

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Tuesday, June 16, 2026  
**Time:** 11:00 am Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** GNP Research, Cooper City, FL  
**Principal Investigator:** Mark Jaffe, MD  
**Protocol:** Fate Therapeutics, Inc., FT819-201  
**NCT Number:** N/A  
**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 11:00 am Eastern 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 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: 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.

#### **Points of Discussion:**

1. The Chair noted that there is an institutional SOP in addition to the study agent specific SOP, which has a bit more detail on study agent preparation and dosing. The Committee found this to be acceptable.
2. The Committee recommended that Biosafety SOP Section 3.3 be revised to include the use of absorbent material on the countertop.
3. The Committee recommended that Biosafety SOP Section 5.2 be revised to include the standard IBC inhalation language.
4. An Institutional Representative confirmed that full biohazardous waste containers are picked up by the waste hauler from the storage room in Suite 102. An Institutional Representative also confirmed that the storage room has a door that closes with posted biohazard signage.
5. The Committee recommended that all site documents be revised to indicate that biohazardous waste is stored in the storage room and that a photo of this room be provided to IBC Services.
6. The Committee recommended that "Sani-Cloth AFB" be replaced "PDI Sani-Cloth AF3 wipes" in all applicable site documents.
7. An Institutional Representative stated that a plumbed eyewash is located in the pharmacy/lab room. The Committee recommended that the site map be revised to reflect this.
8. An Institutional Representative confirmed that after dosing staff use hand sanitizer in the infusion suite and then wash their hands at a sink in the pharmacy/lab room or in a restroom.
9. An Institutional Representative stated that soap is available at all sinks. The Committee recommended that updated photos be provided to IBC Services. Additionally, an Institutional Representative stated that the institution will explore purchasing wall-mounted soap dispensers.
10. An Institutional Representative stated that the water bath and transport container will be provided by the sponsor. The Committee recommended that both be labelled with biohazard symbols and that photos of each be provided to IBC Services when available.
11. An Institutional Representative stated that the biohazardous waste containers onsite have a 13-gallon capacity and are adequate for the institution's needs.
12. An Institutional Representative stated that an Exposure Control Plan (ECP) is currently in place with Jaffe Medical Practice and that a separate Exposure Control Plan (ECP) will be implemented for GNP Research by July 2, 2026. An Institutional Representative stated that study activities are not expected to start until mid-to-late July. The Committee found this to be acceptable.
13. An Institutional Representative stated that building management currently provides pest and rodent control; however, the institution is in the process of establishing its own program with an outside vendor.

### **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 11:19 am Eastern Time.

### **15. Post-meeting notes:** None.

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### **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 Map, 1st Floor, dated 06-05-2026

Site Inspection Checklist, expires 06-12-2028

Photos, dated 06-04-2026

Biohazard Sign, FT819, dated 06-10-2026

SOP, Biosafety for FT819, dated 06-10-2026

GNP Handling of Biohazardous Cellular, Gene Therapy, & Investigational Products SOP, Version 1.0, dated 06-12-2026

Training, Shipping Certification, expires 11-11-2027

CV, Jaffe, M., signed 01-21-2026