

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 24, 2026
Time: 11:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Roumen Balabanov, MD
Protocol: CRISPR Therapeutics AG, CRSP-AID-502
NCT Number: N/A
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1/2 Dose Evaluation Trial of the Safety and Preliminary Efficacy of Anti-CD19 Allogeneic CRISPR-Cas9–Engineered T Cells (CTX112) in Adult Participants With Refractory Neurologic Autoimmune Disease

1. Call to order:

The Meeting was called to order at 11:00 am Central 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 four 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. 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 CTX112 since it consists of primary human cells modified using RNAs and an AAV vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of CTX112 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.

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee discussed that the biological safety cabinet (BSC) certification reports for the Cellular Therapy Lab indicate that certification is performed on an annual basis but that the Biosafety Officer previously noted these are typically certified on a semi-annual basis. The Committee recommended that the Institution confirm whether the BSCs are certified on an annual or semi-annual basis and that future certification reports indicate the correct certification schedule.

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 11:09 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.0, dated 02-18-2026

Investigator's Brochure, Version 4.0, dated 02-13-2026

Product Receipt, Storage, Preparation, and Infusion Manual, Version 3.0, dated 02-13-2026

Biological Risk Assessment and Summary, dated 06-25-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 07-01-2026

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Prentice Hospital, dated 04-25-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Olson MCCT, dated 07-13-2026

Biohazard Sign, Dosing Areas, dated 07-13-2026

Biological Safety Cabinet Certifications, Olson MCCT, expires 03-2027

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Allogeneic Cells, dated 07-10-2026

Training, Shipping Certification, expires 06-05-2027

CV, Balabanov, R., signed 02-08-2024