

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Thursday, June 6, 2024
Time: 4:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator: Shanmuganathan Chandrakasan, MD
Protocol: National Institutes of Health, BCH P00023098
Meeting Type: Continuing Review of Protocol and Site
Title: Phase I/II trial of lentiviral gene transfer for SCID-X1 with low dose targeted busulfan conditioning

1. Call to order:

The Meeting was called to order at 3:58 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 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. 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 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 the modified CD34+ cells since they consist of autologous stem cells modified by a 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 the modified CD34+ cells 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:

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 Committee noted that “G2SCID” refers to the lentiviral vector used to transduce the autologous CD34+ cells, not the study agent, which is referred to as “modified CD34+ cells”. The Committee recommended that both the Biohazard Sign and Biosafety SOP be revised to replace “G2SCID” with “modified CD34+ cells”.
2. The Committee noted the Photos document is missing the photo of the mobile cart with waterbath. The Institutional Representative agreed to update this document with a photo of the mobile cart with waterbath.

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 4:09 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 2.3.2, dated 01-09-2021

Investigator's Brochure, Version 1.0, dated 12-09-2019

Manual of Operations, Version 2.0, dated 02-04-2020

Biological Risk Assessment and Summary, updated 03-16-2022

Site Maps, dated 02-22-2024

Site Inspection Checklist, dated 05-14-2024

Photos, dated 03-19-2024

Biohazard Sign, dated 01-26-2024

SOP, Biosafety for Modified CD34 cells, dated 06-29-2022

Training, Shipping Certifications, expire 2024, 2025

Continuing Review Report Form, dated 03-28-2024

Prior Meeting Minutes, Continuing, dated 06-12-2023