Stanford University Institutional Biosafety Committee

Panel 2 Minutes of Meeting October 16, 2025

Present (Noting)

M. Holodniy, MD (Chair)
Y. Maldonado, MD (Co-Chair)
S. Feldman, PhD
R. Paulmurugan, PhD
S. Oliver, PhD (Alternate)
J. Arunachalam
R. Trujillo, PhD
C. Campos
L. Cegelski, PhD (left 4:43 pm)
S. Vleck, PhD, RBP/CBSP(ABSA)

Also Present (Not Voting)

D. Berdnik, PhD, RBP(ABSA)
A. Fausto, PhD
K. Lin, PhD
R. Moore (VA Palo Alto Health Care System)
K. Nobrega
S. Rayate (Research Compliance Office) (left 4:30 pm)
J. Yamada
Y. Zhang, PhD
Ann Johnson, PhD

The meeting was called to order at 3:57 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 APB 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 APB 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. APB members will have the modified research protocol available to them, and any APB 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 the September 10, 2025 meeting which were distributed electronically to all IBC members prior to this meeting.
    - Approval of September Minutes—motion to approve, unanimous, no dissenters

5. The fifth order of business was IBC Panel Business.
    - The NIH noted receipt of the report of a rDNA exposure via email dated September 30, 2025. The NIH found the report to be sufficient and did not require any further action.
    - S. Vleck shared an overview of the incident and investigation outcomes.
        - A researcher was performing a DNA extraction on E. coli expressing a plasmid that contained a human gene. The human gene was not a toxin, oncogene, or otherwise a gene that elevated an exposure risk.
        - While using an electronic air-displacement pipette, the researcher used the force of the ejected liquid against the bottom of the container to break up the E. coli pellet. A small amount of material splashed out of the container and into their eye.
        - The researcher was not wearing eye protection, though mandatory eye protection was prescribed by the lab's standard operating procedure.
        - They immediately washed their eye in the laboratory's eye wash station and then reported to the Occupational Health Center, where they received appropriate medical treatment. The researcher did not subsequently experience symptoms or show any signs of ocular infection.
        - Corrective actions regarding wearing appropriate eye protection and pipetting safely and gently against the side of the container were discussed with the PI and lab, and the lab has updated their standard operating procedure and practices regarding gentle pipetting. They have also reviewed PPE requirements with all lab members.

6. The sixth order of business was the presentation, discussion and voting on protocols.

Biosafety staff performed the reviews, including considering agent characteristics (e.g., virulence, pathogenicity, environmental stability), the types of manipulations planned, the sources of the nucleic sequences (e.g., species), the nature of the nucleic acid sequences (e.g., structural gene, oncogene), the hosts and vectors to be used, and whether an attempt will be made to obtain expression of a transgene, and if so, the function of the protein that will be produced, as appropriate. The protocols, reviewer comments and PI responses were made available through eProtocol to all IBC members prior to the meeting. All reviewer and member concerns were addressed, with specific protocols discussed in greater detail below. The Panel then presented, discussed, and voted on the following protocols:

1. Clinical Protocol

PI	Protocol
1. Steinberg, G.	[5869] A Multicenter, Sham-controlled, Randomized Study to Evaluate the Safety, Tolerability, and Clinical Responses following Stereotactic Intracranial Implantation of DSP-1083 into Subjects with Parkinson's Disease (A Phase 1/2 Trial)

	New Protocol **Summary:** The purpose of this clinical research study is first-in-human (FIH) study designed to evaluate the safety, tolerability, and clinical responses following implantation of DSP-1083 compared with sham surgery. DSP-1083 areDopaminergic (DA) progenitor cells made using human induced pluripotent stem cells (iPSCs) that were generated by transducing human PBMCs from a healthy donor with Sendai viral vector expressing reprogramming factors. **Training: complete** **Applicable Section of the NIH Guidelines:** Section III-C, III-D **Containment Conditions:** BSL1 **Special Provisions:** Hospital/Clinic Infection Control precautions **Discussion:** ● A Panel Member raised concerns about the scientific rationality and human subjects implications of the sham control, noting it may not represent a true placebo since the procedure was slightly different. The IRB representative noted that the IRB did not have any issues with the sham control. The IBC requested it be noted here that they disagreed with the study's definition of sham procedure, but deferred to the IRB's oversight. ● A Panel Member inquired about additional sterility testing; the presenter confirmed mycoplasma testing was performed and certificate of analysis was provided. ● Panel Members requested complete donor screening information for integrated viruses and other infectious pathogens beyond EBV testing shown in the investigational brochure, based on concerns of potential for transmission between donor and recipient. The presenter noted this was not currently provided. ○ The Panel tabled this protocol based on this lack of information. Voting: None (Tabled) ● The PI is directed to provide the list of communicable disease, viruses, and other criteria that was used to determine/screen the eligibility of the donor to generate the IPSC.

2. Basic Research Protocols

PI	Protocol

1. Utz, P.	[5470] Luminex Antibody Profiling for COVID
	Renewal: Updated Personnel Info, Updated Description, Updated Agents **Summary:** This lab will analyze patient serum to investigate antibody responses following viral infections such as but not limited to COVID-19, RSV, influenza, and HHV-6. The work aims to discover new autoantigens and anti-cytokine antibodies, testing the hypothesis that these antibodies can make individuals more susceptible to infection. Furthermore, the lab will use cell-based assays and quantitative PCR to study host-pathogen interactions for emerging infectious agents. **Training:** Complete **Containment Conditions:** BSL2 **Special Provisions:** Enhanced decontamination and aerosol precautions Additional information **New Agent Added:** Human herpesvirus 6 (HHV6) **Facility Visit:** October 8, 2025 **Discussion:** ● A Panel Member stated that the current protocol title does not fully reflect the scope of the work described, and recommended that before the IBC grant approval, the lab should modify the title to better align with the project's contents. ● A Panel Member raised a question on rationale for using HHV-6+ human bronchoalveolar lavage fluid and tracheal aspirates, as opposed to infecting cells with HHV-6 directly; the Panel Member noted that microbiome or other pathogens in samples could affect cytopathic effect readings. The Panel Members requested a rationale be added to the protocol prior to approval. **Voting:** A motion was made to conditionally approve the protocol and was seconded. Total 9, For 9, Opposed 0, Abstain 0 (L. Cegelski absent for voting) ● Approval contingent on title update and inclusion of a brief rationale for use of human samples rather than purified virus in section 4A.

The meeting was adjourned at 4:54 pm.