

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: Passage Bio, Inc., PBGM01-001
NCT Number: NCT04713475
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1/2 Open-Label, Multicenter, Dose Ranging and Confirmatory Study to Assess the Safety, Tolerability and Efficacy of a Single Dose of PBGM01 Delivered into the Cisterna Magna of Pediatric Participants with Type 1 (Early Onset Infantile) and Type 2a (Late Onset Infantile) GM1 Gangliosidosis (Imagine-1 Study)

1. Call to order:

The Meeting was called to order at 12:09 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 PBGM01, 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 PBGM01 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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. 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 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 12:14 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 7.0, Amendment F, dated 05-24-2023

Investigator's Brochure, Edition 6.0, dated 04-25-2024

Pharmacy Manual, Version 6.0, dated 08-24-2023

Administration Procedure Manual, Version 5.0, dated 09-28-2023

Biological Risk Assessment and Summary, updated 05-13-2024

Site Maps, dated 07-07-2025

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

Photos, dated 11-18-2025

Biohazard Sign PBGM01 dated 05-14-2026

Biological Safety Cabinet Certifications, expire 10-2026

SOP, Biosafety for PBGM01, dated 08-31-2023

Training, Shipping Certification, dated 06-20-2025

CRRF, dated 04-10-2026

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