INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, March 13, 2025**
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**
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 11:00 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 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: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the dosing status.

The Chair provided an overview of the protocol.

The Chair provided an overview of changes since the last review.

Point of Discussion:

1. An Institutional Representative confirmed that seven subjects have been dosed to date.

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

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 confirmed that the yellow biohazardous waste containers are labeled with a biohazard symbol. The Committee recommended that new photos of the yellow biohazardous waste containers located in the study agent preparation and dosing areas, showing the biohazard symbol, be provided to IBC Services.
2. An Institutional Representative confirmed that biohazardous waste containers do not contain an inner waste bag as full containers are closed and then removed by Stericycle.
3. The Committee recommended that a new photo of the transport container, labeled with a biohazard symbol, be provided to IBC Services.
4. The Committee noted that a plumbed eyewash station is in the room immediately adjacent to the study agent preparation room.
5. An Institutional Representative confirmed that the 855-500-2873 phone number on the Biohazard Sign is a 24-hour number. The Committee recommended that the Biohazard Sign be revised to indicate this.
6. The Committee recommended that the Biohazard Sign be revised to include a red biohazard symbol or that it be printed on red or orange colored paper.
7. An Institutional Representative confirmed that the appropriate study agent-specific Biohazard Sign will be posted during study agent handling.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 11:15 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 1.6, dated 01-15-2025
Investigator's Brochure, Version 6.5, dated 09-01-2021
Drug Handling Manual, Version 1.7, dated 06-05-2024
Research Modification Evaluation, Protocol, Version 1.5
Research Modification Evaluation, Protocol, Version 1.6,
Research Modification Evaluation, Protocol Clarification Letter, dated 04-17-2024
Research Modification Evaluation, Protocol Clarification Letter, dated 05-02-2024

Research Modification Evaluation, Protocol Clarification Letter, dated 09-23-2024
Research Modification Evaluation, Sponsor Note-To-File (NTF), dated 09-23-2024
Research Modification Evaluation, Drug Handling Manual, Version 1.7
Biological Risk Assessment and Summary, updated 02-04-2025
Research Modification Evaluation, Change in Storage Location, dated 02-28-2025
Site Map, Kettering Cancer Center 5th Floor, dated 02-27-2025
Site Map, Dosing Rooms 25-26, dated 04-25-2023
Site Inspection Checklist, dated 02-25-2025
Photos, updated 02-27-2025
Biohazard Sign, dated 12-12-2022
Compounding Aseptic Containment Isolator Certification, 3S-15-14331 dated 12-12-2024
Compounding Aseptic Containment Isolator Certification, 3S-15-14565 dated 12-12-2024
SOP, Biosafety for Olvi-Vec, dated 02-25-2025
Training, Shipping Certifications, expire 2025, 2026
CRRF, received 02-25-2025
Prior Meeting Minutes, Continuing, dated 03-12-2024