INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, December 11, 2025**
Time:	11:00 am Central Time
Location:	Zoom Teleconference
Institution:	Tulane University, Metairie, LA
Principal Investigator:	**Maissaa Janbain, MD**
Protocol:	Regeneron Pharmaceuticals, **R131L1265-HEMB-2318**
NCT Number:	NCT06379789
Meeting Type:	Continuing 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 11:01 am Central Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Seven voting members were present, including two local members unaffiliated with the institution and two Institutional Biosafety Officers. Also present were two 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: 7 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 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 reaffirmed this determination.

The Committee previously 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. 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: 7 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. An Institutional Biosafety Officer confirmed that full biohazardous waste containers from the [redacted] are collected on a weekly basis and brought to the [redacted] where they are immediately loaded onto the licensed biohazardous waste hauler's truck. The Committee recommended that site documents be revised to remove the [redacted] as a location where full biohazardous waste is stored.
2. An Institutional Representative could not confirm whether prefilled disposable eyewash bottles are used in the preparation or dosing areas. The Committee recommended that the Institution confirm whether prefilled disposable eyewash bottles will be used and revise site documents as necessary.
3. An Institutional Representative confirmed that biohazardous waste is stored inside rooms with a closeable door and not in a hallway.
4. The Committee recommended that cardboard biohazardous waste containers be kept closed when not in use.
5. The Committee recommended that cardboard biohazardous waste containers not be stored directly on the floor, to minimize the risk of contamination and water damage, and that they be placed in a plastic bin or similar.
6. The Committee recommended that cardboard boxes not be stored in front of the electrical panel in the biohazardous waste storage room at the [redacted] facility.
7. The Committee noted that there are two Biological Safety Cabinets (BSCs) available in the [redacted] and that both are accurately listed on site documents.
8. The Committee noted that there are additional disinfecting agents shown in the Photos document and recommended that site documents be revised to include all disinfecting agents that may be used.
9. An Institutional Representative confirmed that the transport container has a handle.
10. An Institutional Representative confirmed that the Sponsor will not ship the study agent to the site until a subject is scheduled for dosing. The study agent will be prepared in the [redacted], placed in the transport container, and driven by study staff to the [redacted] dosing location.
11. An Institutional Representative confirmed that the drive from the [redacted] to the [redacted] dosing location takes approximately 15-30 minutes, depending on traffic.
12. The Committee noted that there are two components that comprise the study agent and that one is prepared in a syringe and the other is prepared in an infusion bag. An Institutional Representative confirmed that both study agents are transported to the dosing location in the same transport container.
13. An Institutional Representative could not confirm whether the study agent is transported on ice or at ambient temperature.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Biosafety Officers and 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: 7 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:29 am Central Time.