

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, June 17, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Memorial Healthcare System, Pembroke Pines, FL
Principal Investigator: **Hugo Fernandez, MD**
Protocol: TScan Therapeutics, Inc., **TSCAN-001**
NCT Number: NCT05473910
Meeting Type: Continuing Review of Protocol and Site
Title: A Controlled Multi-Arm Phase 1 Umbrella Study Evaluating the Safety and Feasibility of T-Cell Receptor Engineered Donor T-Cells Targeting HA-1 (TSC-100) or HA-2 (TSC-101) in HLA-A*02:01 Positive Subjects Undergoing Allogeneic Peripheral Blood Stem Cell Transplantation

1. Call to order:

The Meeting was called to order at 1:02 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 the Principal Investigator, two 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-2 containment facilities and practices** are required for TSC-100 and TSC101, since they consist of genetically modified allogeneic donor T-cells. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of TSC-100 and TSC-101 locally**, provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. 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

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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 Principal Investigator confirmed that the study agent is thawed in a 37°C water bath. The Committee recommended that Biosafety SOP Section 3.3 be revised to include the temperature of the water bath.
2. The Principal Investigator confirmed that there is an additional staff member in the room during dosing that can escort an individual to the nearest plumbed eyewash station in the event of an eye exposure. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to include this information.
3. The Committee recommended that the Institution confirms how often the plumbed eyewash stations are flushed.
4. The Committee recommended that the biohazardous waste storage container be covered when not in use.
5. The Committee recommended that a biohazard symbol on a red background be posted on the entrance door to the biohazardous waste storage room.
6. The Committee recommended that the Institution provides information regarding how biohazardous waste is transported from the dosing room to the biohazardous waste storage room and how biohazardous waste from the storage room is removed by the licensed biohazardous waste hauler.
7. The Principal Investigator confirmed that the main and alternate phone numbers listed next to his name on the Biohazard Sign are monitored 24/7. The Committee recommended that the sign be revised to reflect this.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and 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 1:19 pm Eastern Time.