

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, August 21, 2026
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Maryland Oncology Hematology, PA, Rockville, MD
Principal Investigator: John Wallmark, MD
Protocol: Genprex, Inc., **ONC-003**
NCT Number: NCT04486833
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 11:02 am Eastern 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 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

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

The Chair noted 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 an 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: 5 NO: 0 ABSTAIN: 0

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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 Committee noted that the Igloo cooler used for internal study agent transport is not leak-proof. The Institutional Representative confirmed that the cooler is only used to transport study agent vials from the storage room to the preparation room and that if removed from the sponsor-provided packaging, vials are placed inside a Ziploc-style bag as an additional form of containment as noted in Biosafety SOP Section 3.4.1.
2. An Institutional Representative could not confirm how prepared infusion bags are transported from the preparation room to the dosing room. The Committee recommended that the Institution follow up with IBC Services regarding this and that site documents be revised accordingly.
3. The Committee recommended that Site Inspection Checklist, Item 21 be revised to indicate that study staff wash their hands with soap and water in rooms where sinks are available.
4. The Institutional Representative confirmed that the posted biohazard sign shown in the Photos documents is located on the entrance door to the preparation room. The Committee recommended that the photo be revised to indicate the location of this signage.
5. The Committee recommended that the generic biohazard sign posted at the entrance to the storage room be printed with the biohazard symbol on a red/orange background and that a close-up view of the sign be provided to IBC Services since the wording on the sign is too blurry to read.
6. The Committee recommended that the biohazard symbols on the yellow biohazardous waste containers be readily visible and not obscured by the bag lining the container.
7. The Institutional Representative confirmed that a photo of the posted study agent-specific biohazard sign has been provided to IBC Services.
8. The Institutional Representative confirmed that plumbed eyewash stations are flushed weekly and that a log of this action is maintained.
9. The Institutional Representative confirmed that the yellow biohazardous waste containers used for gowns and other PPE do not have a lid due to the additional risk of contamination to staff if they must push the PPE down into the hole on the lid. The Institutional Representative confirmed that bags are removed daily and are not left open overnight with PPE inside of them. The Committee determined this to be acceptable.
10. The Committee noted that the biological safety cabinet is due to be re-certified before the end of this month.

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 11:25 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 11.0, dated 04-01-2026

Investigator's Brochure, Version 9.0, dated 11-19-2025

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Pharmacy Manual, Version 7.0, dated 09-03-2024
Research Modification Evaluation, Protocol. Version 11.0
Research Modification Evaluation, Investigator's Brochure, Version 9.0
Biological Risk Assessment and Summary, updated 04-09-2026
Site Map, Suite 200, updated 09-09-2024
Site Map, Suite 300, dated 12-31-2021
Site Inspection Checklist, expires 08-07-2028
Photos, dated 03-19-2026
Biohazard Sign, dated 08-10-2026
Biological Safety Cabinet Certification, expires 08-31-2026
SOP, Biosafety for Reqorsa, updated 08-18-2026
Training, Shipping Certification, expires 03-31-2027
CRRF, dated 05-06-2026
Prior Meeting Minutes, Continuing, dated 08-29-2025