INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, July 1, 2021**
Time:	4:00 pm Eastern Time
Web Participants:	https://wcgclinical.webex.com/wcgclinical/j.php?MTID=m54d6404e59e26caa053ff4c2332a3f98
Telephone Only Participants:	1-877-668-4493 Access Code: 172 391 6141
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Suhag H. Parikh, MD**
Protocol:	Orchard Therapeutics, **OTL-103-4**
Meeting Type:	Initial 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 4:00 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 one non-voting Institutional Representative, two non-member Institutional Representatives, the Principal Investigator 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 Principal Investigator and 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 OTL-103, since it consists of primary human cells modified using a recombinant, replication-defective, SIN lentiviral vector.

The Committee 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.

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 certain items in the Site Visit Checklist be updated to better reflect the variety of studies under IBC overview at the Institution. An Institutional Representative agreed to work with IBC Services updating the Site Visit Checklist for future reviews.
2. An Institutional Representative confirmed that the Plasmatherm device that will be used for thawing the infusion bag will be provided by the Sponsor and will only be used for this study.
3. An Institutional Representative confirmed that biohazard signage is printed on red paper.
4. An Institutional Representative confirmed that a portable eyewash travels with the study agent.
5. An Institutional Representative confirmed that the plumbed eyewash station in the Cellular Therapies Laboratory is accessible to staff members and that they have been trained on the use of this eyewash. In addition, multiple staff members are typically in the laboratory at any given time and are able to assist staff members who may have an eye exposure.
6. An Institutional Representative confirmed that the stainless steel biohazardous waste container in the Cellular Therapies Laboratory has a step-on lid opener/closer and that the part on top of the lid is connected to the hinge.
7. An Institutional Representative noted that the Plasmatherm device will be decontaminated on a yearly basis by the manufacturer and the decontaminated liquid will be disposed of down the sink.
8. The Chair stated that once the Biosafety SOP has been finalized, all study staff members and the Principal Investigator should be trained on this Biosafety SOP prior to beginning study activities.

11. Site requirements:

The Chair reviewed requirements for maintaining IBC approval with the Principal Investigator and 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 4:26 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 4.0, dated 01-28-2021
Investigator's Brochure, Version 12.0, dated 05-01-2020
Clinical Product Manual, Version 00, dated 03-09-2021
Biological Risk Assessment and Summary, dated 06-27-2021
Site Map, Egelson Hospital, updated 06-22-2021
Site Visit Checklist, dated 04-08-2021, updated 06-23-2021
Photos, dated 04-21-2021
Biohazard Sign, dated 05-17-2021
SOP, Biosafety for OTL-103, dated 06-16-2021
Training, Shipping Certification, expires 06-24-2022
CV, Parikh, S, signed 04-07-2020