

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, July 13, 2026
Time: 12:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Saint Peter's University Hospital, New Brunswick, NJ
Principal Investigator: Debra-Lynn Day-Salvatore, MD, PhD, FAAP, FACMG
Protocol: Regenxbio, Inc., RGX-121-3102
NCT Number: NCT07236606
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 3, Open-Label Study to Evaluate the Efficacy, Safety, and Pharmacodynamics of RGX-121 in Pediatric Participants with Neuronopathic MPS II (Hunter Syndrome)

1. Call to order:

The Meeting was called to order at 12:00 pm Eastern 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 two local members unaffiliated with the institution. Also present was the Principal Investigator, one Institutional Representative 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:

The 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-1 containment facilities and practices plus Standard Precautions** are required for RGX-121, since it consists of an AAV vector being administered by injection in a clinical setting. 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 RGX- 121 locally**, provided that other biosafety criteria for study closure are also 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.

Points of Discussion:

1. The Committee recommended that Biosafety SOP Section 2.3 be revised to remove “as well as exposure to unknown/undetected bloodborne pathogens” as the study agent is an AAV vector.
2. The Committee recommended that Site Inspection Checklist, Item #21 be revised to “N/A” for study staff washing their hands with soap and water in rooms where sinks are available since the preparation and dosing rooms do not have sinks inside the room.

11. Site requirements:

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

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 12:09 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 05-16-2025

Investigator's Brochure, Version 7.0, dated 01-30-2025

Pharmacy Manual, Version 1.0, dated 05-05-2025

Biological Risk Assessment and Summary, dated 07-08-2025

Site Maps, dated 07-07-2025

Site Inspection Checklist, expires 06-20-2027, updated 06-26-2026

Photos, dated 11-18-2025

Biohazard Sign, RGX, dated 11-18-2025

Biological Safety Cabinet Certifications, expire 10-2026

SOP, Biosafety for RGX-121, dated 06-26-2026

Training, Shipping Certification, dated 06-20-2025

CRRF, dated 04-13-2026

Prior Meeting Minutes, Initial, dated 07-14-2025