Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting March 18, 2026

Present (Voting)

M. Holodniy, MD (Chair)
S. Feldman, PhD (Co-Chair)
S. Felt, DVM, MPH, DACLAM, DACVPM
P. Yang, PhD
R. Paulmurugan, PhD
S. Oliver, PhD
C. Campos
S. Chen
K. Lin, PhD
J. Arunachalam

Also Present (Not Voting)

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
J. Yamada
K. Nobrega
S. Rayate (left at 4:21 pm)
C. Inacay (left at 4:21 pm)
A. Johnson, PhD
B. Donnelly, PhD
R. Moore

The meeting was called to order at 4:05 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 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 February 18, 2025, which were distributed electronically to all IBC members prior to this meeting.

    - Voting on February minutes—approval, unanimous, no dissenters

5. The fifth order of business was the presentation, discussion and voting on protocols.

a. Clinical Studies

PI	Protocol
1. Muffly, L.	[6055] CCT5133: A Phase II Trial of Obecabtagene Autoleucel Consolidation in Adult Patients with Acute Lymphoblastic Leukemia in First Complete Remission Without Measurable Residual Disease
	New Protocol **Summary:** Obecabtagene autoleucel (obe-cel) is a Chimeric Antigen Receptor T-cell (CAR-T) product with a unique "fast-off" CD19 (Cluster of Differentiation) binder and a 41BB co-stimulatory domain. Adult patients diagnosed with acute lymphoblastic leukemia (ALL) continue to face a grim prognosis. CAR T treatment in ALL is more effective and less toxic when used in low disease burden settings. Here, we propose a Phase II study to determine the efficacy of obe-cel consolidation treatment in adult patients with ALL who are in first MRD-negative CR (Minimal Residual Disease-Negative Complete Remission). **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● No questions **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Dahiya, S.	[6075] CCT5136: A Phase 3, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy of KITE-753 Versus Axicabtagene Ciloleucel in Participants with Relapsed or Refractory Large B-Cell Lymphoma After First-Line Therapy
	New Protocol **Summary:** KITE-753 is an autologous, anti-CD19/CD20 (Cluster of Differentiation) CAR T-cell (Chimeric Antigen Receptor) product generated by the transduction of a participant's T cells with a bicistronic lentiviral vector (LVV) encoding an anti-CD19 CAR and an anti-CD20 CAR. The target population are those diagnosed with Large B-cell Lymphoma (LBCL), a subtype of non-Hodgkin's lymphoma (NHL). The LBCL population with the highest unmet need continues to consist of patients who do not respond to

	first-line combination chemo/immunotherapy. CAR T-cell therapies, such as axicabtagene ciloleucel have revolutionized the treatment landscape for 2L (2nd line)+ r/r (relapsed or refractory) LBCL, demonstrating remarkable efficacy in achieving durable responses in a subset of these patients. However, the majority of patients still relapse or progress after receiving the currently approved CD19-directed CAR T-cell therapies and are in need of more effective treatments. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● No question **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 8, Opposed 0, Abstain 1

b. Basic Studies

PI	Protocol
1. Chiu, W.	[5086] Electron cryomicroscopy (cryo-EM) of pathogens and pathogen-infected cells
	Revision: Added New Agent **Summary:** This project will leverage cryo-EM and cryo-ET to determine high-resolution structures of pathogens (viruses, bacteria, parasites) and infected cells coated in thin ice films. This project will characterize viral genome translation and host responses during infection through collaborative studies, combining structural biology with cellular and biochemical assays. This project will investigate chaperone mechanisms in protein homeostasis, focusing on: (a) protein aggregation, and (b) neuronal protein dysregulation in aging and Alzheimer's disease. **Training:** Incomplete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** Enhanced disinfection **New Agent Added:** *Toxoplasma gondii*

