Stanford University Administrative Panel on Biosafety

The APB is the Institutional Biosafety Committee for Stanford

Minutes of Meeting August 20, 2025

Present (voting)

M. Holodniy, MD (Chair)
Y. Maldonado, MD (Co-Chair)
A. Bhatt, MD, PhD
S. Feldman, PhD
R. Paulmurugan, PhD
S. Oliver, PhD (Alternate)
C. Campos
R. Trujillo, PhD
S. Felt, DVM, MPH, DACLAM, DACVPM
S. Vleck, PhD, RBP/CBSP(ABSA)

Also Present (Not Voting)

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
R. Moore (VA Palo Alto Health Care System)
K. Nobrega
S. Rayate (Research Compliance Office)
L. Taylor, PhD
J. Yamada
Y. Zhang, PhD

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 held virtually online.

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, meeting which were distributed electronically to all APB members prior to this meeting.

    - Tabled due to Panel Member request to consult Office of General Counsel

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

    - Biosafety Personnel Updates
        - The Panel thanks D. Cunanan for her service
    - Panel nomenclature: Name change from APB to Institutional Biosafety Committee
        - Panel Members agreed with proposed change
        - If approved by the Dean of Research, the change will take effect at the start of the the next panel year (October 2025)
    - New APB website shared with Panel Members

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 sufficiently addressed, except as noted in discussions below. The Panel presented, discussed and voted on the following protocols:

Clinical Protocols

PI	Protocol
1. Muffly, L.	[5832] CCT5126: A Single-Arm, Open-Label, Multi-Center, Phase 1b/ 2 Study to Evaluate the Safety, Efficacy, and Cellular Pharmacokinetic Profile of CTD402 in Participants with Relapsed/Refractory T-cell Acute Lymphoblastic Leukemia (T-ALL) and Lymphoblastic Lymphoma (TLBL) (TENACITY-01)
Comments	**New Protocol** **Summary:** The main purpose of the Phase 1b portion is to evaluate the safety and determine the best dose of CTD402 when given via

	intravenous infusion in adolescents and adults with relapsed/refractory (r/r)T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (T-ALL/LBL). The main purpose of Phase 2 is to further assess the effectiveness and safety of CTD402 in patients with r/r T-ALL/LBL. CTD402 is a CD7-targeting universal Chimaeric Antigen Receptor T cell (CAR T) therapy. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL1 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A Panel Member asked, regarding the adverse events, when does the pancytopenia typically develop in the subjects, and did they eventually recover? The Presenter answered, based on the data provided, the cytopenia is prolonged, often lasting several weeks, and confirms patients recover. ● A Panel Member asked what are the iterations in the manufacturing process? Another Panel Member answered that adherence to GMP protocols naturally becomes more strict through development stages under FDA oversight, which is standard. ● A Panel Member asks, regarding the viral vector itself, can you confirm it's a non-SIN (Self-Inactivating) vector? Karen confirms it is a non-SIN vector but that it is still replication incompetent. **Voting**: A motion was made to Approve the protocol and was seconded. Total 10, For 10, Opposed 0, Abstain 0

Basic Protocol

PI	Protocol
1. Pulendran, B.	[4674] Microbes, dendritic cells, immunological memory and vaccines
	Revision: Updated Description, Agents Used **Summary:** The goal of this project is to evaluate the protective efficacy and immunological mechanisms of a novel mucosal adjuvant against SARS-CoV-2 infections using two different animal models. In a collaboration with Tulane University, the Pulendran lab received plasma, bronchoalveolar lavage (BAL), and Peripheral Blood Mononuclear Cells

	(PBMCs) harvested from immunized and SARS-CoV2 (strain KP.3) challenged animals for immune profiling analysis at Stanford. In a second model, the lab will use animals vaccinated with the same adjuvant and challenged with SARS-CoV2 (strain B1.351) to determine weight loss during the administration timeline and viral load in the lungs by qPCR. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Enhanced decontamination and aerosol precautions Additional information **New Agent Added:** SARS-CoV2 strains KP.3 and B1.351 **Facility Visit:** 7/29/2025 **Discussion:** ● A Panel Member asked whether for the second animal model, the lab is doing any in vitro experiments other than checking the viral load in the lungs. The Presenter confirmed that only viral titers in the lung will be analyzed by qPCR and no other experiments will be performed at Stanford. ● A Panel Member asked whether all virus administrations into animals will be performed at Animal Biosafety Level 2 (ABSL2) in a biosafety cabinet (BSC) and what are the precautions taken regarding sneezing of animals during intranasal application procedures. The Presenter clarified that all virus administrations and handling of infected animals will occur inside a BSC, treated animals will be lightly anesthetized before virus administration, and researchers will wear the following PPE: disposable gown, gloves, protective eye glasses, hair bonnet, booties, and a mask. The lab routinely works with other approved aerosol transmitted disease (ATD) agents at ABSL2 and the personnel working on this project has prior ABSL2 experience including specific expertise with the relevant techniques. ● A panel member asked whether the animal work at Tulane falls under Tulane's or Stanford's IACUC purview. The Presenter confirmed that the animal work carried out at Tulane University is covered under Tulane's IACUC purview, no Stanford researchers will be involved in animal work at Tulane, and animal health reports will be reviewed and attached to the protocol for material being transferred to Stanford. **Voting:** A motion was made to approve the protocol and was seconded. Total 10, For 10, Opposed 0, Abstain 0
2. Robinson, W.	[5812] Viral Triggers: Investigating the Role of Viruses in Autoimmune

