INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

**MEETING MINUTES**

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| **Meeting Date:** | **Thursday, September 18, 2025** |
| **Time:** | 12:00 pm Pacific Time |
| **Location:** | Zoom Teleconference |
| **Institution:** | Women's Cancer Center of Nevada, Las Vegas, NV |
| **Principal Investigator:** | **Nicola M. Spirtos, 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 12:03 pm Pacific 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 provided an overview of 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

**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 noted that antiviral agents active against vaccinia virus, such as vaccinia immunoglobulin, are available and recommended that this be noted in the Biological Risk Assessment and Summary and Section 2 of the Biosafety SOP.
2. The Committee recommended that biohazardous waste bins be taken to the storage room after each subject is dosed and that Section 4 of the Biosafety SOP be revised to indicate this.
3. The Committee noted that IATA/Shipping training expires in October 2025 for a study staff member. The Committee recommended that training be completed prior to the expiration and that a new certification be provided to IBC Services.
4. The Committee noted that the Biological Substance, Category B sign (UN 3373) is not required to be on the study agent storage unit and recommended that it be removed.
5. The Committee discussed how sharps are disposed of when working in the Compounding Aseptic Containment Isolator (CACI) and recommended that the institution follow up with IBC Services on the process and the location of a sharps container within the CACI, if available. The Committee also recommended that a photo of this sharps container (if available) be provided to IBC Services.
6. The Committee discussed the appropriate biosafety level for the study agent, noting that BSL-2 was previously determined by the IBC. The Chair noted that BSL-2 is listed on the Biohazard Sign and in the Biological Risk Assessment and Summary.
7. The Committee recommended that an alternative phone number be added to the biohazard sign.
8. The Committee discussed the site map and noted that it is hard to determine where the rooms are since the map is handwritten. The Committee recommended that the institution obtain a new site map, such as a blueprint or diagram, and that the study agent handling areas and institution name be marked accurately on this new site map.
9. The Committee discussed where biohazardous waste is stored, noting that site documents indicate that it is stored in the Pharmacy and Exam Room 10. The Institutional Representative stated that biohazardous waste is not stored in these rooms; it is stored in a storage room, which is not shown on the site map or listed in any of the site documents provided for IBC review.
10. **The Committee determined the following as Conditions of Approval**:
    a. Biohazardous waste storage location is provided to IBC Services and documented on the Site Map, Site Inspection Checklist, and Biosafety SOP
    b. A photo of the biohazardous waste storage location is provided to IBC Services

**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:

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|---|---|
| | APPROVED |
| X | CONDITIONALLY APPROVED |
| | TABLED |
| | DISAPPROVED |

For a vote of CONDITIONALLY APPROVED, the following conditions must be met no later than October 18, 2025 before research can resume:

a. Biohazardous waste storage location is provided to IBC Services and documented on the Site Map, Site Inspection Checklist, and Biosafety SOP

b. A photo of the biohazardous waste storage location is provided to IBC Services

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

**13. Advice to the Institution:** None.

**14. Meeting adjourned:** The meeting was adjourned at 12:30 Pacific Time.

**15. Post-meeting notes:** The conditions of approval were met on the following date: **September 23, 2025.**

**Resolution of conditions for Conditional Approval:**

| Condition No. | Resolution | Date of Resolution | Approved by Chair |
|---|---|---|---|
| a. | The biohazardous waste storage location was provided and documented on the Site Map, Site Inspection Checklist, and Biosafety SOP. | 09-23-2025 | 09-23-2025 |
| b. | A photo of the biohazardous waste storage location was provided to IBC Services. | 09-23-2025 | 09-23-2025 |

**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, Version 1.6
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
Research Modification Evaluation, New Location, dated 03-07-2025
Site Map, dated 03-07-2025
Site Inspection Checklist, expires 03-04-2027, updated 09-02-2025
Photos, dated 09-02-2025
Biohazard Sign, Olvi-Vec, dated 09-02-2025
Compounding Aseptic Containment Isolator Certification, dated 08-14-2025
SOP, Biosafety for Olvi-Vec, dated 09-02-2025
Training, Shipping Certifications, expire 10-2025, 06-2027
CRRF, dated 06-09-2025
Prior Meeting Minutes, Initial, dated 09-18-2024