

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, September 22, 2025
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Hackensack Meridian Health, Hackensack, NJ
Principal Investigator: Stacey Rifkin-Zenenberg, DO
Protocol: Bluebird bio, HGB-210
NCT Number: NCT04293185
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 3 Study Evaluating Gene Therapy by Transplantation of Autologous CD34+ Stem Cells Transduced Ex Vivo with the LentiGlobin BB305 Lentiviral Vector in Subjects with Sickle Cell Disease.

1. Call to order:

The Meeting was called to order at 11:12 am 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 and the Institution's Biosafety Officer. Also present were 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 Biosafety Officer 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 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 bb1111 (LentiGlobin BB305), since it consists of primary human cells modified using a recombinant, replication-defective, SIN 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 bb1111 (LentiGlobin BB305) 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

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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 the locations table in Biosafety Guidelines Section 3.1 be revised to include the [REDACTED] as biohazardous waste storage locations.
2. The Committee recommended that the [REDACTED] Site Map be revised to box out all dosing rooms for clarity.
3. The Committee noted that one of the pieces of equipment used to test the biological safety cabinets (BSCs) was due to be recalibrated in August 2025 although it was current at the time the BSCs were certified.
4. The Biosafety Officer confirmed that the mobile cart and the water bath are labeled with a biohazard symbol. The Committee recommended that the [REDACTED] Photo be revised to indicate this.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer.

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 11:21 am Eastern Time.