Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting April 15, 2026

Present (Voting)

M. Holodniy, MD (Chair)
A. Bhatt, PhD
S. Felt, DVM, MPH, DACLAM, DACVPM
S. Vleck, PhD (BSO)
R. Paulmurugan, PhD
S. Oliver, PhD
C. Campos
R. Trujillo, PhD
J. Arunachalam (left at ~5:25pm)
J. Yamada
K. Nobrega
C. Inacay (left ~5:50pm))
A. Johnson, PhD (left at ~5:40pm)
B. Donnelly, PhD
R. Moore
O. Klein, MD, PhD (arrived at 4:19pm, left at 4:39pm)
K. Dougall (arrived at 4:19pm, left at 4:39pm)
B. Dawes MD, PhD (arrived at 4:45pm, left at 4:59pm)

Also Present (Not Voting)

A. Fausto, PhD

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 4:18 PM by M. Holodniy, Chair. A quorum (five or more voting members) was present. The meeting was hybrid.

Agenda:

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 March 18, 2025, which were distributed electronically to all IBC members prior to this meeting.

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

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

    1. Protocols
        a. Clinical Protocols

PI	Protocol
1. Klein, O.	[6132] An Open-label, First-in-Human, Single Ascending Dose Study of QUAIL-100 in Pediatric and Young Adult Subjects with High-Risk Acute Leukemias and Myelodysplastic Syndrome Who Have Received a TCR αβ+ T Cell/CD-19+ B cell-Depleted Hematopoietic Stem Cell Transplantation (BMT 434)
	New Protocol **Summary:** The purpose of this study is to test a new investigational treatment called QUAIL-100 in patients with high-risk leukemia or myelodysplastic syndrome who have received a stem cell transplant. QUAIL-100 is a novel live, attenuated *Listeria monocytogene*s therapeutic. The *actA*(Actin assembly-inducing protein) and *inlB*(Internalin B) deletions significantly

	attenuate pathogenesis resulting in a greater than 1,000-fold reduction in virulence compared to wild-type *Lm*. The Sponsor has introduced two additional attenuations (ΔribC/ΔribF; genes that encode enzymes critical for generating essential flavin cofactors) to the double-deleted (ΔactA/ΔinlB) (live-attenuated double deleted; LADD) platform of therapeutic Lm resulting in a strain in which four genes are deleted from the genome of wild-type Lm. As a result of these additional deletions, QUAIL-100 cannot grow, replicate, or survive extracellularly leading to a much more attenuated and less virulent strain which still retains its immune modulating effects. QUAIL-100 is designed to stimulate parts of the immune system that may help prevent the cancer from returning after transplant. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A committee member asked if there is a safety monitoring system in place. The researcher responded that there is established safety oversight with predefined stopping rules. ● A committee member inquired about the relative growth kinetics of wild-type Listeria compared to the culture-based method. The researcher confirmed the kinetics should be identical to wild-type Listeria and noted that while PCR testing has been discussed, it is not currently part of routine testing. ● Committee members asked if there has been observed recombination between QUAIL100 and Listeria in the case of co-infection and the researcher answered that it was not observed in any of the adults and no one has mentioned the recombination. ● A committee member questioned how frequently primary CNS disease occurs without detectable bacteremia or systemic involvement. The researcher acknowledged this is uncommon in humans but offered to consult with colleagues for additional verification. ● The committee engaged in a discussion about diagnostic approaches, noting several key points. Listeria's slow growth characteristics in culture can significantly delay diagnostic results when relying solely on traditional culture methods. In contrast, PCR-based testing offers the advantage of potentially much faster turnaround times for detection. Currently, all samples are processed through an established clinical laboratory partnership, and this facility may have existing PCR capabilities that could be utilized. After considering these factors, the committee reached consensus on recommending PCR-testing to the lab. They determined this would be a

	recommendation to the PI, not a condition of approval. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Dahiya, S.	[6120] CCT5127: A Phase 1, Open-Label, Single Center Study of AZD0120 (also known as GC012F), a Chimeric Antigen Receptor T cell Therapy Targeting CD19 and B cell Maturation Antigen (BCMA), in Subjects with Relapsed and Refractory Persistent Autoimmune Cytopenia
	New Protocol **Summary:** AZD0120 is a liquid cell suspension for IV (intravenous) infusion and is composed of autologous T-cells transduced with a LVV(Lentiviral Vectors) encoding a dual anti-CD19 (anti-Chimeric Antigen Receptor) and anti-BCMA (B-cell maturation antigen) CAR. Primary ITP (Immune Thrombocytopenia) and warm (AIHA Autoimmune Hemolytic Anemia) are acquired disorders characterized by immune mediated destruction of platelets and red blood cells (RBCs). The pathogenesis in primary immune-mediated cytopenia is a breakdown in self-tolerance mechanisms across many arms of the immune system, including within antigen-presenting, B, and T cells, ultimately leading to B-cell mediated autoantibody production resulting in peripheral destruction of platelets or RBCs. The presumption is that B cell depletion using AZD0120 will be expectedly profound and will induce sustained benefit for patients with multi-refractory primary immune-mediated cytopenia. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL2 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A committee member asked about the risk of extracting B cells from patients, noting their importance for immune function. Another committee member responded that while such risks exist, the intervention is justified for patients who have failed other immunosuppressant therapies, where the alternative may be fatal. The Biosafety Officer noted that there have not been reports to this committee regarding increased infection rates in previous trials. ● A committee member asked whether the product and sponsor were identical to those used in a previous trial. The Biosafety Officer responded that this would be verified; the committee determined this