	Disease
	Revision: Updated Description, Agents Used **Summary:** This project seeks to investigate the role of human herpesviruses, particularly Epstein-Barr virus (EBV), in the development of autoimmunity. To achieve this, the lab will use lentiviral vectors to deliver individual herpesviral genes into cell lines, allowing functional characterization of these viral proteins. Additionally, the lab will generate infectious EBV particles and use them to transform primary B cells into lymphoblastoid cell lines (LCLs), establishing a model system for EBV infection studies. This lab will then study how LCLs respond to secondary infection with Influenza virus (H1N1) and Herpes viruses (HHV1 & HHV6). These approaches will be complemented by functional assays to examine how EBV and specific viral genes modulate immune cell behavior in autoimmune contexts. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** None Additional information **New Agent Added:** Influenza virus (H1N1) and Herpes viruses (HHV1 & HHV6) **Facility Visit:** 08/04/2025 **Discussion:** ● A Panel Member asked if the virus is inactivated, how do you accurately achieve a specific Multiplicity of Infection (MOI)? MOI is based on infectious units. Is the MOI calculated from the original stock? The Presenter noted MOI was likely based on the titer from the pre-inactivated stock, but exact details on how MOI for the inactivated virus will be determined will be added to the protocol. **Voting:** Motion was made to Approve with Contingency and was seconded. Total 10, For 10, Opposed 0, Abstain 0 Conditions of Approval: 1. Clarify within the protocol how MOI is determined for inactivated virus stocks.

3. Monje-Deisseroth, M.	[5400] Studying neural precursor cells and brain tumor initiating cells and effects of systemic infection on neurobiology virus infection
	Revision: Updated Description, Agents Used **Summary:** This project aims to define the systemic and central nervous system immunopathogenicity of influenza A and SARS-CoV-2 respiratory infections by examining changes in serum/CSF cytokine profiles, circulating immune cells, and neuroimmune trafficking. The lab will measure blood and cerebrospinal fluid cytokine profiles in animals at serial timepoints following a single respiratory challenge, while analyzing immune cell composition and transcriptional states in blood, Cerebrospinal fluid, and brain tissue using sequencing techniques and spatial transcriptomics. Neuroinflammatory responses will be characterized through immunohistochemistry, with additional investigations into infection effects on neuronal function, synaptic plasticity, neurovasculature and myelination using optogenetics, electron microscopy and behavioral assays. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Enhanced decontamination and aerosol precautions Additional information **New Agent Added:** SARS-CoV-2 **Facility Visit**: 8/15/2025 **Discussion:** ● A Panel Member suggested the lab update the protocol title to better reflect expanded protocol focus. The presenter thanked the Member for this suggestion and will provide it to the lab. **Voting:** A motion was made to approve the protocol and was seconded. Total 10, For 10, Opposed 0, Abstain 0
4. Nowatzky, J.	[5831] Biology of Immune Mediated Diseases
	New Protocol **Summary:** The goal is to uncover the biological mechanisms driving autoimmune diseases, focusing on gene expression and immune activity. Using Epstein-Barr Virus (EBV), the lab will create EBV-immortalized lymphoblastoid cell lines (LCLs), which they will then use to study genes

	involved in immune regulation, anti-inflammatory signaling and autoimmunity that underlie disease development and persistence through molecular and protein analysis. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** None **Facility Visit**: 7/31/2025 **Discussion:** ● A Panel Member asked if plasmids or wild type EBV are used. The Presenter answered that the lab plans to use replicon plasmids to produce the virus and may also purchase pre-made EBV supernatants. ● A Panel Member asked if the plasmid used the full genome and if the genome is engineered, does it contain a selectable or reporter marker that can be tracked during infection. The Presenter will request this information from the lab. ● A Panel Member asked how the lab will titrate the supernatant to determine the concentration of infectious units. The Presenter will request this information from the lab. **Voting:** Motion was made to Approve with Contingency and was seconded. Total 10, For 10, Opposed 0, Abstain 0 Conditions of Approval: 2. Clarify and add to the protocol if necessary if the plasmid is the complete genome and contains any selectable markers. 3. Clarify within the protocol how titration will occur.
5. Mignot, E.	[5853] Measurement of Influenza hemagglutinin antibody titers in narcolepsy
	New Protocol **Summary:** This project aims to investigate the association between influenza virus infection or vaccination and the onset of narcolepsy. The lab will use a hemagglutination inhibition assay to assess the presence and quantity of influenza virus (Influenza A and B, non-high pathogenic, purchased from commercial vendors) in study participants. In this assay, influenza virus will be incubated with serial dilutions of participants' serum samples in 96-well plates. The resulting antigen–antibody mixtures will then be

	incubated with commercially available chicken red blood cells to observe whether hemagglutination occurs. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** None **Facility Visit**: 8/7/2025 **Discussion:** ● A Panel Member asks how many virus strains does the lab have and what are they specifically? The Presenter responds that the lab has provided a preliminary list of about 20 potential strains. The final selection will be made from this list. They are all obtained from recognized sources like ATCC and NIBSC. The main criteria for inclusion is that they must be strains recognized by the WHO as targets for vaccine development. The lab will confirm to Biosafety the final selected strains once they are identified. ● A Panel Member asks, regarding the human serum samples, are these already collected specimens from prior studies? And does their use in this new protocol have the necessary IRB approval? The Presenter answers yes, they were collected previously for other studies, and yes, it was confirmed that the appropriate IRB approval is in place for the use of these samples in this work. ● A Panel Member asks how many human subjects do these samples represent? The Presenter notes this information will be requested. **Voting:** Motion was made to Approve with Contingency and was seconded. Total 10, For 10, Opposed 0, Abstain 0 Conditions of Approval: 4. Clarify and add to the protocol how many human subjects the IRB samples represent.

The meeting was adjourned at 5:23 pm.