INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 26, 2026**
Time:	12:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	The MetroHealth System, Cleveland, OH
Principal Investigator:	**Nora Singer, MD**
Protocol:	Fate Therapeutics, Inc., **FT819-102**
NCT Number:	NCT06308978
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1 Study of FT819 in Participants With Moderate to Severe Active Systemic Lupus Erythematosus

1. Call to order:

The Meeting was called to order at 12:00 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 one local member 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:

The 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. Approval of previous meeting minutes:

Minutes Approved - YES: 4 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-2 containment facilities and practices** are required for FT819 since it consists of primary human cells modified by recombinant plasmids and a CRISPR/Cpf1 ribonucleoprotein (RNP) complex. 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 FT819 locally, provided that 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: 4 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 discussed PPE and recommended that study staff wear eye protection and a gown during dosing. The Committee recommended that the Biohazard Sign and Biosafety SOP Section 3.2 be revised to indicate this.
2. The Committee recommended that Biosafety SOP Section 5.1.4 be revised to indicate how linens will be decontaminated.
3. The Committee recommended that a photo of the pre-filled disposable eyewash bottles in the dosing rooms be provided to IBC Services.
4. The Committee noted that the handwashing sink in the preparation room is not hands-free and recommended that a paper towel be used by staff when handling the faucet.
5. The Committee recommended that the Biohazard Sign be revised to indicate which phone number is available 24/7.

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 12:13 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 7.0, dated 04-02-2026
Investigator's Brochure, Version 12.0, dated 02-05-2026
Pharmacy Manual, Version 3.0, dated 02-23-2026
Protocol Administrative Letter, dated 12-17-2025
Research Modification Evaluation, Protocol, Version 6.0
Research Modification Evaluation, Protocol, Version 7.0
Research Modification Evaluation, Protocol Administrative Letter, dated 12-17-2025
Research Modification Evaluation, Investigator's Brochure, Version 10.0
Research Modification Evaluation, Investigator's Brochure, Version 11.0
Research Modification Evaluation, Investigator's Brochure, Version 12.0
Research Modification Evaluation, Pharmacy Manual, Version 3.0
Biological Risk Assessment and Summary, updated 04-17-2026
Site Map, Glick Center, 3rd Floor, dated 06-02-2025
Site Map, Rammelkamp, Cell Therapy Lab, dated 06-11-2026
Site Inspection Checklist, expires 04-29-2027, updated 06-11-2026
Photos, Rammelkamp, Cell Therapy Lab, Glick Center, dated 06-11-2026
Biohazard Sign, FT819, dated 06-02-2025
SOP, Biosafety for FT819, dated 06-11-2026
Training, Shipping Certifications, expire 10-2026, 02-2027, 05-2027, 04-2029
CRRF, dated 03-02-2026
Prior Meeting Minutes, Initial, dated 06-11-2025