

Stanford University Institutional Biosafety Committee

Panel 1 Minutes of Meeting January 21, 2026

Present (Voting)

M. Holodniy, MD (Chair)
S. Feldman, PhD
S. Felt, DVM, MPH, DAACLAM, DACVPM
R. Paulmurugan, PhD
S. Oliver, PhD
R. Trujillo, PhD, arrived 4:00 pm
J. Arunachalam, arrived 3:43pm, left
4:20pm
C. Campos
S. Vleck, PhD, RBP/CBSP(ABSA)

Also Present (Not Voting)

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
K. Nobrega, left 5:05 pm
J. Yamada
Y. Zhang, PhD
S. Rayate, left 4:48pm
R. Moore (VA Palo Alto Health Care
System)
Ann Johnson, PhD
Bryan Donnelly, PhD

Below Arrived at 3:43, Left 4:09 pm
Quan Dong Nguyen, MD, MSC, arrived
Jia-Horung Hung, MD
Hareem Khan, MD
Louis Jison, Ngoc Than, Isaac Sanchez
Negin Yavari, Aubrey Nguyen
Gunay Uludag Kirimli, David Ni Xu
Amir Akhavanrezayat

The meeting was called to order at 3:42 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 December 17, 2025, which were distributed electronically to all IBC members prior to this meeting.
 - Voting on December minutes—approval, unanimous, no dissenters
5. The fifth order of business was the presentation, discussion and voting on protocols.
 - a. Clinical Research Protocols

PI	Protocol
1. Nguyen, Q.	[6023] A Proof-of-Concept Trial to Evaluate the Efficacy and Safety Of Cell Therapy TRX103 Administered Intravenously in Patients with Active, Non-infectious Intermediate, Posterior, and Pan-Uveitis- THE PEACOCX STUDY
	<p>New Protocol</p> <p>Summary: Uveitis is an inflammatory disease of the eye, characterized by an unbalanced local/systemic inflammatory response leading to vision loss due to damage resulting from inflammation. Non-infectious intermediate, posterior, and pan-uveitis are types of uveitis that involve inflammation in the middle, back, or all parts of the uvea without an infectious cause. TRX103 is a new type of cell therapy consisting of engineered immune cell (regulatory T cell) that could travel to sites of inflammation, help the healing process and ‘teach’ naturally produced immune cells (regulatory T cells) how to function properly by releasing IL-10 (interleukin 10) a key chemical (cytokine) in the body that regulates inflammation. Consequently, by boosting the local release of IL-10, TRX103 cells have the potential to correct and restore a balanced intraocular (in the eye) immune system, and could represent an innovative, highly effective, and essential therapeutic option for this unmet need. TRX103 is generated by combining CD4+ T cells in an even ratio (1:1:1) from 3 unrelated healthy donors after independent transduction of these cells in vitro with a lentiviral vector (LVV) encoding for the full-length human interleukin (IL)-10 gene and a truncated (non-signaling) form of the human nerve growth factor receptor (NGFR, CD271) [ΔNGFR].</p> <p>Training: complete Applicable Section of the NIH Guidelines: Section III-C, III-D Containment Conditions: BSL2 Special Provisions: Hospital/Clinic Infection Control precautions</p>

	<p>Discussion:</p> <ul style="list-style-type: none"> • A Panel Member asks who is manufacturing the lentiviral vector and the TRX (T-cell receptor transduced) cells? The reviewer responds that Lentigen Tech Incorporated is responsible for both. The work is conducted by different branches within the company. • A Panel Member asks if the company is planning to enrich CD4+ TRX cells for the final drug product? The reviewer responds that TRX cells are expanded, then engineered. Donor cells are manufactured, pooled, and made available in specific, fixed-dose aliquots for each individual patient. • A Panel Member asks if the pool was created from the same number of cells from each donor? The reviewer answers yes, it is a 1:1:1 donor cell ratio. • The reviewer asks the panel to look at the donor infectious screening protocol; the panel notes they are satisfied with this list. <p>Voting: A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0</p>
--	--

b. Basic Research Protocols

PI	Protocol
1. Bando, J.	[4065] Roles of innate lymphocytes in intestinal tumor growth
	<p>New Protocol</p> <p>Summary: This lab will investigate how intraepithelial innate lymphoid cells eliminate tumor cells in the intestine, where barrier dysfunction and microbial invasion drive inflammation and cancer. This lab will use a mouse model colonized with an E. coli strain that induces DNA damage in epithelial cells to accelerate tumor formation and study these cells' responses. Additionally, they will test whether enhancing intraepithelial innate lymphoid activity in vivo suppresses tumor growth and define the molecular mechanisms underlying intraepithelial innate lymphoid-mediated killing of epithelial tumor cells. Findings from this work could reveal novel immunotherapeutic strategies for colorectal cancer.</p> <p>Training: Complete Applicable Section of the NIH Guidelines: III-D, III-E Containment Conditions: BSL-2</p>

