INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, May 22, 2025**
Time:	3:00 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 3:22 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

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

An 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: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

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: 4 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 Committee noted that all open studies currently overseen by the IBC consist of genetically modified human cells and recommended that one Biosafety SOP for Genetically Modified Human Cells be created since facilities and practices for all studies are either the same or very similar. An Institutional Representative agreed to this arrangement.
2. 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".
3. The Committee noted that typical personal protective equipment (PPE) used when removing items from liquid nitrogen include gloves, body protection and face protection. The Committee recommended that the Institution confirm the PPE worn when removing items from liquid nitrogen and that the Biosafety SOP be updated accordingly.
4. An Institutional Representative confirmed that all genetically modified human cell study agents are thawed outside of the Biological Safety Cabinet (BSC) in the Cellular Therapies Laboratory and then transported to the dosing room in a double-walled container.
5. The Committee recommended that the Site Inspection Checklist Table of Activities be revised to remove the red font noting protocols since the areas listed are applicable to all studies.
6. The Committee noted that all Protocols no longer under IBC oversight be removed from the Biosafety SOP, Biohazard Sign and Site Inspection Checklist.
7. The Committee recommended that all biohazard soiled holding areas be labeled on the exterior with a biohazard symbol. An Institutional Representative agreed to follow-up with Institutional staff members about this recommendation.
8. The Committee recommended that the Institution confirm what IATA and DOT regulations are covered by the "MediaLab (LabCE) Packaging and Shipping Infectious Materials" training.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 3:30 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 2.3.5, dated 04-08-2024
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 2.3.5
Research Modification Evaluation, Protocol, Version 2.3.4
Research Modification Evaluation, Protocol, Version 2.3.3
Biological Risk Assessment and Summary, updated 05-13-2025

Research Modification Evaluation, New Location, dated 01-21-2025
Site Maps, dated 11-18-2024
Site Inspection Checklist, dated 01-14-2025, updated 04-22-2025
Photos, dated 05-05-2025
Biohazard Sign, dated 04-22-2025
SOP, Biosafety for Modified CD34 cells, dated 11-22-2024
Training, Shipping Certification, expires 10-2026
CRRF, dated 05-09-2025
Prior Meeting Minutes, Continuing, dated 06-06-2024