

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, December 9, 2025
Time: 10:00 am Pacific Time
Location: Zoom Teleconference
Institution: Valkyrie Clinical Trials, Panorama City, CA
Principal Investigator: David Berz, MD, PhD, MPH
Protocol: Vironexis Biotherapeutics, Inc., VNX-101-01
NCT Number: NCT06533579
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1/2 Safety, Dose-Finding, and Pharmacokinetics Study of VNX-101 Gene Therapy in Patients with Relapsed or Refractory CD19-Positive Hematologic Malignancies

1. Call to order:

The Meeting was called to order at 10:00 am Pacific 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 three 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-101 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-101 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. An Institutional Representative confirmed that the biological safety cabinet (BSC) was recently recertified. The Committee recommended that the current BSC certification report be provided to IBC Services.
2. An Institutional Representative confirmed that the study agent will be stored in a -80°C freezer. The Committee recommended that a photo of the freezer, labeled with a biohazard symbol, be provided to IBC Services.
3. An Institutional Representative confirmed that the dosing rooms were previously used as offices but have been converted to exam rooms.
4. An Institutional Representative confirmed that the dosing rooms have tile floors.
5. An Institutional Representative confirmed that there are sharps containers inside the dosing rooms.
6. An Institutional Representative confirmed that there is a handwashing sink located near the dosing rooms.
7. An Institutional Representative confirmed that there are prefilled disposable eyewash bottle stations in the preparation room and all dosing rooms and that there is a plumbed eyewash station in the restroom. The Committee recommended that the Site Map be revised accordingly.
8. An Institutional Representative confirmed that the chair pictured in the dosing room is not cloth and that the mattress on the bed has a waterproof cover.
9. An Institutional Representative confirmed that in the event of a spill of the study agent on the bed linens, the linens would be handled by study staff wearing appropriate PPE and discarded as biohazardous waste. The Committee determined this to be acceptable.
10. The Committee recommended that the location name on the Site Inspection Checklist be changed from [REDACTED] to [REDACTED].

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 10:20 am Pacific Time.