# Stanford University Institutional Biosafety Committee

**Committee 2 Minutes of Meeting July 15, 2026**

**Present (Voting)**

M. Holodniy, MD (Chair)
S. Felt, DVM, MPH, DACLAM, DACVPM
A. Bhatt, PhD
L. Cegelski, PhD
R. Paulmurugan, PhD
C. Campos
R. Trujillo, PhD
S. Vleck, PhD (BSO)

**Also Present (Not Voting)**

D. Berdnik, PhD
K. Lin, PhD
J. Sherrill, DVM
A. Johnson, PhD
B. Donnelly, PhD
K. Nobrega
C. Inacay (left 5:08 PM)
S. Rayate (left 4:40 PM)
R. Moore
S. Sindher, MD (joined 3:48 PM, left 4:17 PM)
J. Choi (joined 3:48 PM, left 4:17 PM)
O. Raeber, PhD(joined 3:48 PM, left 4:17PM)
B. Anderson (joined 3:48 PM, left 4:17PM)
A. Long (joined 3:48 PM, left 4:17PM)

Prior to the meeting, all IBC members should review:

- Confidentiality
    - The Committee proceedings are confidential. No protocols, including proprietary information, reviewed by Biosafety or IBC members and/or presented at Committee meetings should be discussed with anyone other than Committee 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 3:48 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 Committee 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 June 17th 2026, which were distributed electronically to all IBC members prior to this meeting.

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

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

    1. Protocols
        a. Clinicals

| PI | Protocol |
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| 1. Sindher, S. | [6241] A Phase 1/2, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation and Expansion Study of ENP-501 in Non-Peanut Allergic Participants and Participants with a Known Peanut Allergy |
| | **New Protocol**<br><br>**Summary:** ENP-501 is made of a peanut allergen extract encapsulated with sheared *Escherichia coli* (E. coli) DNA within lactic-co-glycolic acid (PLGA) nanoparticles coated with an E. coli lipid extract. This is the first in-human Phase 1/2 trial to evaluate the safety, tolerability, and efficacy of oral administrations of ENP-501 in non-peanut allergic (NPA) healthy |

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| | participants and peanut allergic (PA) participants.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** Section III-C<br>**Containment Conditions:** BSL1<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● A Committee Member asked if there were adverse events in previous non allergic patient; the PI answered 1 patient with mild mouth itching resolved with out treatment<br>● A Committee Member asked how screening is done for subjects that are not allergic to peanuts; PI responded that Ig testing and medical/food history review is conducted.<br>● A Committee Member asked what is the PLG dose; the PI said they would have to look into this and respond by email.<br>● A Committee Member asked what type of peanuts are used to extract the protein; the PI said they would have to look into this and respond by email.<br>● A Committee Member asked what is the E. coli lipid composition; the PI said they would have to look into this and respond by email.<br>● A Committee Member asked what is the DNA concentration that is part of the oral dose; the PI said they would have to look into this and respond by email.<br><br>**Voting:**<br>A motion was made to conditionally approve the protocol and was seconded. Total 8, For 8, Opposed 0, Abstain 0<br><br>This project was conditionally approved by the Institutional Biosafety Committee (IBC) on July 15, 2026. 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: Provide answers to the following: 1. What is the E. Coli DNA concentration in the ENP-501? 2. What is the E. Coli lipid composition? 3. What type of PLGA is used? What type of peanuts were used to extract the peanut allergen? |
| 2. Tesi Rocha, C. | [6071] A Phase 1/2a, Multi-Center, Open-Label Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of PBGENE-DMD in Participants with Duchenne Muscular Dystrophy / PBGENE-DMD-01 / Sponsor: Precision BioSciences INC |
| | **New Protocol**<br><br>**Summary:** Duchenne muscular dystrophy (DMD) is a fatal, X-linked muscle wasting disease affecting approximately 1 in 3,600–6,000 live male births. |

