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:	**Laurence Greenbaum, MD, PhD**
Protocol:	Novartis Research and Development, **CDFT383A12101**
NCT Number:	NCT06910813
Meeting Type:	Initial Review of Protocol and Site
Title:	An open-label, multi-center, Phase I/II study to assess safety, tolerability and efficacy of DFT383 in pediatric participants with nephropathic cystinosis, followed by a long-term extension phase.

1. Call to order:

The Meeting was called to order at 2:03 pm Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution. Also present were seven Institutional Representatives and WCG 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 **BSL-2 containment facilities and practices** are required for DFT383**,** since it consists of autologous CD43+ stem cells modified by a self-inactivating lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of DFT383 locally,** provided 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 the study agent will be thawed in the preparation room. The Committee recommended that Biosafety SOP Section 3.3 be revised to remove"/Dosing".
2. The Committee noted that the Biological Safety Cabinets (BSCs) are due for recertification this month and recommended that the Institution submit the newer Certifications to IBC Services upon receipt.
3. The Committee noted that a study staff member's shipping training is set to expire next month and recommended an updated Certification be submitted to IBC Services upon retraining.
4. The Committee recommended that the formatting issue (large space) between Biosafety SOP Sections 3.3 and 3.4, and 4.1 and 5 be fixed.
5. An Institutional Representative confirmed that dosing will only occur in an inpatient setting.

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 2:16 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 3.0, dated 08-05-2025
Investigator's Brochure, Edition 01, dated 05-06-2024
Product Handling Manual, Version 3.0, dated 12-09-2025
Biological Risk Assessment and Summary, dated 08-21-2026
Site Maps, CTL and 10 West, dated 08-18-2026
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 08-17-2026
Photos, dated 06-03-2026
Biohazard Sign, dated 08-20-2026
Biological Safety Cabinet Certifications, Cell Therapy Lab, expire 09-2026
SOP, Biosafety for DFT383, dated 08-20-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, Greenbaum, L., signed 05-14-2025