

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Thursday, May 21, 2026  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** **Aparna Kalyan, MBBS**  
**Protocol:** Vironexis Biotherapeutics, Inc., **VNX-202-01**  
**NCT Number:** NCT 07192432  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A Phase 1/2, First-in-Human Study of VNX-202 Gene Therapy in Patients With HER2-Positive Cancer (SENTRY-HER2)

### **1. Call to order:**

The Meeting was called to order at 9:00 am Central 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 four 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-1 containment facilities and practices plus Standard Precautions** are required for VNX-202 since it consists of an AAV vector administered by IV infusion in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of VNX-202 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 Biosafety Officer confirmed that the study agent is moved between the storage and preparation areas through a pass-through, and is most likely decontaminated with one of the standard disinfecting agents.
2. The Biosafety Officer confirmed that the blue biohazardous waste containers, shown in the Pharmacy photos, are used for both sharps and non-sharps biohazardous waste disposal.
3. The Biosafety Officer confirmed that a small sharps container is placed inside the Biological Safety Cabinet during study agent preparation.
4. The Committee noted that the Biological Safety Cabinet and Bioquell Compounding Aseptic Containment Isolator certifications appear to be due to recertification this month.
5. The Biosafety Officer confirmed that biohazardous waste generated in studies under IBC review is disposed of in the red biohazardous waste containers available in the Olson Pavilion dosing areas.
6. The Committee recommended that the Biohazard Sign be revised to replace 'Ssuite' with 'Suite'.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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 9:13 am Central Time.

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

#### **Documents reviewed:**

Agenda

Protocol, Version 3.1, dated 03-19-2026

Investigator's Brochure, Version 2.0, dated 09-08-2025

Pharmacy Manual, Version 3.0, dated 12-17-2025

Biological Risk Assessment and Summary, updated 04-24-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Galter, 17th Floor, IDS Pharmacy, updated 11-20-2025

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Non-Cell Therapies, expires 03-05-2027, updated 04-17-2026

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Galter, 17th Floor, IDS Pharmacy, dated 04-07-2026

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, VNX-202, dated 04-29-2026

Biological Safety Cabinet Certifications, Galter 17th Floor, expire 05-2026

Bioquell CACI Certification, Galter 17th Floor, dated 06-17-2025

Bioquell CACI Certification, HEPA, Galter 17th Floor, expires 05-2026

SOP, Biosafety for VNX-202, dated 04-30-2026

Training, Shipping Certification, expires 06-05-2027

CV, Kalyan A, signed 08-26-2024