Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting May 20, 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
R. Trujillo, PhD
S. Vleck, PhD (BSO)

Also Present (Not Voting)

A. Fausto, PhD
D. Berdnik, PhD
K. Lin, PhD
J. Sherrill, DMV
B. Donnelly, PhD
S. Rayate (left at ~5:00pm)
C. Inacay (left at ~5:00pm)
B. Donnelly, PhD
K. Nobrega (left at ~5:15pm)
R. Moore (left at ~5:15pm)
J. Sheltzer, PhD (arrived 3:59pm; left 4:28 pm)
S. Thompson, PhD (arrived 4:09pm, left 4:28 pm)

Prior to the meeting, all IBC members should review:

- Confidentiality
    - The Panel proceedings are confidential. No protocols, including proprietary information, reviewed by Biosafety or IBC members and/or presented at Panel meetings should be discussed with anyone other than Panel members.

- Conflict of Interest
    - 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, a financial 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 Interests. 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.

- Designated Member Review
    - Please be reminded that all IBC members have agreed in advance, in writing, to use Designated Member Review 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.

The meeting was called to order at 3:54 PM by M. Holodniy, Chair. A quorum (five or more voting members) was present. The meeting was hybrid.

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 April 15th 2025, which were distributed electronically to all IBC members prior to this meeting.

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

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

    1. Protocols
        a. Clinical Reports

PI	Protocol
1. Spencer, Sean Paul	[5933-01] A Phase 1 Study to Evaluate the Safety of a Complex Gut Bacterial Consortium (MITI 001) for the Treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)
	Report **Summary:** Event: Grade 3 Nausea. Possibly Related to participation in study - MITI-001 is similar to Fecal Microbiota Therapy (FMT) in its mechanism and FMTs have shown nausea as the most common Adverse Event (AE). However, also possibly related to combination of: patient factors (history of post-operative nausea/vomiting), concomitant medications (opioids), antibiotics as part of the study protocol, as well as to MITI-001

	Training: complete **Applicable Section of the NIH Guidelines:** N/A **Containment Conditions:** BSL1 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A Committee Member noted that the subject's symptoms worsened after administration of the investigational product. Additional treatments for symptoms may have exacerbated the condition. ● A Committee Member inquired about potential changes to enrollment procedures moving forward. IRB staff clarified that the IRB has already approved the updated guidelines and will formally approve the report next week during their IRB meeting. ● A Committee Member asked whether this is the first subject in the study. A Staff member confirmed that it was. ● A Committee Member raised concerns about monitoring for future subjects, given the unexpected nature of this AE as Grade 1 or 2 events might go unnoticed or unreported. ● The BSO agreed that Grade 1 or 2 events might go unnoticed and suggested the panel could either request reports from the PI for each subjector request reports for nausea-related events. Committee Members discussed and determined that the PI must report to the IBC on the treatment and outcomes for the second subject treated. **Voting:** A motion was made to accept the report and was seconded. Total 9, For 9, Opposed 0, Abstain 0 ● Final Decision: Require the PI to submit a report after the 2nd subject treatment. PI was notified by email and confirmed they would comply.

b. Clinical Protocols

PI	Protocol
1. Day, J.	[6112] CT-ELP02-01: A Phase 1/2 Open-Label Study to Evaluate the Safety, Tolerability and Efficacy of a Single Dose of ELP-02 Delivered via Lumbar Intrathecal Administration in Charcot-Marie-Tooth-4J (CMT4J).
	New Protocol **Summary:** This is an open-labeled study. The primary objective is to Evaluate the Safety, Tolerability and Efficacy of a Single Dose of ELP-02 Delivered via Lumbar Intrathecal Administration in Charcot-Marie-Tooth-4J