	did not need to be a condition of approval. **Voting:** A motion was made to approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0

b. Basic Protocols

PI	Protocol
1. Labeaud, A.	[5133]Impact of tropical infections on child health
	Revision: Updated Description, Agents Used **Summary:** This lab will study mosquito-borne viruses such as dengue, chikungunya, Rift Valley fever, yellow fever and Zika viruses affecting children and adults in Kenya, Brazil, and Grenada. This lab will investigate transmission patterns, disease burden, and clinical progression through epidemiological studies and diagnostic testing. This lab will analyze human serum samples using multiplex PCR to detect dengue serotypes and screen for Oropouche virus, Mayaro virus, Seoul hantavirus, Sin Nombre hantavirus, Andes hantavirus, and Leptospira spp. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Safety Sharps, No aerosols/splashes generating procedures outside BSCs, Work exclusively with inactivated samples or begin with lysis inactivation as the first step—no procedures that could propagate any agent should be performed. **New Agents:** Mayaro virus, Seoul hantavirus, Sin Nombre hantavirus, Andes hantavirus, and Leptospira spp. **Facility Visit:** March 25, 2026 **Discussion:** ● A committee member asked what specific hantaviruses were tested for in the negative human serum samples. The lab member answered that testing in Grenada was conducted as an antibody seroprevalence study for hantaviruses generally, not as a specific PCR assay, which is why they propose implementing a more sensitive pan-hantavirus multiplex PCR for testing inactivated samples. ● A committee member asked what happened to the one human serum sample in Grenada that tested positive for Chikungunya (CHIKV). The lab member answered that their collaborators in Grenada had

	inactivated and destroyed the sample following detection. ● A committee member asked why they were testing for Seoul (SEOV), Andes (ANDV), and Sin Nombre (SNV) hantaviruses when some aren't endemic to Grenada's mouse ecosystem. The lab member answered that they planned to use an existing triplex assay, and confirmed no viral or bacterial isolation would be attempted, with any Risk Group 3 detections triggering immediate IBC notification and sample inactivation. ● A committee member asked how many non-inactivated samples were currently stored at Stanford and under what conditions. The biosafety reviewer answered that while initial numbers weren't provided, follow-up confirmed 646 active human serum samples and 1 TRIzol-inactivated sample, all stored at -70°C in secured lab freezers. ● The biosafety officer proposed that the committee allow the lab to update primers for Risk Group 2 agents or hantavirus family viruses without having to submit an IBC revision each time, provided that the lab submitted regular updates to the IBC (schedule to be determined), the lab did not pursue new RG3 agent primers without specific IBC approval, and the lab immediately notify the IBC and Biosafety Office if any RG3 agents were identified. The committee discussed and agreed; they determined that the lab should update the IBC each quarter with a list of new primers for RG2 agents. They also agreed that all RG3 agent primers should be submitted to the committee for review and approval prior to any work with the primers. ● A committee member asked if there were additional contingencies for protocol approval. The biosafety reviewer answered that they should additionally formally add the three hantaviruses to the protocol, and require resubmission for any ELISA experiments using febrile serum from Granada. Approval Conditions: ● Quarterly (within no more than 3 months of PCR design) when additional PCRs are utilized, the PI will submit a protocol amendment to add these new PCR targets to the protocol. If no changes are made, no quarterly submission is required. When renewals are submitted, the PI will update the IBC on the identified prevalence of viruses in these targeted samples. ● The PI agrees to only utilize this quarterly notification for Risk Group 2 agents or additional strains of hantavirus in the same family as those already under approval (note: serum from patients with hantavirus may be handled at BSL2 per the CDC).

