Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting November 19, 2025

Present (Voting)

M. Holodniy, MD (Chair)
S. Feldman, PhD
P. Yang, PhD
C. Nagamine, DVM, PhD
R. Paulmurugan, PhD
S. Oliver, PhD (Alternate)
S. Vleck, PhD, RBP/CBSP(ABSA)
R. Trujillo, PhD
C. Campos

Also Present (Not Voting)

J. Arunachalam, left 4:40 pm
D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
K. Nobrega, left 4:55 pm
J. Yamada
Y. Zhang, PhD
A. Johnson, PhD
S. Chen
S. Rayate, left 5:05 pm

The meeting was called to order at 4:32 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 the October 15, 2025 which were distributed electronically to all IBC members prior to this meeting.

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

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

PI	Protocol
1. Prolo, L.	[5856] A Phase 1/2, Multicenter, Open-Label, Dose-Escalation, Safety, Tolerability, and Clinical Activity Study of a Single Dose of JAG201 Gene Therapy Delivered Via Intracerebroventricular Administration in Participants with SHANK3 Haploinsufficiency
	New Protocol **Summary:** This is a Phase 1/2, first in human, open-label, dose-escalation study to evaluate the safety, tolerability, and clinical activity of a single dose of JAG201 administered via intracerebroventricular (ICV) injection in pediatric and adult participants with SHANK3 haploinsufficiency resulting from SHANK3 loss of function mutations and chromosomal deletions encompassing the SHANK3 gene. JAG201 is an adeno-associated virus (AAV) serotype 9 (AAV9) expressing a miniature version of the wildtype (WT) human SHANK3 (miniSHANK3) complementary deoxyribonucleic acid (cDNA), designed to deliver functional miniSHANK3 protein to patients with SHANK3 haploinsufficiency (SHANK3 haploinsufficiency occurs when one copy of the gene is either deleted or contains a loss of function mutation and the remaining functional copy of the gene cannot produce enough protein to preserve normal function). SHANK3 haploinsufficiency is characterized by lifelong and severe neurobehavioral, developmental, motor, and cognitive impairments. **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 if the pediatric subjects already have a catheter in place; the reviewer confirmed the catheter will be placed during administration. ● A Panel Member asked whether the catheter is removed immediately after administration or left in; the reviewer noted they will ask the lab. **Voting:** CONDITIONALLY APPROVED

	A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 This project was conditionally approved by the Institutional Biosafety Committee (IBC) on November 19th, 2025. Please note that no work may be done under a conditional approval. The following condition(s) must be resolved prior to full approval being granted: 1. Please indicate if the catheter will be removed after administration.
2. Steinberg, G.	[5869] A Multicenter, Sham-controlled, Randomized Study to Evaluate the Safety, Tolerability, and Clinical Responses following Stereotactic Intracranial Implantation of DSP-1083 into Subjects with Parkinsons Disease (A Phase 1/2 Trial)
	New Protocol-Tabled in October **Summary:** The purpose of this clinical research study is first-in-human (FIH) study designed to evaluate the safety, tolerability, and clinical responses following implantation of DSP-1083 compared with sham surgery. DSP-1083 areDopaminergic (DA) progenitor cells made using human induced pluripotent stem cells (iPSCs) that were generated by transducing human PBMCs from a healthy donor with Sendai viral vector expressing reprogramming factors. **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 stated that the provided donor screening list was satisfactory and confirmed the product had been efficiently screened and was suitable for use. It was also noted that this information helpfully clarified the "healthy donor" description, which was missing during the previous meeting. ● A Panel Member added that since the FDA requires this information, having the donor screening details is positive and important. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