	(CMT4J). CMT4J, first described in 2007, is an ultra-rare peripheral neuropathy resulting from recessive inheritance of loss-of-function FIG4 (Factor-Induced Gene 4) alleles. CMT4J is a disease with a severe phenotype including motor developmental delay, slow nerve conduction velocities, rapidly progressive paralysis, quadriplegia, respiratory compromise resulting in pneumonias, respiratory failure, and premature death. ELP-02 is an AAV9 (Adeno-associated virus serotype 9) based gene therapy vector that expresses the fully functional form of FIG4 under the control of a synthetic promoter. ELP-02 will be delivered intrathecally and is designed to achieve stable, potentially life-long expression of FIG4 in non-dividing cells. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C **Containment Conditions:** BSL1 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A Committee Member inquired whether similar studies had been conducted in human subjects Staff confirmed this trial is a first in human trial. ● Committee Members noted the absence of additional animal data and asked if translational research typically progresses from a single species to humans; Staff responded that this is sometimes the case for rare diseases. ● A Committee Member asked if preclinical studies had been performed in larger animal models. Staff clarified that the IB does not provide this information but they will inquire with sponsor. It was determined that approval was not contingent upon this information. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Ma, Julie	[6159] A Single-Arm, Open-Label, Multi-Centre, Phase Ib/2 Study Evaluating the Safety and Efficacy of AUTO1 in Pediatric Patients with CD19-Positive Relapsed/ Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (B ALL) and r/r Aggressive Mature B-cell Non-Hodgkin Lymphoma (B NHL).
	New Protocol **Summary:** This study aims to evaluate the safety and efficacy AUTO1 (obecabtagene autoleucel) in pediatric patients with CD19 (Cluster of Differentiation 19)-positive relapsed or refractory (r/r) B ALL (B-cell acute

	lymphoblastic leukemia) and r/r Aggressive Mature B NHL (B-cell Non-Hodgkin Lymphoma) to further explore the use of chimeric antigen receptor (CAR) T cell therapies in populations with significant unmet needs. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL1 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** The Committee had no further questions. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

c. Basic Protocols

PI	Protocol
1. Sheltzer, J.	[5838] Aneuploidy and genomic instability during tumorigenesis
	Revision: Updated agent used and attachment, Tabled in April **Summary:** The goal is to utilize Epstein-Barr Virus (EBV)-latent HG3-CLL cell lines [wild-type (WT) and del(11q)] to investigate aneuploidy-associated vulnerabilities in cancer. These cell lines are genetically identical except for loss of one copy of chromosome 11q in the del (11q) cell line. The lab will not use chemical or biological inducers of EBV lytic replication. Lentivirus is used to make transduced HG3-CLL lines targeting WWTR1 and PPP2R1A, with the hypothesis that cells missing part of chromosome 11q will be more sensitive to losing these genes than normal comparison cells. Transduction efficiency will be monitored via flow cytometry. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL2 **Special Provisions:** N/A **New Agent Added:** Epstein-Barr Virus (EBV) **Facility Visit:** April 3, 2026 **Discussion:** ● The lab presenting the research said a CDC permit has been obtained but obtaining an AMS (Aerosol Management System) was still in

	progress. ● Committee Members asked if the lab will use lentivirus CRISPR vs safer, non-viral methods like CRISPR protein transfection. The lab noted they preferred to use lentivirus, as it is replication-incompetent and will drive constant Cas9 expression. ● Committee Members and the Lab discussed how measures would be implemented to monitor EBV reactivation. The lab proposed using RT-qPCR and GFP-Cas9 reporter constructs for constant expression. They also noted the cells won't be retained, and therefore even if EBV did reactivate, it would be inactivated during disposal . The Committee discussed whether visualization of cytopathic effects (CPE) from EBV would be effective, as well as the sensitivity of RT-qPCR. ● Staff reminded the Committee that precautions included treating all cells as potentially EBV-positive;the committee agreed it would be the best approach. Approval with contingency: 1. Treat all cells as EBV-positive and apply corresponding precautions. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Dahlberg, Peter	[5755] Cryogenic light microscopy, Cryogenic focused-ion-beam milling and scanning electron microscopy, and cryogenic transmission electron microscopy of BSL2 samples cryogenically prepared off-site.
	Revision: Updated (Description, Agents Used) **Summary:** This lab will investigate host-pathogen interactions using cryogenic electron tomography (Cryo-ET) to achieve nanometer-scale resolution of viral, bacterial, and eukaryotic pathogen (e.g., Influenza Virus, Francisella tularensis, Legionella pneumophila) life cycles in their native states. This lab will process frozen samples through grid clipping, cryogenic light microscopy, FIB-SEM milling, and tomographic reconstruction to generate 3D structural data, while implementing strict protocols to maintain sample integrity. This lab will apply these high-resolution imaging techniques to elucidate molecular mechanisms of cellular ingress, replication, and egress, providing foundational insights for therapeutic development against infectious diseases. F. tularensis subsp. novicida, strain U112 (ATCC ® 15482™) is excluded from Select Agent status. **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2

