

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, September 11, 2025  
**Time:** 1:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** Norton Hospital, Louisville, KY  
**Principal Investigator:** Jaspreet Singh Grewal, MD, PhD, MPH, MS  
**Protocol:** TScan Therapeutics, Inc., TSCAN-002  
**NCT Number:** NCT05973487  
**Meeting Type:** Initial Review of Protocol and Site  
**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™.

### 1. Call to order:

The Meeting was called to order at 1:00 pm Eastern Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were nine Institutional Representatives and IBC Services staff. The Chair declared that a quorum was present.

### 4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

### 5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

### 7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for T-Plex T-cell receptor modified T cells (TCR-Ts) since they consist of genetically modified human T cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of T-Plex T-cell receptor modified T cells (TCR-Ts) locally**, provided all other biosafety criteria for study closure are also met.

### 8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

### 9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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### **10. Review of proposed facilities and practices:**

The Chair provided an overview of the arrangement for the facilities and practices.

#### **Points of Discussion:**

1. The Committee recommended that Biosafety SOP Section 5.1 be revised to include spill handling steps for any spills that may occur on reusable bed linens.
2. The Committee recommended that all food and drink be removed from the countertop used for preparing the study agent and that other desktop items that could potentially be contaminated during preparation be cleared from the area.
3. The Committee recommended that the refrigerator shown in the storage room be labeled with a biohazard symbol if it is used to temporarily store the study agent.
4. The Committee recommended that biohazardous waste containers for disposal of personal protective equipment (PPE) and other non-sharp items be made available in the dosing rooms and that a representative photo of these containers be provided to IBC Services.
5. An Institutional Representative confirmed that the study agent would be stored in the dry shipper, which is labeled with a biohazard symbol, until it is time for subject dosing. The Committee recommended that a photo of the labeled dry shipper be provided to IBC Services.
6. An Institutional Representative confirmed that emergency eyewash signs were recently received and that one will be posted near the plumbed eyewash station in the preparation room. The Committee recommended that an updated photo of the plumbed eyewash station and the posted sign be provided to IBC Services.
7. An Institutional Representative confirmed that all the dosing rooms have a similar layout.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives.

### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 1:14 pm Eastern Time.