

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, July 14, 2025
Time: 11:00 am 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: N/A
Meeting Type: Initial 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 11:01 am 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 the Principal Investigator, 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. 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-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 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.

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.

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 Principal Investigator confirmed that both the [REDACTED] and [REDACTED] phone numbers on the Biohazard Sign are monitored 24/7. The Committee recommended that the sign be revised to reflect this.
2. An Institutional Representative confirmed that an updated Biohazard Sign with new secondary contact information will be provided to IBC Services.
3. An Institutional Representative confirmed that a surgical arm is used for study agent dosing and is reusable but was unable to confirm whether a reusable speculum is used. The Committee recommended that the Institution follow-up with IBC Services regarding which reusable surgical tools are used for dosing and to revise site documents as needed.
4. An Institutional Representative confirmed that the black RCRA hazardous waste containers are used for disposal of study agent-related waste. The Committee recommended that the Institution confirm that this practice is acceptable per state and local regulations.
5. The Committee recommended that all waste containers used for the disposal of biohazardous waste be labeled with a biohazard symbol.
6. An Institutional Representative confirmed that a sharps container will be placed inside the biological safety cabinet (BSC) during study agent preparation.
7. An Institutional Representative confirmed that the storage freezer, as shown in the Photos document, is used for study agent storage and that there is no refrigerator. The Committee recommended to relabel the photo as "Freezer" rather than "Refrigerator/Freezer."
8. The Committee recommended that the comment in Site Inspection Checklist, Item 22 be revised to "plumbed" rather than "plumed."

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: 5

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:17 am 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 07-07-2025

Photos, dated 07-07-2025

Biohazard Sign, RGX-121, dated 06-22-2022

Biological Safety Cabinet Certifications, expire 10-2025

SOP, Biosafety for RGX-121, dated 07-07-2025

Training, Shipping Certification, dated 06-20-2025

CV, Day-Salvatore, DL., signed 11-04-2024