	Special Provisions: No aerosols/splash generating procedures outside BSC **New Agents Added:** *Francisella novicida (F. tularensis* subsp. *novicida)*, strain U112 (ATCC ® 15482™) **Facility Visit:** January 8, 2026 **Discussion:** The Committee had no further questions. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
3. Bertaina, Alice	[5782] Study of new therapies in pediatric leukemia models and strategies to overcome graft versus host disease
	Revision: Updated (Description, Agents Used, Animals/Cells, Risk, Attachments) **Summary:** This project evaluates an attenuated strain of Listeria monocytogenes (Lm) bacteria called QUAIL-100 as a tool to stimulate the immune system in pediatric leukemia patients. Many patients face a high risk of cancer returning after a bone marrow transplant. QUAIL-100 will be tested for activation of gamma-delta T cells, which are specialized immune cells capable of hunting and killing cancer cells. Unlike wild-type Lm, QUAIL-100 is engineered to be unable to grow in the human bloodstream, making it a safe method to stimulate an immune response. By studying how these immune cells respond in vitro and in patients from a clinical trial, the aim is to develop a new therapy that prevents cancer relapse and improves survival for children with leukemia. The safety and efficacy of QUAIL-100 as a novel gamma-delta T cell activation strategy will be tested in culture in peripheral blood mononuclear cells (PBMCs) from healthy donor or leukemia patients post-hematopoietic stem cell transplantation (HSCT). Activation profiles/ mechanisms that can enhance the design and implementation of clinical trials for QUAIL-100-activated gamma-delta T cells will be evaluated. Activation phenotypes, cytokine production, and cytotoxicity of T cells stimulated by QUAIL-100 will be studied. **Training:** Complete **New Agent Added:** Listeria monocytogenes (attenuated) **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** N/A **Facility Visit:** May 15, 2026 **Discussion:** ● A Committee Member asked about the goal for the T-cell

	measurements proposed in this study. Biosafety responded that this study aims to better understand T-cell activation, subsets, and exhaustion profiles induced by QUAIL in vitro. This study will be performed in parallel with the approved clinical trial for QUAIL to optimize treatments and better understand the molecular mechanisms of T-cell activation in vitro and in patients. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
4. Carette, Jan	[5904] Genetic screens to identify host factors required for pathogens
	Revision: Updated (Description, Agents Used, Attachments) **Summary:** This lab will use haploid genetic screens to systematically identify human host genes essential for viral infection and replication. The lab will implement strict oversight protocols for any genes demonstrating proviral enhancement and exclude host factors that significantly increase viral pathogenicity. The objective is to uncover host-pathogen interaction mechanisms, which could lead to new antiviral therapies targeting host proteins. Following identification, the function of key genes will be characterized to determine their role in the viral life cycle and their interactions with viral proteins. Additionally, the lab will study the role of innate immunity by creating a library of interferon-induced gene knockout cell lines. These will be screened to determine their individual contributions to the antiviral response against pathogens, including respiratory viruses (e.g., influenza virus) and mosquito-borne viruses (e.g., dengue virus, Zika virus). **Training:** Complete **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** Safety Sharps, Enhanced decontamination and aerosol precautions **New Agent Added:** St. Louis encephalitis virus **Facility Visit:** May 14, 2026 **Discussion:** The Committee had no further questions. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

5. Sharaf, N.	[6135] Bacterial lipoprotein based nanoparticles as novel antimicrobial agents for treatment of Staphylococcus aureus infection.
	New Protocol **Summary:** This lab will develop bacterial lipoprotein-based nanostructures to enhance antimicrobial drug delivery against Staphylococcus aureus (S. aureus). This lab will express modified lipoproteins in Escherichia coli using bacterial vectors with ampicillin resistance, followed by purification via affinity chromatography. This lab will engineer these nanostructures with: (1) specific cell wall-binding domains, (2) dual drug-loading capacity (covalent conjugation), and (3) optimized bactericidal activity validated through time-kill and biofilm assays. **Training:** Complete **Agent:** Staphylococcus aureus **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** N/A **Facility Visit:** May 13, 2026 **Discussion:** ● The Committee confirmed that aerosol management is required for the lab's work and will include the following safety measures in the protocol: (1) establishing procedures for containment, decontamination, and reporting of spills to minimize exposure risks and (2) mandating the use of appropriate personal protective equipment, such as gloves, lab coats, and respiratory protection if needed, when handling materials with aerosol risks. ● The Committee agreed that the biogram was needed for this work and was a contingency for approval. Approved with contingencies: ● Biogram ● Aerosol management requirements added to protocol **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
6. Rao, D.	[6153] Imaging protease activity in living subjects
	New Protocol **Summary:** This project aims to develop new imaging probes that allow

