

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, July 15, 2026
Time: 10:00 am Eastern Time
Location: Zoom Teleconference
Institution: ProMedica Toledo Hospitals, Sylvania, OH
Principal Investigator: Adam Walter, MD
Protocol: Genelux Corporation, Olvi-Vec-022
NCT Number: NCT05281471
Meeting Type: Continuing Review of Protocol and Site
Title: A randomized phase 3 study assessing the efficacy and safety of Olvi-Vec followed by Platinum-doublet Chemotherapy and Bevacizumab compared with Physician's Choice of Chemotherapy and Bevacizumab in women with Platinum-Resistant/Refractory Ovarian Cancer (OnPrime/GOG-3076 Study)

1. Call to order:

The Meeting was called to order at 10:00 am Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Three voting members were present, including one local member unaffiliated with the institution. Also present were two 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: 3 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-2 containment facilities and practices** are required for the study agent Olvi- Vec since it consists of an attenuated, conditionally-replicative vaccinia virus administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of Olvi-Vec 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: 3 NO: 0 ABSTAIN: 0

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Committee had no questions or concerns about the facilities and practices.

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: 3

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:08 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 1.6, dated 01-15-2025

Protocol Clarification Letter, dated 07-29-2025

Investigator's Brochure, Version 6.6, dated 04-11-2025

Drug Handling Manual, Version 1.9, dated 07-22-2025

Research Modification Evaluation, Protocol Clarification Letter, dated 07-29-2025

Research Modification Evaluation, Drug Handling Manual, Version 1.9

Biological Risk Assessment and Summary, updated 08-05-2025

Site Map, Pharmacy and Infusion Center, dated 07-21-2025

Site Inspection Checklist expires 06-19-2027, updated 07-06-2026

Photos, dated 07-06-2026

Biohazard Sign, dated 06-23-2025

Biological Safety Cabinet Certifications, expire 11-2026

SOP Biosafety for Olvi-Vec, dated 07-21-2025

Training, Shipping Certifications, expire, 08-2026, 11-2026, 01-2027

CRRF, dated 04-01-2026

Prior Meeting Minutes, Initial, dated 07-02-2025