	Facility Visit: Scheduling **Discussion:** ● A Committee Member asked where samples will be loaded. Biosafety responded in the procedure room maintained at negative pressure relative to the corridor. ● Committee members discussed if all researchers who will work with T. gondii should consult the Occupational Health Center (OHC) before starting work to discuss T. gondii seropositivity status and susceptibility. Committee members agreed to recommend OHC consultation. Approval Conditions: ● The IBC strongly advises all researchers who will work with T. gondii to consult the Occupational Health Center (OHC) before starting work to discuss T. gondii seropositivity status and susceptibility. ● Researchers must complete annual Bloodborne Pathogen training prior to receiving approval. ● Training must be completed. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Thaiss, C.	[5666] The study of environment-body-brain interactions in purpose bred mice
	Revision: Updated Personnel, Updated Agents **Summary:** This lab will investigate gut-brain-immune-metabolic interactions using murine models to decipher how dietary, pharmacological, and stress interventions alter neuroimmune signaling, microbiota dynamics, and disease progression. The lab will use viral vector strategies (AAV, PRV, CAR-T cells) to manipulate neural circuits and immune responses and characterize age- and sex-dependent effects on tumor-immune interactions through multi-omics and spatial transcriptomics. The lab will translate insights by mapping how chronic inflammation accelerates neurodegeneration in diabetic Alzheimer's models via tumor microenvironment analysis and identifying biomarkers linking gut permeability, systemic inflammation, and behavioral outcomes. **Training:** Incomplete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2

	Special Provisions: Enhanced Decontamination **New Agent Added:** *Mycobacterium avium, Mycobacterium bovis* **Facility Visit:** March 3, 2026 **Discussion:** ● Committee Members discussed if all researchers who will work with Mycobacterium bovis BCG should consult the Occupational Health Center (OHC) before starting work to discuss seropositivity status and susceptibility. Committee members agreed to recommend OHC consultation. ● A Committee Member asked whether biograms were provided. Biosafety responded that no biogram was available, but that the lab would like guidance on how to proceed with biograms. The Committee determined that a biogram was required; the IBC chair will provide assistance to the lab. ● A Committee Member asked whether proper disinfectants will be available for decontaminating animal housing. Biosafety confirmed yes, and noted that EH&S will provide a list of EPA-approved disinfectants suitable for use in animal housing. ● A Committee Member asked where their *in vivo* work be conducted. Biosafety responded that the lab would like to conduct work at the off-campus vivarium. The Committee members discussed and, in support of current VSC policies, confirm that work must be done in appropriate BSL2 vivariums for on campus dedicated to infectious agents. Approval Conditions: ● Researchers will consult the Occupational Health Center (OHC) before starting work, and specifically regarding TB testing for work with Mycobacterium bovis BCG. ● Animal work with both Mycobacterium bovis BCG & Mycobacterium avium must be conducted on campus in the biohazardous animal suites dedicated to infectious agents. ● A biogram for Mycobacterium bovis BCG and Mycobacterium avium Chester is required ● The lab must ensure that all experimental locations where we will work with Mycobacterium bovis BCG or Mycobacterium avium will have the adequate environmental disinfectants available

	• Researchers must complete annual Bloodborne Pathogen training prior to receiving approval. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
3. Daniels, K.	[6082] Engineering receptors and signaling adapters to control cell function
	New Continuing: Clone of 4828 **Summary:** Replication-competent HIV strains are generated to study how engineered immune cells control viral spread. The lab will take engineered immune cells and add HIV to the cells in succession over a period of 18 days and perform live cell imaging to see if the T-cells can continue to fight off HIV. After 18 days, the cells will be fixed and stained for flow cytometry. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL2 **Special Provisions:** Enhanced disinfection **New Agent Added:** Human Immunodeficiency Virus **Facility Visit:** March 4, 2026 **Discussion:** • A Committee Member asked for the strain of HIV the lab is working with and Biosafety confirmed it was ACH2. • A Committee Member asked if there would be a lid on the plate when it was in the live cell imager and Biosafety noted they would follow up with the lab to confirm that there will be a plate kept on due to plate moving from live cell imager to BSC so frequently. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

The meeting was adjourned at 5:08 PM.