INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, July 2, 2025**
Time:	11:00 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:	Initial 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 11:01 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 six 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. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee 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 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.

8. 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

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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 Biosafety SOP Section 5.2.4 be revised to indicate that eyewash bottles are used first in the event of an eye exposure in a room without a plumbed eyewash and then the staff member is escorted to the closest plumbed eyewash.
2. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to replace “thoroughly” with “15 minutes.”
3. An Institutional Representative confirmed that the pharmacy is located in the middle of the infusion area.
4. An Institutional Representative confirmed that disposal eyewash bottles are available in the dosing rooms. The Committee recommended that the site map be revised to reflect this.
5. An Institutional Representative confirmed that there are two plumbed eyewashes onsite and that they are flushed at least once weekly.

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 11:15 am Eastern Time.