INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, September 3, 2026**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Robert Sidonio, Jr., MD**
Protocol:	CSL Behring, LLC, **CSL222_3004**
NCT Number:	NCT07080905
Meeting Type:	Continuing Review of Protocol and Site
Title:	Phase 3, Open-label, Single-dose, Multicenter Study Investigating Efficacy, Safety, and Tolerability of CSL222 (Etranacogene Dezaparvovec) Administered to Adolescent Male Subjects (≥ 12 to < 18 Years of Age) with Severe or Moderately Severe Hemophilia B

1. Call to order:

The Meeting was called to order at 2:16 pm 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 seven 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:

The Institutional Representative confirmed that the notice of the meeting was not publicly posted per Institutional policy.

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 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 CSL222 since it consists of an AAV-vector administered 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 CSL222 locally**, provided that all 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 Committee recommended that the Biohazard Sign be revised to include a 24/7 phone number and updated study staff contact information.
2. An Institutional Representative confirmed that Observation Room 5110 has a plumbed eyewash station and that prefilled disposable eyewash bottles are available in the dosing rooms during study agent infusion. The Committee recommended that the Site Map be revised to replace the reference to the plumbed eyewash station in the Exam Room annotation box with a note stating the prefilled disposable eyewash bottles are available. The Committee recommended it be noted that Observation Room 5110 has a plumbed eyewash station.
3. An Institutional Representative confirmed that at least one study staff member has current IATA Shipping Training. The Committee recommended that the Institution submit at least one current IATA Shipping Training Certification to IBC Services.
4. An Institutional Representative confirmed that the laminar flow clean bench is not used to prepare the study agent. The Committee recommended that the second page of the Biological Safety Cabinet Certification document be removed.
5. An Institutional Representative confirmed that the unit used to store the study agent is labeled with a study-specific biohazard sign when the study agent is in storage.
6. An Institutional Representative confirmed that the internal transport container is labeled with a study agent specific biohazard sign.

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 2:31 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 2, dated 09-30-2025
Investigator's Brochure, Version 8.0, dated 02-03-2026
Investigational Medicinal Product Manual, Version 2.0, dated 10-22-2024
Investigational Medicinal Product Preparation & Administration Instructions, Version 3.0, dated 02-14-2025
Research Modification Evaluation, Protocol, Amendment 2
Research Modification Evaluation, Investigator's Brochure, Version 8.0
Biological Risk Assessment and Summary, updated 07-10-2026
Site Map, PRU, 5th Floor IDS Pharmacy, dated 03-26-2026
Site Inspection Checklist, PRU IDS Pharmacy, expires 07-18-2027, updated 08-27-2026
Photos, PRU, IDS Pharmacy, dated 08-27-2026
Biohazard Sign, dated 09-09-2025
Biological Safety Cabinet Certification, PRU, 5th Floor IDS Pharmacy, expires 09-2026
SOP, Biosafety for CSL222, dated 08-27-2026
Training, Shipping Certification, PRU, expires 07-02-2026

CRRF, dated 06-25-2026
Prior Meeting Minutes, Initial, dated 09-22-2025