Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting February 18, 2026

Present (Voting)

M. Holodniy, MD (Chair)
S. Feldman, PhD
A. Bhatt, MD, PhD
S. Felt, DVM, MPH, DACLAM, DACVPM
P. Yang, PhD
R. Paulmurugan, PhD
C. Campos
S. Chen
S. Vleck, PhD, RBP/CBSP(ABSA)

Also Present (Not Voting)

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
J. Yamada
Y. Zhang, PhD
S. Oliver, PhD
K. Nobrega
S. Rayate
C. Inacay
A. Johnson, PhD
B, Donnelly, PhD
J. Sanz, PhD
S. Sidana, MD (4:17PM-4:37PM)
S. Claire, MPH (4:17PM-4:37PM)

The meeting was called to order at 4:17 PM by M. Holodniy, Chair. A quorum (five or more voting members) was present. There was a meeting break between 4:44PM-5PM. 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 January 18, 2025, which were distributed electronically to all IBC members prior to this meeting.
    - Voting on January 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. Day, J.	[5970] A Phase 1, Multicenter, Open-label, Dose-Finding Study to Investigate the Safety and Pharmacodynamics of a Single Intrathecal Injection of INS1202 in Patients with Amyotrophic Lateral Sclerosis
	New Protocol **Summary:** This is a Phase 1 clinical study designed to evaluate the safety, tolerability, and pharmacodynamics of a single intrathecal administration of INS1202 in adults with amyotrophic lateral sclerosis (ALS), including participants with and without SOD1 (Superoxide Dismutase 1) gene mutations. INS1202 is a recombinant, self-complementary adeno-associated virus serotype 9 (scAAV9) vector that delivers a short-hairpin RNA (shRNA) sequence targeting human SOD1 mRNA, with the goal of reducing SOD1 protein expression in the central nervous system. SOD1 is a crucial enzyme encoded by the SOD1 gene, vital for neutralizing toxic superoxide radicals in cells by converting them to less harmful oxygen and hydrogen peroxide, acting as a major antioxidant, and its mutations are a well-known cause of familial ALS. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C **Containment Conditions:** BSL1 **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. Sidana, S.	[6013] CCT5135: A Phase 1 Study to Evaluate the Safety of KLN-1010, a Novel, In Vivo Gene Therapy to Generate Anti-BCMA CAR-T Cells in Patients with Relapsed and Refractory Multiple Myeloma

	New Protocol **Summary:** This is a multi-center, first-in-human dose escalation and dose expansion study of KLN-1010 in patients with relapsed and refractory multiple myeloma (RRMM) in multiple countries. KLN-1010 is a pseudotyped third-generation, self-inactivating (SIN), replication-incompetent, recombinant lentivirus. It has 2 synthetic envelope proteins, including a tropism molecule (anti-CD3 single-chain variable fragment [scFv]) and a mutation in vesicular stomatitis virus glycoprotein (VSVG) that inhibits low-density lipoprotein receptor binding. These envelope proteins specifically target, activate, and transduce CD3-positive T cells with a transgene encoding an elongation factor 1 alpha promoter and a fully human anti- BCMA(B-cell maturation antigen) CAR (chimeric antigen receptor). The BCMA CAR contains a transmembrane domain, a CD3 zeta T-cell activation domain, and a 4-1BB costimulatory domain. Antigen-specific activation of anti-BCMA CAR-positive T cells results in proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● An IBC Member asked where the IP is manufactured. Biosafety responded that it is manufactured at the sponsor's manufacturing facility. ● An IBC Member asked if there are release criterias. Biosafety responded that release criteria have been provided for Endotoxin, Mycoplasma, and Sterility. ● An IBC Member asked if there is biodistribution data for humans. Biosafety responded that there are none currently ● An IBC Member requested a report after the 1st patient was treated. Biosafety confirmed this was made a condition of approval and communicated to the PI and study team. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
3. Alexander, J.	[6065] A Phase 1, Open-label, Single-arm Study of APR-2020 in Transfusion-dependent, Steroid-resistant Pediatric and Adolescent Subjects with RPS19 deficient Diamond-Blackfan Anemia by Transplantation of Autologous CD34+ Stem Cells Transduced with

	CLIN-LV-EFS-coRPS19-PRE* (APR-2020) (BMT433) IRB 84691
	New Protocol **Summary:** Study APR-2020-001 is a Phase 1, first-in-human, open-label study to assess the preliminary safety, tolerability, and efficacy of APR-2020 in steroid resistant, transfusion-dependent, pediatric, and adolescent subjects with RPS19 (Ribosomal Protein S19)-deficient Diamond-Blackfan Anemia (DBA). Up to 4 subjects are to be enrolled and dosed with APR-2020 following a non-genotoxic pre-infusion protocol. DBA is characterized by early-onset hypoplastic anemia. Congenital anomalies are observed in approximately 50% of affected individuals and more than one anomaly is observed in up to 25% of individuals. Additional features include growth deficiency and predisposition to malignancy. APR-2020 is composed of autologous human CD34+ hematopoietic stem and progenitor cells (HSPCs) derived from mobilized peripheral blood from patients with RPS19-deficient DBA. The CD34+ cells are transduced with highly purified and concentrated third generation lentiviral vector (LVV) carrying the normal RPS19 gene in the presence of cytokine molecules to stimulate vector integration into HSPCs genomic DNA. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● An IBC Member noted appropriate safety guard rails were in place. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

b. Basic Studies

PI	Protocol
1. Yang, P.	[5228] Chemical Biology Studies of Viruses
	Renewal: Updated Description, rDNA, Synthetic Nucleic Acid Molecules, Agents used, Animals/cells, risk, and attachments **Summary:** This project focuses on the development of small molecule

