

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, March 31, 2026
Time: 8:00 am Mountain Time
Location: Zoom Teleconference
Institution: Rocky Mountain Cancer Centers, Lone Tree, CO
Principal Investigator: Robert M. Jotte, MD, PhD
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 8:00 am Mountain 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 one local member unaffiliated with the institution. Also present were five 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 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: 4 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. An Institutional Representative confirmed that the plumbed eyewash station is located outside of the preparation room. The Committee recommended that Site Inspection Checklist, Item #22 be revised accordingly.
2. An Institutional Representative confirmed that the plumbed eyewash station noted in the Photos document as being in the dosing room is located at the Nurse's Station outside of the dosing room. The Committee recommended that the photo be re-labeled to reflect the correct location of the plumbed eyewash station.
3. An Institutional Representative confirmed that a photo of the non-expired prefilled disposable eyewash bottles was 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:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:13 am Mountain Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 10.0, dated 02-11-2025

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

Pharmacy Manual, Version 7.0, dated 09-03-2024

Research Modification Evaluation, Investigator's Brochure, Version 9.0

Biological Risk Assessment and Summary, updated 12-02-2025

Site Map, Lone Tree, dated 03-17-2026

Site Inspection Checklist, expires 03-03-2027, updated 03-09-2026

Photos, dated 03-17-2026

Biohazard Sign, dated 03-26-2024

Biological Safety Cabinet Certification, dated 01-20-2026

SOP, Biosafety for Reqorsa, dated 03-09-2026

Training, Shipping Certification, expires 07-28-2027

CRRF, dated 12-03-2025

Prior Meeting Minutes, Continuing, dated 03-17-2025