INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, June 2, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Lysosomal & Rare Disorders Research & Treatment Center, Inc. - LDRTC, Fairfax, VA
Principal Investigator:	**Ozlem Goker-Alpan MD**
Protocol:	Spur Therapeutics, **FLT201-03**
NCT Number:	N/A
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 3 Safety and Efficacy Trial of FLT201 Gene Therapy in Patients with Gaucher Disease Type 1

1. Call to order:

The Meeting was called to order at 1:10 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 was one Institutional Representative 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. 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-1 containment facilities and practices plus Standard Precautions** are required for FLT201, since it consists of an AAV vector administered by injection in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of FLT201 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.

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 recommended that Biosafety SOP Section 1 be revised to describe the study agent as, "FLT201, a recombinant AAV vector containing a synthetic capsid (AAVS3) that targets the liver and encodes human glucocerebrosidase (GCase)."
2. The Committee recommended that Biosafety SOP Section 3.5 be revised to read as, "…flushed with saline using a new syringe. Syringes and tubing..."

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 1:20 pm Eastern Time.