

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, June 6, 2022
Time: 11:00 am Eastern Time
Web Participants: <https://us06web.zoom.us/j/89445678215?pwd=d1QwTzNoVEc2NC96UEM4T0J5QlpJUT09>
Telephone Only Participants: 1-888-788-0099 Access Code: 894 4567 8215
Institution: Children’s Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator: **Suhag H. Parikh, MD**
Protocol: Bioverativ Therapeutics, Inc., **003SCD101**
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1/2, Open-Label, Multicenter, Single-Arm Study to Assess the Safety, Tolerability, and Efficacy of BIVV003 for Autologous Hematopoietic Stem Cell Transplantation in Patients With Severe Sickle Cell Disease

1. Call to order:

The Meeting was called to order at 11:11 am 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 one non-voting Institutional Representative, one non-member 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: 4 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 BIVV003, since it consists of primary human cells modified via mRNA transfection. 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 BIVV003 locally**, provided that other biosafety criteria for study closure are also 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

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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 recommended that "Sani-Cloths" be replaced with "Sani-cloth AF3 Germicidal Wipes" throughout the Biosafety SOP as applicable.
2. The Committee noted that IATA Shipping Certification is set to expire by the end of the month and recommended that the Institution submit updated/newer Shipping Training Certification(s) when they become available.
3. An Institutional Representative confirmed that training on the Biosafety SOP is current for study staff members and agreed to submit an updated photo of the training log to IBC Services.

11. Site requirements:

The Chair reviewed 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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:17 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Amendment 4.0, dated 04-03-2020

Investigator's Brochure, Edition 3, dated 07-30-2020

Cell Therapy Manual, Version 3.0, dated 11-24-2020

Biological Risk Assessment, and Summary, updated 04-20-2021

Site Map, Egelston Hospital, updated 06-22-2021

Site Inspection Checklist, dated 05-18-2022

Photos, dated 09-09-2021

Biohazard Sign, dated 10-12-2021

Biological Safety Cabinet Certification, Cellular Lab, expires 08-2022

SOP, Biosafety for BIVV003, dated 07-02-2021

Training, Shipping Certification, expires 06-24-2022

Continuing Review Report Form, dated 03-15-2022

Prior Meeting Minutes, Modification, dated 10-06-2021