Stanford University Administrative Panel on Biosafety

The APB is the Institutional Biosafety Committee for Stanford

Minutes of Meeting September 10, 2025

Present (voting)

M. Holodniy, MD (Chair)
S. Feldman, PhD
R. Paulmurugan, PhD
P. Yang, PhD
S. Oliver, PhD (Alternate)
J. Arunachalam
R. Trujillo, PhD arrived 3:33 pm
S. Chen (Alternate) arrived 3:45 pm
S. Felt, DVM, MPH, DACLAM, DACVPM arrived 3:33 pm
S. Vleck, PhD, RBP/CBSP(ABSA)

Also Present (Not Voting)

N. Wall, PhD
D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
R. Moore (VA Palo Alto Health Care System)
J. Yamada
Y. Zhang, PhD
C. D'Apuzzo (Guest, left at 3:43)
L. Coleman (Guest, left at 3:43)

The meeting was called to order at 3:31 PM by M. Holodniy, Chair. A quorum (five or more voting members) was present. The meeting was hybrid.

Early 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 APB 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 APB 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. APB members will have the modified research protocol available to them, and any APB 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 the July 16, 2025 and

August 20, 2025 meetings which were distributed electronically to all APB members prior to this meeting.

- Approval of July and August Minutes—approval, unanimous, no dissenters

5. The fifth order of business was APB Panel Business.

- NIH Notice NOT-OD-25-082 (Vleck)
    - The Panel and Office of General Council discussed the NIH requirement to publish minutes.
- APB new naming convention (Vleck)
    - The Administrative Panel on Biosafety (APB) will officially change its name to Institutional Biosafety Committee (IBC), effective October 1 in the new panel year, in order to align with recent changes made to the IACUC name and how the panel is referred to in NIH documents. Changes to written documents will take place over the panel year.
- Preliminary report to NIH of potential exposure to rDNA (Vleck)
    - The Panel was informed of a splash to the eye of cloning E. coli containing rDNA that occurred during a DNA extraction step. This rDNA work was exempt from panel oversight. A full report will be submitted to the NIH within 30 days of the exposure. The full report will be discussed with the panel at the next meeting; the panel had no questions at this time.
- Feedback request: Pilot PI Presentations (Lin)
    - The Panel agreed the presentations were mostly helpful, and should be required for new protocols, new products, complex protocols, and PIs in the early stages of their careers with regard to clinical trials.

Protocol Review

6. The sixth order of business was the presentation, discussion and voting on protocols.

Biosafety staff performed the reviews, including considering agent characteristics (e.g., virulence, pathogenicity, environmental stability), the types of manipulations planned, the sources of the nucleic sequences (e.g., species), the nature of the nucleic acid sequences (e.g., structural gene, oncogene), the hosts and vectors to be used, and whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced, as appropriate. The protocols, reviewer comments and PI responses were made available through eProtocol to all APB members prior to the meeting. All reviewer and member concerns were addressed, with specific protocols discussed in greater detail below. The Panel then presented, discussed, and voted on the following protocols:

Clinical Protocol

PI	Protocol
1. Weng, W.	[5628-1] CCT5111: A Phase 1/2 Dose Evaluation and Cohort Expansion Study of the Safety and Efficacy of Anti-CD70 Allogeneic CRISPR-Cas9-Engineered T Cells (CTX131) in Adult Subjects With Relapsed/Refractory Hematologic Malignancies
	Report **Summary:** CTX131, is an anti-CD70 allogeneic T cell immunotherapy. Female subject treated with a 2nd round of CTX131 experienced a Grade 5 immune effector cell-associated neurotoxicity syndrome and sepsis. Both assessed as possibly related to CTX131. Note: CRISPR team has determined Stanford will no longer participate in this trial and the trial will be closed at Stanford. The related IBC protocol will be closed after this report is accepted. **Voting**: A motion was made to Accept the report and was seconded. Total 10, For 10, Opposed 0, Abstain 0

Basic Protocol

PI	Protocol
1. Einav, D.	[5878] Molecular and systems virology of RNA viruses
	New Continuing: Clone of 4593 **Summary:** The goal of the new project is to study the pathology in neurons after Influenza A (H1N1), West Nile Virus (WNV), and Human pegivirus (Hepatitis G virus (HGV)) infections in an induced pluripotent stem cell (iPSC)-derived dopaminergic neuron (DA) model in culture. Viral infections will be performed in iPSC-derived DA engineered to carry monogenic mutations associated with Parkinson's disease (PD) risk, alongside their isogenic wild-type control lines. This experimental design allows for assessment of whether potential PD-linked genetic backgrounds alter susceptibility to viral infection, neuronal survival,

	mitochondrial quality control, or transcriptional reprogramming. Infected DA neurons will be cultured for 7-10 days and analyzed for viral titers by plaque assay and quantitative polymerase chain reaction (qPCR). Downstream assays include immunostainings, Western blots, and RNA-seq analysis for transcriptional profiling. Already approved viruses on this protocol such as SARS-CoV2, Zika Virus, Venezuelan Equine Encephalitis Virus (VEEV-TC83), and Dengue Virus strains will be used for comparison to elucidate virus specificity for susceptibility of infection of PD-risk mutations in DA neurons. **Training: Complete** **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Aerosol precautions, enhanced PPE for SARS-Cov-2 Additional information **New Agent Added:** Influenza A Virus (H1N1), West Nile virus (WNV), Hepatitis G Virus **Facility Visit:** 8/26/2025 **Discussion:** ● A Panel Member asked whether different Influenza A Virus isolates will be used for co-infections. The presenter clarified that different isolates will be handled separately inside a biosafety cabinet (BSC). ● A Panel Member asked whether the flu vaccine was recommended to researchers handling Influenza A Virus. The presenter confirmed that the seasonal flu vaccine was recommended during the lab visit and confirmed that the risk section contains a vaccine recommendation statement. ● A Panel Member inquired about the disposal and chemical guidance for work with the herbicide paraquat. The presenter confirmed that the lab is instructed to handle paraquat as hazardous chemical waste as stated on the protocol. The BSO added that the Research Safety group can provide the lab with further safety guidance on paraquat handling and disposal. **Voting:** A motion was made to approve the protocol and was seconded. Total 10, For 10, Opposed 0, Abstain 0

The meeting was adjourned at 4:23 pm.