

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, September 4, 2026
Time: 9:30 am Pacific Time
Location: Zoom Teleconference
Institution: Beverly Hills Cancer Center, Beverly Hills, CA
Principal Investigator: Solomon Forouzesh, MD
Protocol: Fate Therapeutics, Inc., FT819-201
NCT Number: NCT07570862
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 2, Open-Label, Single-Arm Trial of FT819 in Participants With Refractory Moderate-to-Severe Systemic Lupus Erythematosus With Lupus Nephritis

1. Call to order:

The Meeting was called to order at 9:31 am Pacific 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:

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 FT819 since it consists of primary human cells modified by recombinant plasmids and a CRISPR/Cpf1 ribonucleoprotein (RNP) complex.

The Committee 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.

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.

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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 Institutional Representative confirmed that the internal transport container shown in a site photo is not relevant to this study. The Committee recommended that a photograph of the hard-sided, sealable transport container used to bring the thawed infusion bag to the dosing room be provided to IBC Services.
2. The Institutional Representative confirmed that biohazardous waste is stored in the Pharmacy, not the first floor. The Committee recommended that this be reflected in site-specific documents provided for review.
3. The Institutional Representative confirmed that the alternate phone number on the Biohazard Sign is available 24/7.
4. The Committee recommended that a biohazard symbol be placed on the door to the Infusion room when dosing of the study agent takes place.
5. The Committee recommended that the flowers and drink refrigerator be removed from the Infusion Room and an updated photo be sent to IBC Services.
6. The Committee recommended that site documents, including Biosafety SOP Section 5.1, be updated to indicate how bed linens will be decontaminated in the event of a spill.
7. The Committee recommended that all biohazardous waste containers in infusion rooms be placed in easily accessible locations within the room.
8. The Institutional Representative confirmed that there is hand soap and paper towels available next to the sinks in the Pharmacy and Dosing Rooms.
9. The Institutional Representative confirmed that the study agent is stored in the cryoshipper until use. The Committee recommended that a temporary biohazard symbol be placed on the cryoshipper upon arrival, and an updated photo be sent to IBC Services.
10. The Institutional Representative confirmed that the carpet has been removed from all infusion rooms. The Committee recommended that updated photos be provided to IBC Services.

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 9:58 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 2.0, dated 03-18-2026

Investigator's Brochure, Version 12.0, dated 02-05-2026

Pharmacy Manual, Version 3.0, dated 02-23-2026

Biological Risk Assessment and Summary, dated 03-23-2026

Site Maps, dated 08-25-2026

Site Inspection Checklist, expires 05-12-2027, updated 08-25-2026

Photos, dated 08-25-2026

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Biohazard Sign, FT819, dated 08-25-2026
SOP, Biosafety for FT819, dated 08-25-2026
Training, Shipping Certifications, expire 2027
CV, Forouzesh, S., dated 08-24-2026