INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, May 07, 2021**
Time:	2:00 pm Eastern Time
Web Participants:	https://wcgclinical.webex.com/wcgclinical/j.php?MTID=mec466df0cf367148f8281d9e6cd3a47e
Telephone Only Participants:	1-844-621-3956 Access Code: 160 979 1321
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Lakshmanan Krishnamurti, 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 2:01 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 BIVV003, since it consists of primary human cells modified via mRNA transfection. The Committee reaffirmed this determination.

The Committee previously determined that **IBC oversight would continue for 3 months after the last subject's last dose locally of BIVV003**, 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: 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 Chair noted that the Institution submitted a Research Related Incident Report to IBC Services stating that the Institution had not completed a Biosafety SOP Training log for their study staff. The Chair also noted that the Institution has trained and documented all study staff on the Biosafety SOP in their corrective action plan.
2. The Committee recommended that the Site Visit Checklist Locations Table be updated to reflect the appropriate protocols next to the appropriate locations.
3. 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.
4. 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.
5. An Institutional Representative confirmed that eye protection is reusable and decontaminated before and after use.
6. 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.

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 2:21 pm Eastern Time.

15. Post-meeting notes: After the meeting ended, and during a second IBC review meeting for the site, the Committee recommended that the Biohazard Sign be printed on red or orange paper.

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
Research Modification Evaluation, Protocol, Amendment 4
Research Modification Evaluation, Investigator's Brochure, Edition 3
Biological Risk Assessment and Summary, updated 04-20-2021
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
Biological Safety Cabinet Certification, Cellular Lab, expires 09-2021
SOP, Biosafety for BIVV003, dated 04-22-2021
Training, Shipping Certification, expires 06-24-2022
Continuing Review Report Form, dated 02-12-2021
Deviation-Research Related Incident Report Form, dated 04-16-2021
IBCS Research Related Incident Assessment, dated 05-04-2021
Prior Meeting Minutes, Continuing, dated 04-21-2020