INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, November 6, 2026**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	OhioHealth Research Institute, Columbus, OH
Principal Investigator:	**Aine Clements, 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 11:18 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 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: 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-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: 5 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 study staff will wear one glove, leaving a glove-free hand for opening doors while transporting the study agent per a previous IBC recommendation. The Committee recommended that Biosafety SOP Section 3.4.1 be revised to indicate that study staff will wear one glove during transport.
2. The Committee noted that the Biological Safety Cabinets (BSCs) used for study agent preparation are due for re-certification in November 2026 and recommended that the new BSC certifications be provided to IBC Services when available.
3. The Committee recommended that the Biohazard Sign be revised to indicate a 24/7 phone number.
4. The Committee recommended that a photo of the biohazard signage at the entrance to room G2002 be provided to IBC Services.
5. The Committee recommended that Site Inspection Checklist (#19) be revised to indicate that PROSAT sterile 70% isopropyl alcohol is used on the BSC after the initial decontamination using PDI Super Sani-Cloth wipes.
6. The Committee recommended that a plastic tray be placed underneath cardboard biohazardous waste containers.
7. The Committee recommended that the room number for the preparation pharmacy be added to site documents if available.

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 11:30 am Eastern Time.

15. Post-meeting notes:

None.

Documents reviewed:

Agenda
Protocol, Version 1.7, dated 09-03-2026
Investigator's Brochure, Version 6.6, dated 04-11-2025
Drug Handling Manual, Version 1.9, dated 07-22-2025
Research Modification Evaluation, Protocol, Version 1.7
Biological Risk Assessment and Summary, updated 10-16-2026
Site Maps, dated 01-15-2025
Site Inspection Checklist, expires 10-20-2027, updated 02-25-2026
Photos, dated 10-27-2025
Biohazard Sign, dated 10-07-2024
Biological Safety Cabinet Certifications, expire 11-30-2026

SOP, Biosafety for Olvi-Vec, dated 11-20-2025
Training, Shipping Certification, expires 09-10-2028
CRRF, dated 08-03-2026
Prior Meeting Minutes, Continuing, dated 11-10-2025