

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, June 12, 2023
Time: 3:00 pm Eastern Time
Web Participants: https://us06web.zoom.us/j/82018417857?pwd=Yi9qVzcwclplNUJlZnlHbkZ4cE9Edz09
Telephone Only Participants: 1-888-788-0099 Access Code: 820 1841 7857
Institution: Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator: Suhag H. Parikh, MD
Protocol: Orchard Therapeutics, OTL-103-4
Meeting Type: Continuing Review of Protocol and Site
Title: A Single Arm, Open Label Clinical Study of Hematopoietic Stem Cell Gene Therapy with Cryopreserved Autologous CD34+ Cells Transduced with Lentiviral Vector encoding WAS cDNA in Subjects with Wiskott-Aldrich Syndrome (WAS)

1. Call to order:

The Meeting was called to order at 3:24 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Three voting members were present, including one local member unaffiliated with the institution. Also present were 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:

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. Approval of previous meeting minutes:

Minutes Approved - YES: 3 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the dosing status.

The Chair provided an overview of the protocol.

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 OTL-103, since it consists of primary human cells modified using a recombinant, replication-defective, SIN lentiviral vector. 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 OTL-103 locally, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

Table with 2 columns: Vote, Determination. Row 1: X, APPROVED. Row 2: , CONDITIONALLY APPROVED. Row 3: , TABLED. Row 4: , DISAPPROVED.

DETERMINATION VOTE - YES: 3 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 Committee discussed the efficacy of disinfecting agents, including PDI Sani-Cloth AF3 wipes and CaviWipes, and determined that both are effective against the study agent.
2. The Chair noted that Virex II solution is also listed as a disinfecting agent, and an Institutional Representative will follow up with IBC Services on whether or not it is used for work surfaces. The Committee recommended that site documents be updated accordingly upon receipt of the follow-up information.
3. The Committee recommended that typos in the site map be revised.
4. An Institutional Representative confirmed that a Biological Safety Cabinet (BSC) is not used for study agent preparation for this protocol.
5. The Committee recommended that site documents be revised to indicate which protocols require a BSC as well as which protocols use the different dosing rooms.
6. An Institutional Representative confirmed that disposable eyewash bottles are transported on a mobile cart into rooms without a plumbed eyewash. The Committee recommended that site documents be revised accordingly to reflect this.
7. The Committee recommended that the expiration dates of the disposable eyewash bottles be provided to IBC Services.

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: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:28 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 5.0, dated 02-25-2022

Investigator's Brochure, Version 14.0, dated 04-25-2022

Clinical Product Manual, Revision 01, dated 11-04-2021

Biological Risk Assessment and Summary, updated 05-20-2022

Site Maps, updated 05-10-2023

Site Inspection Checklist, dated 05-10-2023

Photos, dated 05-10-2023

Biohazard Sign, dated 10-12-2021

SOP, Biosafety for OTL-103, dated 06-29-2022

Training, Shipping Certification, expire 2024, 2025

Continuing Review Report Form, dated 03-21-2023

Prior Meeting Minutes, Continuing, dated 06-06-2022