INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, July 24, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Sheila McThenia, MD**
Protocol:	BrainChild Bio, Inc, **BCB276-PRT-0001**
NCT Number:	NCT07680439
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 2 Pivotal Study of BCB-276, a B7-H3-Specific CAR T Cell Locoregional Immunotherapy for Diffuse Intrinsic Pontine Glioma

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 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 the notice of the meeting was not publicly posted per Institutional policy.

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 **Biosafety Level 2 containment facilities and practices** are required for BCB-276 since it consists of primary human cells modified using a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of BCB-276 locally**, provided that all other criteria for study closure are 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. An Institutional Representative confirmed that a sink and plumbed eyewash station are located inside of the room where the Biological Safety Cabinet (BSC) is located. The Committee recommended that the Site Map be updated to indicate that a sink and plumbed eyewash station are available in the study agent preparation room.
2. An Institutional Representative confirmed that the storage, preparation, and biohazardous waste storage rooms are located within the Cell Therapies Lab are not assigned separate room designations.
3. An Institutional Representative confirmed that the sponsor will provide the Institution with a ThawSTAR® CSV2 Automated Thawing System. The Committee recommended that a photo of this device once received (as depicted in Section 14.9 of the Product Administration Manual), be submitted to IBC Services. The Committee noted that if the study agent is thawed in a waterbath instead of the sponsor-provided thawing system, that Biosafety SOP Sections 3.2, 3.6.3, and 5.1.4b be revised accordingly.
4. An Institutional Representative confirmed that subjects will be dosed in an Outpatient setting via a pre-placed catheter.
5. The Committee noted that the Institution agreed to place a sharps container with the BSC during study agent preparation.

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 06-03-2026
Investigator's Brochure, Edition 1.0, dated 04-17-2026
Product Administration Manual, Version 1.0, dated 11-17-2025
Biological Risk Assessment and Summary, dated 07-20-2026
Site Maps, dated 06-04-2026
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 07-17-2026
Photos, dated 06-03-2026
Biohazard Sign, dated 07-08-2026
Biological Safety Cabinet Certifications, Cell Therapy Lab, expire 09-2026
SOP, Biosafety for BCB-276, dated 07-08-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, McThenia, S., signed 09-11-2025
Addendum to CV, McThenia, S, received 07-2026