	antivirals. The Yang lab uses target-based and phenotypic screening to discover lead compounds against targets of interest. They perform medicinal chemistry to optimize the activity, selectivity, and mechanism of action of these small molecules. Furthermore, virological and biochemical assays are employed to determine the mode of action of target small molecules. This includes experiments in cell culture with live virus, single-cycle reporter virus, subgenomic replicons, virus-like particles, and cells expressing individual or subsets of viral proteins. In this renewal, Cedar virus is added as a BSL2 surrogate system to study Henipavirus replication and antiviral activity exerted by inhibition of the viral polymerase, encoded by the L protein. The primary goal of the project is medicinal chemistry optimization of small molecule, direct-acting antivirals against Henipaviruses, and using the rCedV-Luciferase system enables the measuring of antiviral potency in cell culture to (1) validate activity against live virus under BSL2 conditions and (2) examine broad-spectrum activity of our compounds. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL2 **Special Provisions:** None **New Agent Added:** Cedar Virus **Facility Visit:** February 4, 2026 **Discussion:** ● P. Yang was absent for Discussion and Voting. ● Committee members agreed that all safety precautions are met for the work with Cedar virus. **Voting:** A motion was made to approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0
2. Dassama, L.	[5436] Characterization of lipids, host-cell interactions, and genetic manipulation tools in bacteria
	Renewal: Added New Agent **Summary:** The project aims to use modern mass spectrometry methods to describe the lipid composition of Treponema pallidum and Borrelia burgdorferi, both are human pathogens deficient in lipid synthesis. Such characterization will reveal: a. lipids that might be synthesized by the 2 bacteria (hence suggesting novel biosynthetic capabilities) or b. lipids enriched in the bacteria when compared to their growth media

	(thus pointing to efficient transporters that mediate the uptake of these lipids) and c. an understanding about bacteria-host interactions. Bacteria will be cultured in the lab and their lipids extracted. The CRISPR silencing platform to allow gene silencing of putative lipid transporters and biosynthetic enzymes. In this renewal, Borrelia burgdorferi was added as an additional pathogen while all proposed experiments were previously already approved for working with Treponema pallidum. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL2 **Special Provisions:** None **New Agent Added:** Borrelia burgdorferi **Facility Visit:** January 28, 2026 **Discussion:** ● An IBC Member asked whether any sharps are involved in this project. Biosafety responded that all sharps will be replaced by disposable plastic items as mentioned in the methods and precaution section of the protocol. ● Committee Members agreed that a previous biogram accepted by the IBC in 2019 for the same bacterial strain is acceptable. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
3. Bintu, L.	[5608] Lentiviral and AAV transduction of mammalian cell lines to dissect chromatin regulation
	Renewal: Updated Personnel, Added New Agents **Summary:** This lab will investigate how mammalian and viral chromatin regulators (including HDACs, DNMTs, KRAB domain proteins, and viral proteins) control gene expression during differentiation, signaling, and viral infection. This lab will focus on synthetic loci regulation while avoiding oncogenes or toxins. This lab will study herpesviruses (CMV, KSHV, HSV1/2, HHV6) to understand how viral proteins alter host gene expression programs. This lab will analyze both immediate and sustained (days-to-weeks) transcriptional changes induced by these chromatin regulators in various cell models.

	Training: Incomplete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** None **New Agent Added:** Herpes Simplex Virus 1 or 2 (HSV1/2), Human Herpesvirus 6A or 6B (HHV6A/B). **Facility Visit:** February 4, 2026 **Discussion:** ● An IBC Member inquired about the source of the clinical isolate strain the lab plans to purchase and use and the strain's drug resistance profile. Biosafety responded that they will instruct the lab to include this information in the protocol and will share the details with the Committee once the protocol is updated. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
4. Dahlberg, P.	[5817] Application and development of advanced cryogenic correlative light and electron microscopy
	Revision: Added New Agents **Summary:** This lab will develop new fluorescence-based methods in model cell culture systems to guide downstream cryo-Electron Tomography (cryo-ET) data collection for studies of cellular processes under healthy and disease-relevant conditions. This lab will generate and study replication-incompetent lentiviral vectors encoding lysosomal biosensors (LAMP1-mCherry, FIRE-pHLy). This lab will study pathogen-host interactions using *Toxoplasma gondii, Borrelia burgdorferi*, Sendai virus, and α-synuclein aggregates. This lab will prepare plunge-frozen samples of infected or biosensor-expressing cells for high-resolution cryo-ET. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** Enhanced decontamination **New Agent Added:** *Toxoplasma gondii*, Sendai Virus, Alpha-synuclein protein, *Borrelia burgdorferi* **Facility Visit:** February 3, 2026 **Discussion:**

	• Biosafety asked committee members whether frozen BSL-2 agents could be handled outside a BSC with appropriate precautions. Committee members approved this for non-ATD pathogens where primary exposure risk is through sharps; they also stated that for alpha-synuclein work, the lab must ensure all contaminated materials/grids are disposed of in the appropriate pathway. • An IBC Member requested clarification on disposal of ethane/other freezing agents post-grid preparation. Biosafety responded they will direct the lab to collaborate with Lab Safety to establish appropriate disposal protocol and add the information to protocol. • An IBC Member inquired about the workspace layout for plunge freezing. Biosafety responded they will confirm there is adequate space for the researcher to work comfortably (e.g., no obstructions during grid loading, sufficient room for cryo materials, and plunge freeze setup). • The IBC strongly advises researchers to consult the Occupational Health Center (OHC) before starting work to discuss T. gondii seropositivity status and susceptibility. Biosafety communicated this to the lab. **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 6:08PM.