	<p>Special Provisions: N/A Facility Visit: December 15, 2025</p> <p>Discussion:</p> <ul style="list-style-type: none"> ● A Panel Member asks what were the planned endpoint procedures for the mice? The reviewer is currently waiting to hear back from the lab on this question and has asked for it to be included in the protocol; it is likely that the lab is collecting only colon tissue for analysis and flow cytometry but this will be confirmed and added to the protocol. ● The BSO and IBC Chair clarified the amendment process to protocol: <ul style="list-style-type: none"> ○ If colon tissue collection is the only additional procedure, the lab will add this to the protocol to satisfy the condition. ○ If there are any other proposed experiments or tissue collections post-infection, the reviewer will determine, with assistance from the BSO and IBC Chair as needed, if the risk is sufficient that the additional proposed tissues or experiments must return to the IBC for full review. <p>Approval Conditions:</p> <ol style="list-style-type: none"> 1. Add type of samples to be collected at in vivo endpoint and describe what will be done with these samples. <p>Voting: A motion was made to conditionally approve the protocol and was seconded. Total 7, For 7, Opposed 0, Abstain 0.</p> <p>One member refrained from voting due to an association with the lab; they were not considered to have a conflict of interest.</p>
2. Dahlberg, P.	[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.
	<p>New Protocol</p> <p>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 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.</p>

	<p>Training: Complete Applicable Section of the NIH Guidelines: III-D Containment Conditions: BSL-2 Special Provisions: Enhanced decontamination and disposal Facility Visit: January 8,2026</p> <p>Discussion:</p> <ul style="list-style-type: none"> • A Panel Member asks what is the source of the specialized grids for the experiment? The reviewer answers they are supplied by an external collaborator. • A Panel Member asks, has the collaborator completed the required cryogen safety training for handling these materials? The reviewer notes the training status will be verified and completed if necessary. • A Panel Member asks is the procedure room maintained at negative pressure relative to the corridor, as a key containment measure? The reviewer will be confirmed with the investigator. <p>Approval Conditions:</p> <ol style="list-style-type: none"> 1. Verification of completed cryogen safety training. 2. Confirmation of negative pressure in the procedure room relative to the corridor. <p>Voting: A motion was made to conditionally approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0</p>
3. Bushin, L.	[5913] Microbial Bioproduction IBC Protocol
	<p>New Protocol</p> <p>Summary: This project aims to discover and characterize biosynthetic pathways and their molecular products and produce target compounds of interest at gram-scale and explore their bioactivities. <i>Pseudomonas aeruginosa</i> bacteria will be used for DNA isolation with the purpose to amplify multiple genes by PCR, clone these into expression plasmids, and produce recombinant, non-infectious proteins (biosynthetic enzymes) in BSL1 host bacteria to engineer microbes for the production of specialized compounds (chemicals and materials) for biocatalytic applications.</p> <p>Training: Complete Applicable Section of the NIH Guidelines: Section III-D Containment Conditions: BSL2 Special Provisions: none Facility Visit: November 24, 2025</p>

	<p>Discussion:</p> <ul style="list-style-type: none"> • A Panel Member asked about the nature of genes used as inserts for the genetic engineering of RG1 bacteria. Biosafety confirmed that no toxins or genes that could enhance the pathogenicity of the bacteria will be used which is stated on the protocol in the project description and rDNA section. • Panel Members agreed that Antimicrobial Sensitivity Testing (AST) data from published literature in 2008 and 2009 are not sufficient. A current biogram for the <i>Pseudomonas aeruginosa</i> PA01 strain was requested to grant full approval. <p>Approval Conditions:</p> <ol style="list-style-type: none"> 1. A current biogram must be provided. <p>Voting: A motion was made to conditionally approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0</p>
4. Tiao, G.	[5957] The Molecular Determinates of Virus Induced Biliary Atresia
	<p>New Protocol</p> <p>Summary: The goal is to study virus-driven immune mechanisms underlying biliary atresia (BA) and identify potential therapeutic targets to modify disease progression using rotavirus and reovirus strains in combination with cholangiocyte models and neonatal mouse models. Murine and human cholangiocytes are infected and analyzed using molecular, biochemical, and immunologic assays to define signaling pathways, cytokine responses, and viral trafficking mechanisms. In vivo, genetically modified mouse strains are used to study host immune pathways involved in biliary atresia pathogenesis by being infected with rotavirus or reovirus and then bile ducts and livers are collected at specific time points. Particular focus is placed on the viral interaction with the Hsc70 receptor and its role in inducing or inhibiting BA.</p> <p>Training: Incomplete Applicable Section of the NIH Guidelines: III-D Containment Conditions: BSL2 Special Provisions: None Facility Visit: Will be scheduled once lab is fully moved to Stanford</p> <p>B. Donnelly left the meeting prior to discussion and voting.</p> <p>Discussion:</p>

- Panel members discussed Rotavirus mutations, viral differences associated with these mutations, and the impacts of those mutations on the disease model.
- A Panel Member asked if there was any known association with the mutant form of Rotavirus with biliary atresia, such any publications. The reviewer will follow up with the PI.
- The Biosafety Officer stated since the lab will be working with diphtheria toxin, TDAP vaccine should be recommended to lab members, which they can receive through the Occupational Health Center. The reviewer will inform the lab and put it in the protocol.

Approval Conditions:

1. Provide information regarding association of the disease outcome with the mutations.
2. Confirm that all lab members have been informed to contact Occupational Health regarding TDAP vaccines.

Voting:

A motion was made to conditionally approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0

The meeting was adjourned at 5:30 pm.