	• For any PCR of a Risk Group 3 agent other than hantaviruses, the PI must seek and receive approval from the IBC prior to performing the PCR. • If any PCR for a RG3 sample are found to be positive, the PI will immediately notify the IBC via biosafety-officer@lists.stanford.edu and biosafetyeprotocol@lists.stanford.edu. The PI agrees that no work of any kind will be done with any samples related to this positive result until Biosafety and the IBC have reviewed and advised the PI on additional containment and requirements, with the exception of heat-inactivated serum samples or work with DNA/RNA only. • Any ELISA experiments using febrile human serum from Grenada must be resubmitted to the panel for approval. **Voting:** A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0
2. Sheltzer, J.	**[**5838] Aneuploidy and genomic instability during tumorigenesis
	Revision: Updated agent used, description, risk, and attachment **Summary:** The goal is to utilize 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. Transduction efficiency will be monitored via flow cytometry. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2 **Special Provisions:** Enhanced decontamination, Aerosol Management System **New Agent Added:** Epstein-Barr Virus (EBV) **Facility Visit:** April 3, 2026 **Discussion:** • A committee member raised the question of whether lab members should obtain baseline EBV status through Occupational Health Clinic (OHC) testing. After discussion, it was determined that such testing would not be necessary since epidemiological data indicates the majority of the adult population tests seropositive for EBV antibodies. The committee concluded that universal baseline testing would not

	provide meaningful additional safety information given the high prevalence of prior EBV exposure in the general population. • The committee expressed concerns about the theoretical risk that CRISPR-based gene editing might trigger EBV reactivation in modified cells. While the lab did not have definitive data on this specific risk, the committee requested that the research team conduct a thorough literature review to investigate whether the particular genes targeted in their CRISPR system have any known association with EBV reactivation pathways. This precautionary measure aims to ensure all potential risks are properly evaluated before proceeding. • Committee members engaged in detailed discussion about the choice of viral vector, specifically using lentivirus for CRISPR delivery rather than potentially safer non-viral methods like CRISPR protein transfection. The committee sought clearer justification for this selection, as alternative delivery methods might reduce certain risks while potentially achieving similar experimental outcomes. • The committee decided to table the protocol after discussing the above concerns. They requested that both the PI and lead researcher attend the next IBC session to address these questions directly and provide additional clarifications about the experimental design, safety considerations, and project scope before the committee would consider approving the protocol. **Voting:** The protocol was Tabled and moved to the next IBC meeting.
3. Einav, D.	[5878] Molecular and systems virology of RNA viruses
	Revision: Updated (Agents Used) **Summary:** This lab will develop broad-spectrum antivirals by studying host-pathogen interactions in Flaviviridae [including Dengue virus (DENV), Zika virus (ZIKV), West Nile virus (WNV)], coronaviruses (SARS-CoV-2, MHV-1, HCoV-OC43), human immunodeficiency virus (HIV), and non-infectious Vesicular Stomatitis Virus (VSV) pseudotypes bearing glycoproteins derived from Ebola virus (EBOV). A key focus is infectious bursal disease virus (IBDV, strain R903/78) superinfection, which triggers protective immune responses without replicating in mammals. This lab will map viral-host protein interactions, profile immune activation, and validate findings in murine models to identify host-based antiviral targets. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL2/ABSL-2

	Special Provisions: Spatial and temporal separation of work; No aerosols/splashes generating procedures outside BSC; Safety Sharps **New Experiment Added:** To evaluate the therapeutic efficacy of IBDV superinfection in mice model **Facility Visit:** March 30, 2026 **Discussion:** ● A committee member asked the biosafety specialist for clarification on whether co-infected cells were being introduced to mice or if the mice would be co-infected with the agents. The biosafety specialist answered that the lab plans to directly co-infect mice with the agents and confirmed that no human cells will be involved in these experiments. **Voting:** A motion was made to approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0
4. Kuo, C.	[6133] Signaling Pathways in Cancer, Infectious Disease, Gastrointestinal Homeostasis and Angiogenesis
	New Continuing: Cloned of 4874 **Summary:** This lab investigates signaling pathways governing intestinal biology and viral pathogenesis. The Wnt pathway (19 growth factors) regulates intestinal cell division, while VEGF (Vascular Endothelial Growth Factor) controls angiogenesis. SARS-CoV-2 Spike's effects on intestinal regeneration are compared to H1N1-PR8-GFP (influenza A strain Puerto Rico/8/34 with GFP reporter) T cell responses. Vaccinia studies use MVA (Modified Vaccinia Ankara) and HSV-1 (Herpes Simplex Virus-1) in human skin to model tissue-resident immunity. RSV (Respiratory Syncytial Virus) projects map lung immune responses and antiviral candidates. All studies focus on human-specific mechanisms with translational potential. **Training:** Complete **Applicable Section of the NIH Guidelines:** Section III-D **Containment Conditions:** BSL-2 **Special Provisions:** Safety Sharps, No aerosols/splashes generating procedures outside BSC **New Experiment Added:** Human herpesvirus 1 Strain F live confocal imaging **Facility Visit:** April 13, 2026 **Discussion:**

	• A committee member asked if the lab's personal confocal microscope has an aerosol management system. The biosafety reviewer confirmed that the equipment does include proper aerosol management controls. • A committee member asked the biosafety specialist if any enhanced decontamination is required for this specific project, as the lab had included "BSL-2+" on their workflow schematic. The biosafety specialist answered that this was a typo on the slide, clarified that all work will be conducted at standard BSL-2 containment, and stated that the lab will be instructed to correct their workflow documentation accordingly. **Voting:** A motion was made to approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0

The meeting was adjourned at 6:07 PM.