INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, February 12, 2026**
Time:	11:00 am Arizona Time
Location:	Zoom Teleconference
Institution:	Phoenix Children's Hospital, Phoenix, AZ
Principal Investigator:	**Shanna White, MD**
Protocol:	Regeneron Pharmaceuticals, **R131L1265-HEMB-2318**
NCT Number:	NCT06379789
Meeting Type:	Initial Review of Protocol and Site
Title:	A Two-Part Open-Label Study of REGV131-LNP1265, A CRISPR/CAS9-Based Coagulation Factor IX Gene Insertion Therapy In Participants With Hemophilia B

1. Call to order:

The Meeting was called to order at 11:00 am Arizona 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 five 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for REGV131-LNP1265 since it consists of a gene editing product administered directly to subjects which can permanently modify the cellular genome within the body.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of REGV131-LNP1265 locally**, provided that all biosafety criteria for study closure are met.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 Biosafety SOP Section 3.3.1 be revised to indicate that a luer-lock system will be used to connect the syringes if dilution is required.
2. The Committee recommended that Biosafety SOP Section 3.3.2 be revised to indicate that the infusion bag contains diluent.
3. The Committee recommended that photos of the biohazardous waste containers in the dosing rooms, with visible biohazard symbols, be provided to IBC Services.
4. The Committee recommended that the Biological Safety Cabinet (BSC) be labelled with a biohazard symbol while the study agent is being prepared inside it.
5. The Committee recommended that the study agent specific biohazard sign be posted at the entrance to the dosing rooms during administration. The Committee recommended that site photos of the dosing rooms be revised to indicate that the sign will be posted.
6. The Committee recommended that biohazardous waste containers in the soiled work room be kept lidded when not in use and that they not be overfilled. The Committee recommended that site photos of the soiled work room be revised to indicate this.
7. The Committee noted that the Training/Shipping certification provided for IBC review does not indicate an expiration date or the materials used for training. After further discussion, the Committee noted that it appears that the training is valid for two years.
8. An Institutional representative stated that a refrigerator may be used for temporary storage of the prepared study agent if dosing is delayed for some reason. The Committee recommended that a photo of the refrigerator, labelled with a biohazard symbol, be provided to IBC Services.
9. The Committee discussed whether disposable eyewash bottles could be placed in the preparation room. An Institutional Representative stated that the plumbed eyewash is located in the ante room, just outside of the preparation room, and is accessible through a hands-free door. The Committee found this to be acceptable and recommended that Site Inspection Checklist(#22) be revised to reflect this.

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 11:23 am Arizona Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Amendment 2, dated 11-07-2024
Investigator's Brochure, Edition 2.0, dated 10-01-2024
Pharmacy Manual, Version 3.0, dated 12-19-2024
Biological Risk Assessment and Summary, updated 01-07-2025
Site Map, Phoenix Children's Hospital, 7th Floor, dated 12-09-2025
Site Map, Phoenix Children's Hospital, Pharmacy, dated 01-20-2026
Site Inspection Checklist, expires 11-18-2027

Photos, Phoenix Children's Hospital, dated 02-02-2026
Biohazard Sign, REGV131-LNP1265, dated 01-13-2026
Biological Safety Cabinet Certifications, dated 11-21-2025
SOP, Biosafety for REGV131-LNP1265, dated 02-02-2026
Training, Shipping Certification, expires 10-15-2027
CV, White, S., signed 05-17-2024