INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, November 11, 2025**
Time:	4:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Ascension St. Vincent Indiana, Indianapolis, IN
Principal Investigator:	**Amy D. Shapiro, 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 4:01 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 four Institutional Representatives, the Principal Investigator, 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 (Containment Level 2)** 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: 5 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 Section 5.2.4 of the Biosafety SOP be revised to indicate that the eye will be flushed for up to 15 minutes.
2. An Institutional Representative confirmed that safety needles will be used for the preparation of the study agent, and the needles will be recapped via the safety mechanisms.
3. The Committee recommended that a biohazard sign be posted at the entrance to the areas where the study agent is handled and that photos of the posted signage be provided to IBC Services.
4. The Committee recommended that a biohazard symbol be placed on the study agent storage unit and that a new photo of the labelled storage unit be provided to IBC Services.
5. The Committee recommended that all biohazardous waste containers be lidded when not in use.
6. The Committee discussed the specific study agent transport requirements as noted in the Pharmacy Manual, which note that the container should be insulated, sunlight protected, and should not exceed 25°C. The Committee noted that the transport container, as shown in site photos, is not insulated and would not protect the study agent from the sun.
7. An Institutional Representative stated that coolers are available for study agent transport, and the Committee found this to be acceptable. The Committee recommended that the cooler be labelled with a biohazard symbol and a photo be submitted to IBC Services.
8. An Institutional Representative stated that temperature monitoring devices are available onsite if needed for the study agent transport container.
9. The Committee noted that the institution could ask the sponsor if a study agent transport container with temperature monitoring could be provided for use onsite.
10. An Institutional Representative confirmed that the preparation and dosing locations are two separate buildings, located across the street from each other.
11. An Institutional Representative confirmed that a sharps container will be present inside the Biological Safety Cabinet (BSC) during study agent preparation.
12. An Institutional Representative stated that there are non-sharps biohazardous waste containers in the dosing rooms. The Committee recommended that photos of these be provided to IBC Services.
13. The Committee recommended that the Biohazard Sign be revised to indicate a 24/7 phone number for the [redacted]
14. An Institutional Representative stated that biohazardous waste is stored in a biohazard waste closet on the first floor of the [redacted] The Committee recommended that site documents be revised to reflect this.
15. The Committee recommended that the specific room number/area for biohazardous waste storage at the [redacted] be provided to IBC Services and that site documents be revised accordingly.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the Principal Investigator.

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 4:35 pm Eastern Time.