INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, May 16, 2025**
Time:	2:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	The Valley Hospital, Paramus, NJ
Principal Investigator:	**Eli Kirshner, MD**
Protocol:	Genprex, Inc., **ONC-003**
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase 1/2 Open-Label, Dose-Escalation and Clinical Response Study of Quaratusugene Ozeplasmid in Combination with Osimertinib in Patients with Advanced, EGFR-Mutant, Metastatic Non-Small Cell Lung Cancer who have Progressed after Treatment with Osimertinib (Acclaim-1 Trial)

1. Call to order:

The Meeting was called to order at 2:00 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 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. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

8. Determination for biosafety level and period of IBC oversight:

The Committee previously determined that **BSL-1 containment facilities and practices plus Standard Precautions** are required for Reqorsa®, since it consists of a lipid nanoparticle (LNP)-encapsulated plasmid dosed via intravenous infusion. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of Reqorsa® locally,** provided that other biosafety criteria for study closure are also met. The Committee reaffirmed this determination.

9. 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

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 stated that the Biological Safety Cabinet (BSC) used for preparation was last certified in October 2024. An Institutional Representative also stated that the BSC is not currently in use since the Pharmacy is undergoing renovations due to flooding in January 2025.
2. An Institutional Representative noted that the BSC is a Class II, B2 cabinet but the BSC certification from October 2023 indicates it is a Class II, A2 cabinet.
3. An Institutional Representative stated that there is another pharmacy onsite but that the one undergoing renovation is the preferred one for this protocol.
4. The Committee noted that the study agent could be prepared on a countertop instead of a BSC due to the nature of the agent. An Institutional Representative stated that, per institutional policy, preparation of the study agent should occur in a BSC.
5. An Institutional Representative stated that enrollment of new subjects stopped after the flooding in January 2025 and that subject enrollment is paused until the pharmacy renovations are complete.
6. **The Committee determined as a Condition of Approval** that:
    a. The BSC in the Pharmacy is re-certified once the renovation is complete, and the BSC certification is provided to IBC Services.
7. The Committee discussed why a sharps container is not inside the BSC. An Institutional Representative stated that the BSC is small (4 feet) and that there is not enough room to work inside it if a sharps container is there. An Institutional Representative also stated that due to the large volume of material that goes in and out of the BSC, a larger sharps container outside of it works better. The Committee found this to be acceptable.
8. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to replace “If the study agent is removed …” with “When the study agent is removed …”
9. The Committee noted that the protocol is not listed on the biohazard sign but that the study agent is and found this to be acceptable.
10. The Committee discussed the yellow and black containers shown in site photos, which are designated for hazardous waste. An Institutional Representative stated that the yellow containers are used for trace amounts of hazardous waste and that the black containers are used for measurable amounts of hazardous waste.
11. The Committee noted that red biohazardous waste containers are also available in study agent handling areas.
12. An Institutional Representative stated that sharps containers are available in both red and white as well as different sizes.
13. An Institutional Representative confirmed that the study agent storage unit and the door to the biohazardous waste storage room have both been labelled with biohazard symbols. The Committee recommended that new photos of each be provided to IBC Services.
14. An Institutional Representative confirmed that the biohazardous waste storage area is kept locked and that biohazardous waste is picked up by the waste hauler at least weekly.
15. An Institutional Representative confirmed that a plumbed eyewash station is located near the loading dock, where biohazardous waste is stored. The Committee recommended that the site map be revised to indicate this.
16. An Institutional Representative confirmed that the sides of the internal transport container have been labelled with biohazard symbols. The Committee recommended that a new photo of the container be provided to IBC Services.

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:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met before research can resume:

a. The BSC in the Pharmacy is re-certified once the renovation is complete, and the BSC certification is provided to IBC Services.

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:40 pm Eastern Time.

15. Post-meeting notes: The condition of approval was met on the following date: **January 29, 2026.**

Resolution of condition for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a.	**The BSC in the Pharmacy was re-certified and the certification was provided to IBC Services.**	**01-29-2026**	**01-29-2026**

Documents reviewed:

Agenda
Protocol, Version 10.0, dated 02-11-2025
Investigator's Brochure, Version 8.0, dated 02-21-2025
Pharmacy Manual, Version 7.0, dated 09-03-2024
Research Modification Evaluation, Protocol, Version 9.0
Research Modification Evaluation, Protocol, Version 10.0
Research Modification Evaluation, Investigator's Brochure, Version 7.0
Research Modification Evaluation, Investigator's Brochure, Version 8.0
Research Modification Evaluation, Pharmacy Manual, Version 7.0
Biological Risk Assessment and Summary, updated 02-26-2025
Site Maps, dated 04-05-2024
Site Inspection Checklist, dated 04-29-2025
Photos, dated 04-29-2025
Biohazard Sign, dated 02-27-2024
Biological Safety Cabinet Certification, dated 10-23-2023
SOP, Biosafety for Reqorsa, dated 04-24-2024
Training, Shipping Certification, expires 02-26-2026
CRRF, dated 05-05-2025
Prior Meeting Minutes, Initial, dated 04-22-2024