# Stanford University Institutional Biosafety Committee

**Panel Minutes of Meeting December 17, 2025**

**Present (Voting)**

M. Holodniy, MD (Chair)
S. Feldman, PhD
Ami Bhatt, MD, PhD
P. Yang, PhD
S. Felt, DVM, MPH, DACLAM, DACVPM
J. Arunachalam
R. Trujillo, PhD
S. Chen
S. Vleck, PhD, RBP/CBSP(ABSA)

**Also Present (Not Voting)**

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
K. Nobrega
J. Yamada
Y. Zhang, PhD
S. Rayate (Research Compliance Office)
R. Moore (VA Palo Alto Health Care System)

The meeting was called to order at 4:43 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 November 17, 2025 which were distributed electronically to all IBC members prior to this meeting.
    - Voting on November 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 |
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| 1. Galetta, K. | [5949] A Phase 1 Open-label, Multiregional, Multicenter, Basket Study Evaluating the Safety and Efficacy of KITE-363, an Autologous Anti-CD19/CD20 CAR T-cell Therapy in Participants with Relapsed/Refractory Autoimmune Neurologic Diseases |
| | **New Protocol**<br><br>**Summary:** The purpose of this study is to evaluate the safety and tolerability of KITE-363 (Autologous peripheral-blood T cells are transduced with 3rd generation replication-deficient lentiviral vector to introduce bicistronic anti-CD19 and anti-CD20 CAR gene) in participants with Relapsed/Refractory Autoimmune Neurologic Diseases (relapsing forms of Multiple Sclerosis (MS) (relapsing-remitting multiple sclerosis and active secondary-progressive multiple sclerosis), progressive forms of MS (primary-progressive multiple sclerosis and non-active secondary-progressive multiple sclerosis), generalized myasthenia gravis (MG), and chronic inflammatory demyelinating polyneuropathy (CIDP).<br>This study has a dose-escalation phase called Phase 1a and a dose-expansion phase called Phase 1b. The results of Phase 1a will help determine the recommended dose for Phase 1b.<br><br>**Training:** complete<br>**Applicable Section of the NIH Guidelines:** Section III-C, III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● A Panel Member asked another Panel Member their thoughts on comments regarding the administration of B-cell antigens via CAR T-cells. The second Panel Member stated that it is a manageable risk. The first Panel Member agreed, characterizing it as a medium-toxicity intervention. A Panel Member noted that the project has a reasonable safety review team and significant prior experience.<br>● A Panel Member stated, within the CAR T-cell field, this is considered a low-to-medium risk. |

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| | **Voting:**<br>A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 |
| 2. Weng, W. | [5965] Obe-cel (Obecabtagene autoleucel, AUTO1): Autologous Enriched T Cells Transduced with a Lentiviral Vector to Express a Novel Anti-CD19 Chimeric Antigen Receptor (CD19 [CAT] CAR) |
| | **New Protocol**<br><br>**Summary:** This is a single-arm, open-label, Phase II study to determine the efficacy and safety of Obecabtagene autoleucel in participants with severe, refractory systemic Lupus Erythematosus (SLE) with Active Lupus Nephritis (LN). Resetting the aberrant autoimmunity in participants with severe, refractory SLE with active LN through deep depletion of B cells using a CD19 chimeric antigen receptor T cell (CAR T) therapy is a potential strategy for achieving sustained remission.<br><br>**Training:** complete<br>**Applicable Section of the NIH Guidelines:** Section III-C, III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● No concerns<br><br>**Voting:**<br>A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 |

b. Basic Research Protocols

| PI | Protocol |
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| 1. Brunet, A. | [5643] Molecular mechanisms of aging and longevity |
| | **Revision: Updated Personnel Info, Update Agents Used**<br><br>**Summary:** This is a revision where the lab added Dengue. Dengue will be used to determine the impact of antibiotics on virus replication. The lab will produce Dengue, infect mammalian cells and then collect the cells to analyze them. They will be infecting the cells in the presence of antibiotics for 24 hours. The viral titer will then be determined by performing plaque assays. Uninfected control wells are included to assess background and confirm assay specificity. |

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| | **Training:** Complete<br>**Applicable Section of the NIH Guidelines:** III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** None<br><br>**New Agent Added:** Dengue<br>**Facility Visit:** 12/9/25<br><br>**Training:** complete<br>**Applicable Section of the NIH Guidelines:** Section III-C, III-D<br>**Containment Conditions:** BSL2<br>**Special Provisions:** Hospital/Clinic Infection Control precautions<br><br>**Discussion:**<br>● A Panel Member inquired about the hypothesis behind using an antibiotic against a virus. The Reviewer explained that the lab's previous work showed this antibiotic has shown antiviral effects against other RNA viruses and the lab wants to test if it also affects other RNA viruses.<br>● Discussion on the risk assessment regarding project personnel and potential for heightened risk of adverse clinical outcomes with second or higher Dengue exposure, particularly if traveling to tropical areas. This was addressed in the risk section and the lab was directed to contact the Occupational Health Center.<br><br>**Voting:**<br>A motion was made to approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 |