

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, March 23, 2026
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Kettering Health Network, Kettering, OH
Principal Investigator: Thomas J. Reid, 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 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:

Four voting members were present, including one local member 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: 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-2 containment facilities and practices** are required for 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: 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. The Committee recommended that the Biohazard Sign posted on the storage freezer be revised to so that the biohazard symbol is on a red or orange red background or the entire sign is printed on red or orange red paper, and that an updated photo of the storage freezer with sign be submitted to IBC Services.
2. The Committee recommended that the photo on the right side of Slide 16 in the Photos document be removed since it is not relevant to this study.
3. The Institutional Representative confirmed that the study agent is stored in the white freezer as shown on Slide 16 of the Photos document. The Committee recommended that the photo of the grey freezer be removed from Slide 2 of the Photos document.
4. The Institutional Representative confirmed that the door to the biohazardous waste storage area is only accessible to staff members and confirmed that the placard with the biohazard symbol is standard for rooms that store biohazardous waste at the Institution.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 11:16 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, Investigator's Brochure, Version 6.6

Research Modification Evaluation, Drug Handling Manual, Version 1.8

Research Modification Evaluation, Drug Handling Manual, Version 1.9

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

Site Map, Dosing Rooms 25-26, dated 04-25-2023

Site Map, Kettering Cancer Center 5th Floor, dated 03-14-2025

Site Inspection Checklist, expires 02-25-2027, updated 02-09-2026

Photos, updated 02-11-2026

Biohazard Sign, dated 03-14-2025

Compounding Aseptic Containment Isolator Certification, 3S-15-LGU-14331, dated 12-04-2025

Compounding Aseptic Containment Isolator Certification, 3S-15-LGU-14565, dated 12-04-2025

SOP, Biosafety for Olvi-Vec, dated 03-16-2026

Training, Shipping Certification, expires 07-01-2027

CRRF, dated 12-02-2025

Prior Meeting Minutes, Continuing, dated 03-13-2025