	visualization of protease activity in tumors inside living animals. Proteases such as Granzyme B are released by immune cells during anti-tumor responses and can serve as indicators of immune activity during cancer therapy. By combining optical fluorescence imaging and positron emission tomography (PET), real time immune responses in tumor biology will be monitored in live animals via non-invasive imaging to contribute to the development of more effective imaging methods for diagnosing and monitoring cancer. Raji cells will be used as a mouse tumor model because they allow evaluation of imaging probes and immune responses in a living system before translation to clinical studies. Raji cells are a human Epstein-Barr Virus (EBV)-positive Burkitt lymphoma B-cell line and generally considered EBV "non-producer" cells because their EBV genome contains deletions that prevent completion of productive viral replication and formation of infectious virions. For downstream assays, immunofluorescence imaging will be performed on fixed tumor tissue sections stained with antibodies and Enzyme-Linked Immunosorbent Assay (ELISA) will be used to determine Granzyme B levels. **Training:** Complete **Agent:** Epstein-Barr Virus, transformed cell line **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-2 **Special Provisions:** N/A **Facility Visit:** April 29, 2026 **Discussion:** ● Biosafety asked on behalf of the Rao lab whether the mice administered with Raji cell for tumor induction may be housed under ABSL1+ conditions because no viable EBV will be produced or shed. A veterinary committee member responded that such a request would be accepted in the planning meeting for these animal experiments with the Veterinary Service Center (VSC) if the lab desires ABSL1+ housing conditions. The location for administration and subsequent housing will be determined during a meeting with the Rao lab and the VSC prior to the start of the experiments. ● Biosafety asked whether in the future other protocols using Raji cells for tumor induction in animals should be presented to the IBC panel or rather be treated as a Designated Member Review (DMR) protocol given that EBV virions won't be produced or shed. The IBC members agreed that future projects using Raji cells should be presented to the panel because every study is different and a blank exception for Full Committee Review (FCR) should not be granted. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0

7. Rao, D.	[6155] Development of probes and assays for detecting Mycobacterium tuberculosis
	New Protocol (BSL3) **Summary:** This project aims to develop a faster and more accurate method for diagnosing tuberculosis (TB) using bacteriophages that naturally attach to TB bacteria. Because these phages can carry residues of RG3 Mycobacterium tuberculosis (Mtb) bacteria, the phage will be amplified in the BSL3 laboratory. The core of the research involves attaching these phages to magnetic nanoparticles to create a "capture probe". By mixing these probes with patient samples, magnets can be used to pull out any present TB bacteria. An attenuated, low-risk Mtb strain will be employed to safely test how well the magnetic separation works. Ultimately, this process allows for the rapid detection of TB through bioluminescence, providing results much faster and more cost effective than traditional culture methods and enabling earlier treatment for patients. **Training:** Complete **New Agent Added:** DS6A bacteriophage **Applicable Section of the NIH Guidelines:** III-D **Containment Conditions:** BSL-3 **Special Provisions:** N/A **Facility Visit:** April 29, 2026 **Discussion:** ● A Committee Member asked whether a Mycobacterium smegmatis specific bacteriophage was used for proof-of-concept testing. Biosafety confirmed that the M. smegmatis phage was used at BSL2 for proof-of-concept testing but that phage is not recognized efficiently by the more virulent bacteria from Mtb complex. Therefore, the lab proposed to repeat the same experimental design with a new bacteriophage specific for the Mtb complex to yield more sensitive detection rates in their assay. ● The IBC agreed that this study's approval is contingent upon the provision of sufficient inactivation data for Mtb to remove materials from BSL3 containment. ● Biosafety requested guidance about how to approve the proof of inactivation of Mtb bacteria in the bacteriophage preparation before moving it out of BSL3 containment into BSL2. The IBC agreed that the lab should submit the inactivation data to Biosafety who will decide whether the data are acceptable for lifting the contingency or are required to be returned to the IBC for further re-evaluation. **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 5:56 PM.