INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, September 22, 2025**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Robert F. Sidonio Jr., MD**
Protocol:	CSL Behring, LLC, **CSL222_3004**
NCT Number:	NCT07080905
Meeting Type:	Initial 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 3:01 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 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 could not confirm if notice of the meeting was publicly posted. The Committee recommended that the notice of the meeting be publicly posted for one week from today and that any questions or comments received be forwarded to IBC Services.

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 CSL222 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 CSL222 locally,** provided that all 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: 4 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 recommended that the Biohazard Sign be revised to include a 24/7 phone number.
2. The Committee noted that the Biological Safety Cabinet (BSC) used for study agent preparation is due for re-certification in September 2025. The Committee recommended that the new BSC certification be provided to IBC Services when available.
3. The Committee recommended that the institution follow up with IBC Services on whether there is a sharps container inside the BSC.
4. The Committee recommended that the study agent transport container and storage unit be labelled with biohazard symbols. The Committee recommended that new photos of each, showing the biohazard symbols, be provided to IBC Services.
5. The Committee discussed where biohazardous waste is stored within the pharmacy, noting that site photos don't indicate biohazard signage for waste storage. The Committee recommended that the institution follow up with IBC Services on this.
6. An Institutional Representative confirmed that a handwashing sink and plumbed eyewash are located in the pharmacy. The Committee recommended that the site map be revised to indicate this.
7. An Institutional Representative confirmed that all exam rooms have handwashing sinks.
8. The Committee recommended that disposable eyewash bottles be made available in the exam rooms and that site documents be revised to indicate this.

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 3:12 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 1, dated 11-14-2024
Investigator's Brochure, Version 6.0, dated 02-16-2024
Investigational Medicinal Product Manual, Version 2.0, dated 10-22-2024
Investigational Medicinal Product Preparation & Administration Instructions, Version 3.0, dated 02-14-2025
Biological Risk Assessment and Summary, dated 08-06-2025
Site Map, dated 09-09-2025
Site Inspection Checklist, expires 07-18-2027
Photos, dated 09-09-2025
Biohazard Sign, dated 09-09-2025
Biological Safety Cabinet Certification, expires 09-2025
SOP, Biosafety for CSL222, dated 09-09-2025
Training, Shipping Certification, expires 07-02-2026

CV, Sidonio Jr., R., signed 01-10-2024