3. Dunn, J.	[5916] A SINGLE-ARM, OPEN-LABEL, PHASE I STUDY TO DETERMINE THE SAFETY, TOLERABILITY, AND PRELIMINARY EFFICACY OF OBE-CEL IN PARTICIPANTS WITH REFRACTORY PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS
	New Protocol **Summary:** Obe-cel is prepared from enriched autologous T cells that are transduced with a lentiviral vector to express a novel, second generation CAR targeting CD19 with a 4-1BB and CD3-ζ endodomain (CD19 CAR T cells). This is a single-arm, open-label, Phase 1 study to evaluate the safety, tolerability, and preliminary efficacy of obe-cel in participants with refractory Progressive forms of Multiple Sclerosis. **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 found the protocol to be straightforward, noting the product is already used for other diseases and that all other requirements have been met. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
4. Arai, Sally	[5930] A Phase 1b, Open-label, Multi-cohort Study of AZD0120, an autologous CD19/BCMA Targeting Chimeric Antigen Receptor T-cell, in Adults with Autoimmune Diseases (IRB 83399)
	New Protocol **Summary:** AZD0120 is a liquid cell suspension for IV infusion that is composed of autologous T-cells transduced with a Lenti Viral Vector encoding a dual anti-CD19 and anti-BCMA CAR. This is a Phase 1b, open-label, multi-centre, multi-cohort clinical study of AZD0120, a CD19/BCMA dual CAR T-cell therapy, to evaluate the safety and tolerability in adult participants with systemic sclerosis (SSc), idiopathic inflammatory myopathies (IIM), or difficult-to-treat rheumatoid arthritis (D2T RA). **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 if patients in this study have the same conditions as the patients in the Japan study; the reviewer informed the panel that the Japan study involves patients with lupus. ● A Panel Member stated that while the conditions are slightly different, they are both inflammatory; they also noted the oversight of the study. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
5. Betof Warner, A.	[5939] IMA203-101, Phase 1/2 study evaluating genetically modified autologous T cells expressing a T-cell receptor recognizing a cancer/germline antigen as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors (ACTengine® IMA203-101)
	New Protocol **Summary:** Each IMA203 T-cell product is a cell suspension that contains engineered T-cells expressing T-cell receptor specific to PRAME (Preferentially Expressed Antigen in Melanoma)-004 target peptide presented by HLA-A*02:01. IMA203CD8 is the second-generation product candidate targeting the PRAME HLA-A*02 peptide. To evaluate safety and tolerability of treatment with ACTengine IMA203/IMA203CD8 products as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors. **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 noted that there were no comments or concerns and that all other requirements have been met. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
6. Day, J.	**[5946] A single-arm, open-label, dose-escalation study to evaluate the safety, tolerability and efficacy of a single intravenous infusion of AB-1009 in adult participants with late onset Pompe disease (LOPD)**

	New Protocol **Summary:** AB-1009 is an Adeno-Associated Virus (AAV) vector containing the Acid α-glucosidase (GAA) gene under the control of a liver-specific promoter. Upon administration via a single intravenous (IV) infusion, the GAA gene delivered by the AAV vector expresses and secretes GAA primarily from transduced hepatocytes. Pompe disease is a rare disorder of metabolism inherited in an autosomal recessive manner, caused by deficiency of the lysosomal enzyme GAA due to mutations in the GAA gene. **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 noted that there were no comments or concerns and that all other requirements have been met. **Voting:**A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

2. Basic Research Protocols

PI	Protocol
1. Chen, L.	[4712] Retinoic Acid Mediated Transmission in Synaptic Plasticity
	Revision: Updated Description, Agents Used, Animals/Cells, Safety, Risk **Summary:** The lab is studying how Varicella-Zoster Virus (VZV) might cause nerve pain. VZV doesn't naturally infect mice so human cells infected with VZV will be inoculated into the hind foot. Three days later, the researchers will perform behavioral testing to test whether mice show signs of nerve pain or sensitivity in the affected foot using the Von Frey test (tests mechanical sensitivity or allodynia) or Cold plantar test (tests how mice respond to a cool surface). The behavioral testing is done every 3-5 days for 4-5 weeks. No samples will be collected from the mice. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL2

