



Minutes

CW Institutional Biosafety Committee Institutional Biosafety Committee 8/12/2025 1:00 pm Zoom

1 Statements of Confidentiality and Conflicts of Interest

Quorum and Meeting Access: The Chair called the meeting to order at 1:00 pm and noted that the meeting was open to the public. Quorum existed at the start of the meeting with 8 voting members present. A quorum was maintained for the entire meeting.

Confidentiality: The Chair reminded the committee that while the meeting is open to the public, the information discussed during the meeting should be treated as confidential.

Conflict of Interest: The Chair asked the committee if any members needed to declare a conflict of interest with respect to any matter on the agenda. The Chair notified committee members that if they had a conflict of interest, they must leave the room during the final discussion and voting on that IBC submission.

2 Attendees

Committee Members Present

Lewis Bowen III (Finance and Administration)	Biological Safety Officer
Kunal Gupta (Neurosurgery)	R/SNA Technology Expert
Anna Huppler (Pediatrics)	R/SNA Technology Expert
Eric Jensen (Research Office)	Animal Containment Expert
Tyce Kearl (Medicine)	HGT Expert
	R/SNA Technology Expert
Nikki Lytle (Surgery)	R/SNA Technology Expert
Angela Mathison (Surgery)	R/SNA Technology Expert
Amy Pichler (Children's Wisconsin (no MCW faculty appt))	HGT Expert
Qizhen Shi (Pediatrics)	R/SNA Technology Expert
Matthew Surdel (Medicine)	R/SNA Technology Expert

Committee Members Absent

Kenneth Allen (Research Office)	Alternate Animal Containment Expert, Non-Voting
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James Case (Non-MCW)	Non-Affiliated Member
Lezi E (Cell Biology, Neurobiology and Anatomy)	R/SNA Technology Expert
Benjamin Gantner (Medicine)	Chair
Rebecca Roush (Children's Wisconsin (no MCW faculty appt))	Alternate HGT Expert, Non-Voting
Cheryl Singer (Children's Wisconsin (no MCW faculty appt))	Alternate HGT Expert, Non-Voting
Laura Stephens (Non-MCW)	Non-Affiliated Member

3 Meeting Minutes Reviewed at this Meeting

7/8/2025 (Zoom)

Motion:	Minutes Approved
Yes Votes:	8
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	8

4 New Business

1. Administrative Report

There was no Administrative Report.

5 Application Reviews

IBC20250018 FLT201-03

Principal Investigator:	Michael Muriello
Motion:	Decision Pending Changes
Yes Votes:	10
No Votes:	0
Abstained:	0
Recused:	0
Total Votes:	10
NIH Guidelines:	Section III-C-1, Section III-F-8 (C-I)
Biosafety Level(s):	BSL2

Deliberations: (Committee members joined the meeting at 1:02 pm and 1:06 pm. Quorum was maintained with 10 voting members.) The Vice Chair introduced this new Institutional Biosafety Committee (IBC) application, and the Primary Reviewer went on to describe the study. This application will support a Phase 3, non-randomized, multi-centered, efficacy and safety trial of FLT201 in patients ages ≥18 years with Gaucher disease type 1 who are on stable treatment with enzyme replacement therapy (ERT) or substrate reduction therapy (SRT) for at least 2 years. FLT201 is a hepatotropic AAV (AAVS3) used to deliver a replacement glucocerebrosidase gene (GCase variant 85 of GBA1). Approximately 45 participants will receive a single intravenous (IV) infusion of FLT201. Following the infusion, participants will be closely monitored for a minimum of 8 hours, and then their progress followed for 5 years. Patient blood samples will be collected before day of infusion, blood urine and semen will be collected serially post-infusion during the study. The Committee confirmed that all personnel listed in the application completed safety training appropriate for work with the materials described. The Primary and Secondary Reviewers requested that the PI update the human gene transfer (HGT) standard operating procedure (SOP) for clarity, expand upon the description of risks of exposure to the experimental product, and clarify the biological safety level (BSL) required for use of FLT201. The Biological Safety Officer (BSO) requested that the PI describe the PPE

5**Application Reviews**

and engineering controls that will be used. After brief discussion, upon a motion duly made by the Primary reviewer and seconded, the Committee voted to approve this new application pending the requested changes.

6**Adjournment**

There being no further business, the meeting was adjourned at 1:09 pm. The next regularly scheduled meeting will be held on Tuesday, September 9, 2025 at 1:00 pm in Zoom.