

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, May 07, 2021  
**Time:** 2:00 pm Eastern Time  
**Web Participants:** <https://wgcclinical.webex.com/wgcclinical/j.php?MTID=mec466df0cf367148f8281d9e6cd3a47e>  
**Telephone Only Participants:** 1-415-655-0001 Access Code: 160 979 1321  
**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 2:22 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, 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 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**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

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### **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 Committee recommended that the Site Visit Checklist Locations Table be updated to reflect the appropriate protocols next to the appropriate locations.
2. The Committee recommended that site documents be updated to reflect that there are no special provisions required for study staff upon entry into rooms in which the study agent will be handled.
3. An Institutional Representative confirmed that in the rare event that multiple study agents will be handled concurrently that all work surfaces will be decontaminated before and after handling each study agent.
4. An Institutional Representative confirmed that eye protection is reusable and decontaminated before and after use.
5. The Committee discussed how the water in the water bath is disposed of and how the water bath is decontaminated after thawing procedures. Institutional Representatives were not able to confirm these procedures. The Committee recommended that the institution follow up with IBC Services and that site documents be updated accordingly based on the information received.
6. The Committee recommended that the Biohazard Sign be printed on red or orange paper.

### **11. Site requirements:**

The Chair reviewed 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: 5

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 2:31 pm Eastern Time.

### **15. Post-meeting notes:** None.

#### **Documents reviewed:**

Agenda

Protocol, Version 2.3.1, dated 03-02-2020

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 2.3.1

Biological Risk Assessment and Summary, updated 02-11-2021

Site Map, Egelson Hospital, updated 03-12-2021

Site Visit Checklist, dated 04-08-2021

Photos, dated 04-21-2021

Biohazard Sign, dated 03-12-2021

SOP, Biosafety for Modified CD34 cells, dated 04-26-2021

Training, Shipping Certification, expires 06-24-2022

Continuing Review Report Form, dated 02-03-2021

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Prior Meeting Minutes, Initial, dated 04-08-2020