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| | Mutations in the DMD gene, most commonly multi-exonic deletions or duplications, account for nearly 80% of cases. The objective of PBGENE-DMD treatment is to precisely excise exons 45–55 of the dystrophin gene, creating an in-frame edit that produces a near full-length, functional dystrophin protein that is found in a subset of patients with Becker muscular dystrophy (BMD) who naturally harbor a del45–55 genotype; such individuals typically have a much milder phenotype, sometimes asymptomatic until adulthood, supporting the potential clinical relevance of this approach. PBGENE-DMD is comprised of an adeno-associated virus serotype 9 (AAV) delivered vector transgene encoding the two ARCUS nucleases, DMD19-20L.431 and DMD35-36L.457. The ARCUS technology is a gene-editing therapeutic modality composed of an engineered nuclease that binds and cleaves a unique recognition sequence in the human genome.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** Section III-C<br>**Containment Conditions:** BSL1<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● A Committee Member asked how is the IP giving; the reviewer answered it was giving intravenously<br>● A Committee Member asked if serum chemistry is measured and is this part of the informed consent; the reviewer confirmed yes to both.<br>● Committee members requested a report be submitted after the 1st patient is treated. This was communicated to the PI in the approval notes of the protocol.<br><br>**Voting:**<br>A motion was made to conditionally approve the protocol and was seconded.<br>Total 8, For 8, Opposed 0, Abstain 0 |
| 3. Betof, A. | [6211] 2024-0397: A Phase 1/2 Study of KSQ-004EX, autologous Tumor Infiltrating Lymphocytes engineered to inactivate genes encoding SOCS1 and Regnase-1, in Patients with Select Advanced Solid Tumors |
| | **New Protocol**<br><br>**Summary:** KSQ-004EX is an autologous engineered tumor-infiltrating lymphocyte (TIL) product with CRISPR/Cas9 mediated dual-inactivation of suppressor of cytokine signaling 1 (SOCS1) and Regnase-1. SOC1 is a negative regulator of cytokine responses in T cells, while Regnase-1 is an endoribonuclease encoded by the ZC3H12A gene and a key regulator of T cell inflammatory responses. The dual inactivation of SOCS1 and Regnase is anticipated to enhance antitumor functionality of TILs. Stanford will |

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| | participate in Phase I of the trial.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** Section III-C<br>**Containment Conditions:** BSL1<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br>**Discussion:**<br>● A Committee Member asked what type of cancer was treated in the previous clinical; the reviewer answered melanoma.<br>● A Committee Member asked if Stanford patients will receive IL-2 treatment; the reviewer answered it would depend what cohort the subjects get assigned to.<br><br>**Voting:**<br>A motion was made to conditionally approve the protocol and was seconded.<br>Total 8, For 8, Opposed 0, Abstain 0 |
| 4. Elmariah, H. | [6228] BMT435: A Phase 1/3 Study Evaluating the Efficacy and Safety of T-Cell Receptor Engineered Donor T Cells in Subjects Undergoing Allogeneic Peripheral Blood Stem Cell Transplantation (ALLOHA) |
| | **New Protocol**<br><br>**Summary:** TSC-101 is a genetically engineered, donor-derived T-cell therapy. The engineered product expresses an exogenous TCR (α and β chains, specific for the HA-2 minor histocompatibility antigen) as well as codon-optimized CD8 to enhance signal transduction through the TCR.<br>Additionally, a 16 amino acid sequence (ELPTQGTFSNVSTNVS), encoding a portion of the human CD34 molecule, is fused to the N-terminus of the CD8α chain to provide a genetically encoded tag with which to purify transgenic cells (to reduce potential graft versus host disease risk) and/or track infused drug product in patients. Stanford will participate in Phase 3 of the trial. The Phase 3 portion of the study is a genetically-randomized, internally controlled study designed to compare subjects who receive TSC-101 following reduced intensity conditioning (RIC) hematopoietic cell transplant (HCT) with control subjects who receive RIC HCT as SOC.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** Section III-C<br>**Containment Conditions:** BSL1<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● A Committee Member asked how the sponsor got the transposon into the donor T cells; the reviewer answered that they will ask the clinical |

