INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, December 8, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Corewell Health, Grand Rapids, MI
Principal Investigator:	**Jena M. Krueger, MD**
Protocol:	Regenxbio, Inc., **RGX-202-1101**
NCT Number:	NCT05693142
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1/2/3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD)

1. Call to order:

The Meeting was called to order at 10:00 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 was one Institutional Representative, 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-1 containment facilities and practices plus Standard Precautions** are required for RGX-202, since it consists of an AAV vector administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of RGX-202 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.

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 noted that the Biological Safety Cabinet (BSC) Certification is set to expire in January 2026.
2. The Committee recommended that Biosafety SOP section 3.3 be revised to add that the syringe is capped after preparation.
3. The Committee recommended that Biosafety SOP Section 4.1 be revised to replace “biohazardous waste bin” with “sharps container” since the study agent is provided in glass vials which should be discarded into a sharps container.
4. The Principal Investigator confirmed that each dosing room has a sink and a plumbed eyewash station is located in an area near the dosing rooms. The Committee recommended that Site Inspection Checklist item 22 be updated to also indicate that eyewashes are not available in dosing rooms and that a comment be added noting that for this study, a plumbed eyewash station is located near the dosing rooms.
5. The Principal Investigator noted that the Photos labeled as “Dosing Rooms” are not actually the rooms themselves, but are areas outside of the dosing rooms. The Principal Investigator confirmed that each dosing room is set up in a similar fashion.
6. The Committee recommended that the Institution submit representative photos of a dosing room, and that these photos should include the general set up of these rooms, as well as the sink, sharps container(s), and biohazardous waste container(s).
7. The Committee recommended that a photo of the inside of the biohazardous waste storage room [redacted] be provided to IBC Services.
8. The Committee noted that it appears some posted biohazard signage is printed only in black and white, as shown in a Photos document. The Committee recommended that the posted biohazard signage be printed on red or orange paper or printed in color with the symbol on an orange or red background, per best biosafety practices.
9. The Committee noted that a sharps container as shown in a Photo appears to be sitting on a wheeled cart. The Committee recommended that the Institution confirm that the wheel cart is manufactured specifically for securing a sharps container.
10. The Committee noted that the sharps container on the wheeled cart appears to a handwashing sink and recommended that this sharps container be moved away from the sink.
11. The Committee noted that the Shipping Certification lacks the specific DOT/IATA regulations and recommended that the Institution’s records contain the specific requirements (49 CFR/IATA 6.2). The Committee noted that this training is provided by the CDC and that information about this training can be found here: https://reach.cdc.gov/course/packing-and-shipping-dangerous-goods-what-laboratory-staff-must-know.

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: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:28 am Eastern Time.