

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, August 11, 2026  
**Time:** 1:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** McGill University Health Centre, Montreal, Quebec  
**Principal Investigator:** Margaret Warner, 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 1:06 pm Eastern Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Four members were present, including one local member unaffiliated with the institution. 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: 4 NO: 0 ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair noted 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 (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 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: 4 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. The Committee had no questions or concerns or regarding these.

### **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 1:11 pm Eastern 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, 4th floor C04.35, dated 03-16-2026

Site Map, Pediatric Oncology Pharmacy, dated 07-22-2025

Site Map, Central Pharmacy, dated 05-05-2026

Site Map, Biohazardous Waste Storage, dated 03-16-2026

Site Inspection Checklist, McGill University Health Centre, expires 07-24-2028

Photos, 4th floor C04.35 and Waste, dated 05-05-2026

Photos, Central Pharmacy, C01.6010.3, dated 05-03-2026

Photos, Pediatric Oncology Pharmacy, B07.5215.5, dated 07-28-2025

Biohazard Sign, Dosing, dated 08-17-2025

Biohazard Sign, Preparation, dated 08-17-2025

Biological Safety Cabinet Certification, B07.5215.5, dated 04-28-2026

SOP, Biosafety for REGV131-LNP1265, dated 07-06-2026

Training, Shipping Certification, expires 11-08-2026

CRRF, dated 04-30-2026

Prior Meeting Minutes, Initial, dated 08-29-2025