INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, December 18, 2025**
Time:	12:00 pm Pacific Time
Location:	Zoom Teleconference
Institution:	Providence Sacred Heart Medical Center & Children's Hospital, Spokane, WA
Principal Investigator:	**Melanie Bergman, 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 12:00 pm Pacific 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 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: 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 provided an overview of changes since the last review.

Point of Discussion:

1. The Committee noted that the Protocol recommends that the study agent be handled at BSL-1. The Chair noted that the IBC determines biosafety levels based on risks associated with the study agent and handling procedures, independent of sponsor suggestions.

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. The Committee recommended that the institution follow up on whether study staff wear a face shield when handling the study agent outside of a Biological Safety Cabinet (BSC) and that site documents be revised accordingly upon receipt of the follow-up information.
2. The Committee recommended that the institution follow up on whether non-safety needles are used and that site documents be revised accordingly upon receipt of the follow-up information.
3. The Committee recommended that the Biohazard Sign be revised to indicate a 24/7 phone number.

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 12:11 pm Pacific Time.