

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, September 26, 2025
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: Northside Hospital, Atlanta, GA
Principal Investigator: Melhem Solh, 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 10:01 am Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including two local members unaffiliated with the institution. Also present were four 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: 4 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: 4 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.

Point of Discussion:

1. The Committee had no questions or concerns about the facilities and practices.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:09 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 5, dated 02-11-2025

Investigator's Brochure, TSC-100, Edition 3.0, dated 03-07-2025

Investigator's Brochure, TSC-101, Edition 4.0, dated 07-17-2025

Pharmacy Manual, Version 3, dated 07-31-2024

Research Modification Evaluation, Protocol, Amendment 3

Research Modification Evaluation, Protocol, Amendment 4

Research Modification Evaluation, Protocol, Amendment 5

Research Modification Evaluation, Investigator's Brochure, Edition 2.0

Research Modification Evaluation, Investigator's Brochure, Edition 3.0

Research Modification Evaluation, Investigator's Brochure, Edition 4.0

Biological Risk Assessment and Summary, updated 08-15-2025

Site Map, BMT Unit, 4th Floor, dated 01-29-2024

Site Map, HSC Laboratory, dated 01-29-2024

Site Inspection Checklist, GMHC, expires 02-10-2027, updated 09-03-2025

Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025

Photos, HSC Lab, BMT Unit, dated 07-03-2025

Biohazard Sign, Genetically Modified Human Cells, dated 09-04-2025

SOP, Biosafety for Genetically Modified Human Cells, dated 09-03-2025

SOP Addendum, Biosafety for Allogeneic Cells, dated 09-03-2025

Training, Shipping Certification, expire 03-10-2026, 04-30-2026

CRRF, dated 06-02-2025, updated 09-08-2025

Prior Meeting Minutes, Continuing, dated 09-25-2024