

2. ANNOUNCEMENTS/DISCUSSIONS

[REDACTED]

3. APPROVAL OF MINUTES

The Minutes of the August 28, 2025, meeting were approved. (5 for, 0 against, 0 abstained)

4: NEW SUBMISSIONS

TSCAN-002-IBC **PI:** Curley, Thomas MD

Title A Phase 1 Basket Study Evaluating the Safety and Feasibility of T-Plex, Autologous Customized T Cell Receptor-Engineered T Cells Targeting Multiple Peptide/HLA Antigens in Participants with Antigen-positive Locally Advanced (Unresectable) or Metastatic Solid Tumors: PLEXI-T™

Board Decision Modifications Required to Secure Approval

Vote **Total: 5 Votes For: 5 Votes Against: 0 Abstentions: 0**

The Committee discussed the protocol and had the following comments:

Tissues, Blood, or Body Fluids:

- a. Please indicate that the shipping container is marked with a Biohazard label.

Primary Cells or Cell Lines:

- a. Please provide a more detailed explanation of how these materials will be used in humans.
- b. The question "Will these materials be transported?" refers to transportation with the [REDACTED] facilities. Please indicate how the agents will be transported from the storage area to the infusion area.

Human Subjects Used In Experiments:

- a. You indicate that [REDACTED] are infusionists. Please include them in the Nurses/Infusionists table.
- b. Please refer to the IDS Policy in the response regarding procedures, work practices and/or engineering controls, instead of "n/a."

Chemical Agents/Chemotherapeutic Agents:

- a. The question "Will these materials be transported?" refers to transportation with the [REDACTED] facilities. Please indicate how the agents will be transported from the storage area to the infusion area.

Risk Group and Containment Practices:

- a. You indicate that arrangements have not been made with the Housekeeping Department to prevent accidental exposure and environmental contamination. Please indicate how Housekeeping will be aware of any biohazard concerns.
- b. You answered No to the question "Does the research involve any potential for airborne transmission of agent(s)?" However, in the response above, you mention "aerosol through handling the bags." Please comment.

5. ADJOURNMENT

The Chair adjourned the meeting at 10:10 am.