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| | team.<br>● A Committee Member asked if the previous clinical trial had the same dose as the proposed clinical trial; the reviewer confirmed yes.<br><br>**Voting:**<br>A motion was made to conditionally approve the protocol and was seconded.<br>Total 8, For 8, Opposed 0, Abstain 0 |

b. Basic Protocols

| PI | Protocol |
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| 1. Yang, P. | [5228] Chemical Biology Studies of Viruses |
| | **Revision: Updated Synthetic Nucleic Acid Molecules, agents used, and animals/cells**<br><br>**Summary:** Work in the Yang Lab focuses on the development of small molecule antivirals as probes of molecular mechanism and as prototype drugs for the treatment of infections. Medicinal chemistry is used to optimize the activity, selectivity, and mechanism of action of these small molecules by performing virological and biochemical assays to determine mode of action. 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. This also includes experiments in vitro with purified recombinant proteins and RNAs and replication membranes isolated from cells infected with virus or harboring a subgenomic replicon. For some compounds, studies in murine models are explored in the Yang lab testing the in vivo efficacy of compounds in murine models after infection.<br>In this revision, new recombinant DNA is added to study the large L polymerase of Henipavirus which is already approved on the protocol. A minigenome system handled at BLS2 will be used in vitro to study transcription inhibition of protein L from Hendravirus.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** enhanced decontamination<br>**New Agent Added:** rDNA (Hendravirus genes L, N, P)<br>**Facility Visit:** February 4, 2026<br><br>**Discussion:**<br>● A Committee Member asked if the PI has the full components of Hendra or Nipah genome; the reviewer confirmed the research group |

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| | has a limited portion of the genome for Hendra, and although they have more of the genome present on plasmids for Nipah, they do not have the full genome in the lab and lack at least 1 gene required for pathogenesis.<br><br>**Voting:**<br>A motion was made to approve the protocol and was seconded.<br>Total 8, For 8, Opposed 0, Abstain 0 |
| 2. Robinson, W. | **[5812] Viral Triggers: Investigating the Role of Viruses in Autoimmune Disease** |
| | **Renewal: Updated personnel info and agents used**<br><br>**Summary:** This project seeks to investigate the role of human herpesviruses, particularly Epstein-Barr virus (EBV), in the development of autoimmunity. To achieve this, the lab will use lentiviral vectors to deliver individual herpesviral genes into cell lines, allowing functional characterization of these viral proteins. Additionally, the lab will generate infectious EBV particles from the B95.8 cell line and use them to transform primary B cells into lymphoblastoid cell lines (LCLs), establishing a model system for EBV infection studies. This lab will then study how LCLs respond to secondary infection with Influenza virus (H1N1) and Human Herpes Virus 1 (HHV1) or 6 (HHV6). Various assays such as sequencing of live sorted cells, immunohistochemistry, and cytokine profiling, will examine how EBV and specific viral genes modulate immune cell behavior in autoimmune contexts.<br>In this renewal, 3 additional HHV strains (Herpes Simplex Virus 2, Varicella-Zoster Virus, and Cytomegalovirus) are added to be employed in the same, already approved procedures as HHV1 and HHV6.<br><br>**Training:** Complete<br>**Applicable Section of the NIH Guidelines:** III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** N/A<br>**New Agent Added:** Herpes Simplex Virus 2, Varicella-Zoster Virus, and Cytomegalovirus<br>**Facility Visit:** January 26, 2026<br><br>**Discussion:** None.<br><br>**Voting:**<br>A motion was made to approve the protocol and was seconded.<br>Total 8, For 8, Opposed 0, Abstain 0 |