INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, April 21, 2026**
Time:	1:00 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**
NCT Number:	NCT03311503
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 1:27 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 the notice of the meeting was not publicly posted per Institutional policy.

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 protocol and status of the study.

The Chair noted 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

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 Institutional Representative confirmed that a red biohazard container on wheels is used to discard sharps but was unsure if non-sharps waste is also discarded into this container. The Committee noted that disposable of non-sharps waste in a sharps container increases the chance that an inadvertent needlestick injury could occur and highly recommended that separate containers be used for sharps and non-sharps biohazardous waste.
2. The Committee recommended that Slides 6 and 11 in the Photos document, dated 04-20-2026, be revised to replace the word “biohazardous” with “sharps”.
3. The Committee discussed the most recent photos available for review and recommended that the Institution follow-up with IBC Services about the following:
    a. Confirm what type of container non-sharps biohazardous waste is disposed of in the Lab where preparation of the study agent will occur.
    b. Submit a photo of the container used for non-sharps biohazardous waste.
4. The Chair noted that the Institution recently provided IBC Services with a “24/7” phone number for the Biohazard Sign and that it will be revised to include this information.
5. The Committee acknowledged that while plumbed eyewash stations are available in areas where the study agent will be handled, it is recommended that prefilled eyewash bottles also be readily available in rooms during study agent handling to allow for immediate use in the event of eye exposure
6. The Committee recommended that Site Inspection Checklist Item #22 be revised to note that plumbed eyewash stations and prefilled disposable eyewash bottles are available in the Inpatient dosing area.

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 1:32 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 2.3.6, dated 12-09-2024
Investigator's Brochure, Version 1.0, dated 12-09-2019
Manual of Operations, Version 2.0, dated 02-04-2020
Research Modification Evaluation, Protocol, Version 2.3.6
Biological Risk Assessment and Summary, updated 10-22-2025
Site Maps, dated 11-18-2024
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 04-03-2026
Photos, dated 03-25-2026
Photos, dated 04-20-2026
Biohazard Sign, Genetically Modified Human Cells, dated 04-07-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 03-19-2026

SOP Addendum, Genetically Modified Human Cells, dated 03-19-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CRRF, dated 03-17-2026
Prior Meeting Minutes, Continuing, dated 05-22-2025