INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Thursday, June 12, 2025** |
| **Time:** | 9:00 am Central Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | University of Oklahoma, Health Sciences Center, Oklahoma City, OK |
| **Principal Investigator:** | **Manu Pandey, MD** |
| **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 9:00 am Central 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 and the Institution's Biosafety Officer. Also present was one Institutional Representative 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:**

The 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 cell products (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 cell products (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.

**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 nitrile or latex gloves be worn underneath cryogloves that are used when removing the study agent from the cryoport/liquid nitrogen tank.
2. The Committee recommended that a biohazard symbol be added to the biohazardous waste container in the [redacted] biohazardous waste storage area.
3. The Committee noted that there are 26 dosing rooms highlighted on the [redacted] map but that site documents reference rooms 1-25. The Committee recommended that the Institution follow up with IBC Services to confirm the number of rooms used and that all site documents be revised accordingly.

**11. Site requirements:**

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

**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 9:12 am Central Time.