
3. The third order of business was the reminder that all IBC members have agreed in advance, in writing, to use Designated Member Review (DMR) subsequent to Full Committee Review when a modification is needed to secure approval of any of the protocols being discussed and voted on today. IBC members will have the modified research protocol available to them, and any IBC member may at any time request Full Committee Review of the protocol.
4. The fourth order of business was review and voting on the minutes of May 20th 2026, which were distributed electronically to all IBC members prior to this meeting.
 - Voting on May minutes—approval, unanimous, no dissenters
5. The fifth order of business was the presentation, discussion and voting on protocols.
 1. Protocols
 - a. Clinical Reports

PI	Protocol
1. Wheeler, M.	[6073] A Phase 1/2 Multicenter, Open-Label, Dose-Escalation and Dose-Expansion Trial to Assess the Safety, Tolerability, Pharmacodynamics, and Preliminary Efficacy of AFTX-201 Administered to Adult Participants with BCL2-Associated Athanogene 3 (BAG3) Mutation-Associated Dilated Cardiomyopathy: UPBEAT Trial
	New Protocol Summary: The purpose of this study is to measure safety and any benefits to the heart with AFTX-201, a gene therapy that is infused through an IV in participants with heart disease from mutations in a gene called BCL-2 associated athanogene 3 (BAG3). AFTX-201 is an investigational recombinant Adeno Associated Virus (AAV) gene therapy consisting of a novel non-replicating recombinant AAV capsid (ATC-0187), a muscle-specific promoter, and the full-length human BAG3 transgene. AFTX-201 is being developed for the treatment of dilated cardiomyopathy (DCM) associated with mutations in BAG3, a rare disease without

	available disease modifying therapies. DCM is the most common cause of heart failure (HF) in the young and the most frequent indication for heart transplantation Training: Complete Applicable Section of the NIH Guidelines: Section III-C Containment Conditions: BSL1 Special Provisions: Hospital/Clinic Infection Control precautions Discussion: Voting: A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
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a. Basic Protocols

1. Weinacht, K.	[5010] Manipulating Pluripotent and Hematopoietic Stem and Progenitor Cell Biology and Function as a Platform for Disease Correction and Targeted Therapies
Comments	Revision: New Agent Summary: This lab will use recombinant DNA technology to engineer cells for research and gene therapy. The lab plans to design lentiviral constructs to understand how mutations affect hematopoietic stem cell/iPSC differentiation, how to correct these mutations, and how gene-corrected cells can functionally recover via over-expression or shRNA knock-down. It will develop nucleases to precisely edit the genome, either to study gene absence or insert wildtype genes. The lab will transfect DNA or RNA into cells to induce targeted genomic modifications. The lab's goals include studying gene mutation repair in differentiated cells, assessing functional restoration after gene correction, and exploring new cellular functions through gene transfer or expression modulation. Training: Complete Applicable Section of the NIH Guidelines: III-D & III-E Containment Conditions: BSL-2 Special Provisions: Aerosol Management

	New Agent Added: Epstein-Barr Virus (EBV), transformed cell line Facility Visit: June 9, 2026 Discussion: The IBC agreed that the PI needs to complete the Aerosol Transmissible Disease (ATD) training before this project is approved. Voting: A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Brophy, J.	[6169] Plant transformation - Brophy lab
Comments	New Protocol Summary: The goal is to engineer plant root systems to improve water use efficiency and increase drought tolerance. Researchers will develop and test synthetic genetic circuits (synthetic DNA) that control root growth patterns by identifying regulatory DNA elements and optimizing gene expression in specific root cell types. Using plant transformation techniques, microscopy, fluorescence-based assays, and plasmid-based DNA engineering methods, the project will evaluate how modified root architectures affect plant performance under water-limited conditions. Training: Complete Applicable Section of the NIH Guidelines: III-E Containment Conditions: BSL1 Special Provisions: N/A Facility Visit: June 9, 2026 Discussion: - Committee Member asked what gene is inserted and the PI answered it was mostly fluorescence proteins and regulators for root development. - Committee Member asked if the goal was for potential application for roots to be altered in a way to be drought resistant and/or heat resistant and the PI answered she is interested in the plants ability to tolerate stress. Currently interested in droughts but if found to be helpful, may introduce into crop plants. - The BSO mentioned the PI has implemented good security measures to make sure plant DNA is not getting out of the facility

	and pests in the facility aren't bringing anything out. • Committee Member asked about rules growing plants in lab spaces and BSO responded the BMBL pushes to eliminate non-experimental plants in spaces. • Committee Member asked where seeds are stored and the Reviewer said they are stored in the fridge and they are also used to continuously grow plants. Voting: A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
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The meeting was adjourned at 4:44 PM.