	Special Provisions: None Additional information **New Agent Added:** Varicella-Zoster Virus (VZV) **Facility Visit:** October 29, 2025 **Discussion:** ● A Panel Member asked why the researcher was planning to wear an N95 mask during behavioral testing if VZV doesn't shed in mice. The reviewer responded that the researcher prefers to wear masks when working with animals. The Panel Member asked for it to be stated in the IBC protocol that wearing an N95 mask is voluntary. ● A Panel Member asked if researchers working with VZV should consult with the Occupational Health Center (OHC) prior to starting work, even if they have a history of chickenpox or vaccination. The panel determined the reviewers should be directed to consult with the OHC, and the OHC would determine in each case if medical surveillance or other follow up is recommended. **Voting:** CONDITIONALLY APPROVED A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 This project was conditionally approved by the Institutional Biosafety Committee (IBC) on November 19th, 2025. Please note that no work may be done under a conditional approval. The following condition(s) must be resolved prior to full approval being granted: ● Add language into the protocol regarding voluntary use of N95. ● Add language to the protocol that all researchers must contact OHC prior to starting work with VZV.
2. Chiu, W.	[5086] Electron cryomicroscopy (cryo-EM) of pathogens and pathogen-infected cells
	Renewal: Updated Are you using, Project Locations, Description, Agents/Used, Animals/Cells, Risk **Summary:** BC-3 cells will be (a B-lymphocyte cell line from a patient with a lymphoma) transfected with Kaposi's Sarcoma-associated Herpesvirus (KSHV) from a collaborator. Cells will be shipped pre-frozen on the cryo-em grid. Electron cryomicroscopy (cryo-EM) will be used to image the infected cells.

	Training: Complete **Applicable Section of the NIH Guidelines:** N/A **Containment Conditions:** BSL2 **Special Provisions:** none **Additional information** **New Agent Added:** KSHV **Facility Visit:** October 29, 2025 **Discussion:** ● A Panel Member notes there are no comments or concerns from IBC and that all other requirements have been met **Voting:** Approved A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
3. Yang, P.	[5228] Chemical Biology Studies of Viruses
	Revision: Updated rDNA, Synthetic Nucleic Acid Molecules, Agents used, Animals/Cells, Risk **Summary:** The goal of this project is to develop small molecule antivirals and validate new antiviral targets and mechanisms of virus infection. The lab will identify lead antiviral compounds and optimize their activity, selectivity, and mechanism of action. In this revision, the lab added various SARS-CoV2 infectious full-length and reporter strains as well as an attenuated deletion mutant strain SARS-CoV2deltaMac1. The goal is to perform in vitro live microcopy of reporter viruses after infection of host cells, immunohistochemistry of infected, fixed cells, and protein and RNA detection with or without adding antiviral compounds. Various established inactivation methods for SARS-CoV2 published in the literature will be used. **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:** rSARS-CoV-2 reporter strains **Facility Visit:** October 17, 2025 **Discussion:**

	• A panel member asked to change the signage posted on the door to the room for live imaging from:"SARS-CoV2 work in progress" to "live, infectious SARS-CoV2 work in progress" to indicate more clearly the nature of the experiment. This signage will be posted during the loading of the samples onto the microscope stage and live imaging. The presenter confirmed that this administrative control is added in the precautions section of the protocol. • A panel member inquired about restricted access to the room while the loading of infectious samples onto the microscope stage and live imaging is performed. The presenter confirmed that the door will be locked and can only be accessed by personnel with a physical key, wearing appropriate PPE, and approved for this project. **Voting:** APPROVED A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0**.**
4. Boyd, S.	[5500] Studies of human immune responses to SARS-CoV-2 infection; Continuation
	Renewal: Updated Are you using, Personnel Info, Project Locations, Description, Agents Used, Risk **Summary:** This project aims to investigate the pathology and immunology of SARS-CoV-2 infection and vaccination by studying how the host immune system responds in both healthy and patients with underlying conditions such as controlled HIV infection. This research tries to identify the immunological characteristics of an effective vaccine response in infected individuals, which could guide the development of diagnostic and prognostic tools, improve vaccine design, and inform future therapeutic strategies. Follow-up analyses will include evaluation of humoral immune responses and pseudovirus neutralization assays to assess neutralizing antibody activity. **Training:** Incomplete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Enhanced decontamination and aerosol precautions **Additional information** **New Agent Added:** HIV **Facility Visit:** November 13th, 2025

