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:	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 11:18 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair provided an overview of 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: 5 NO: 0 ABSTAIN: 0

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 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 11:23 am 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 07-07-2025
Photos, dated 07-07-2025
Biohazard Sign, PBGM01, dated 7-31-2023
Biological Safety Cabinet Certification, expire 10-2025
SOP, Biosafety for PBGM01, dated 08-31-2023
Training, Shipping Certification, dated 06-20-2025

CRRF, dated 04-02-2025, updated 05-29-2025
Prior Meeting Minutes, Continuing, dated 07-02-2024