

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: 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 3:00 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 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**, 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: 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 formatting errors and typos in the Biosafety SOP and 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 3:18 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, 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 Modified CD34 cells, 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