	Discussion: ● A Panel Member asked whether HIV-1 patient samples would be used with live SARS-CoV-2. The reviewer clarified that this work is intended for comparison with their other SARS-CoV-2 research. ● A Panel Member asked where the healthy samples are being sourced from. The reviewer responded that this IBC protocol is linked to an IRB protocol; the reviewer will verify and confirm the source. **Voting:** CONDITIONAL APPROVAL A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 Contingencies: Confirm that the linked IRB protocol explicitly approves the collection of 'healthy patient' samples and defines the criteria for what constitutes a 'healthy patient' for this purpose. If it does not, provide this information and the associated IRB.
5. Levy, M.	[5667] Studying the role of the intestinal microbiome in purpose bred mice
	Revision: Updated Are you using, Other Panels, Project Locations, Description, Agents Used, Animals/Cells, Risk **Summary:** This lab will explore metabotherapy which uses metabolites as vehicles and targets to prevent and treat disease. Their research focuses on deciphering the unidentified metabolites in the human gastrointestinal tract, investigating how host, microbiome, dietary, and environmental molecules impact whole-body physiology. The lab aims to understand how these intestinal metabolites regulate health outcomes and apply this knowledge to develop therapeutic interventions for conditions like cancer and infections. This work will also utilize acute (Armstrong) and chronic (Clone 13) strains of lymphocytic choriomeningitis virus (LCMV), to investigate host-pathogen interactions and the effects of viral persistence on cellular function. This lab confirms that it does not currently plan to work with LCMV-infected mouse brain tissue. The described work does not qualify as a Dual-Use Research of Concern (DURC) experiment, and this determination has been evaluated and confirmed by the institutional biosafety and biosecurity team. **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:** Lymphocytic Choriomeningitis Virus (Armstrong common laboratory strain and the Clone-13 variant) **Facility Visit:** October 15, 2025 **Discussion:** ● A Panel Member inquired where the mice would be housed, specifically asking if there is an ABSL2 facility at the Arc Institute. The Reviewer confirmed that mouse work would be conducted at the 3174 Porter animal housing and experimental rooms. The panel discussed that generally only viral vector work is done at ABSL2 at this facility and the majority of work with infectious diseases in animals is done in specific ABSL2 suites on campus. It was determined that this work should be done in the on campus ABSL2 animal facility and that lab personnel should be responsible for all animal work including cage changes, as is typical for infectious agent work. Additionally, all work should be done in a BSC. Biosafety noted they will work with the lab regarding transport to main campus as needed. ● A Panel Member strongly recommended that lab workers wear N95 masks due to the known risk of personnel acquiring infections from handling bedding and infected mice, noting the inherent hazard of handling infected animals. The panel agreed this should be done for any handling of animals outside the BSC. ● A Panel Member asked why the two strains of LCMV are being injected at different anatomical locations; the Reviewer stated this information was not included but they would inquire with the lab. ● A Panel Member also asked if the animals are sedated during injections; the reviewer confirmed that the mice will be sedated during the administration of LCMV. **Voting:** CONDITIONAL APPROVAL A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 Contingencies: 1. All animal work must be conducted at the RAF facility 2. Researchers wear N95 respirators when handling infected mice or cages, especially during procedures outside of a Biosafety Cabinet.