



December 18, 2025

Melanie Bergman MD
Providence Sacred Heart Medical Center & Children’s Hospital

Dear Dr. Bergman,

SUBJECT: INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION

Sponsor: Genelux Corporation
Protocol: **Olvi-Vec-022**, Version 1.6, dated 01-15-2025
Protocol 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)

The Institutional Biosafety Committee (IBC) for Providence Sacred Heart Medical Center & Children’s Hospital has reviewed this research and made the following determination:

MEETING DATE: December 18, 2025

MEETING TYPE: Continuing Review of Protocol and Site

IBC DETERMINATION: **Approved** **Disapproved**
 Conditionally Approved **Tabled**
Applicable Section of the NIH Guidelines: III-C-1

EXPIRATION DATE: December 31, 2026

Biosafety Level approved for this site: **BSL-2**
IBC Oversight Period approved for this site: **6 months after the last subject’s final dose**

This IBC is administered by WCG IBC Services. If we can be of assistance, please contact us at IBCServices@wcgirb.com or by phone at (360) 252-2850.

If you have changes to your research to submit, please complete the “IBCS Change in Research Submission Form” on our website (<https://www.wcgirb.com/how-to-submit/ibc-forms/>), and submit the completed form with any other applicable documents to IBCServices@wcgirb.com.

- cc: Jodie Mactagone, Providence Sacred Heart Medical Center & Children's Hospital
- Joni Baxter RN, BSN, CCRC, CCDS, Providence Sacred Heart Medical Center & Children's Hospital
- Daniel B. Getz MD, Providence Sacred Heart Medical Center & Children's Hospital
- Susan Hood, Providence Sacred Heart Medical Center & Children's Hospital
- Carissa Urvat, Providence Sacred Heart Medical Center & Children's Hospital
- Marley Wolgast, PSI CRO
- Katya Korobitsyna, PSI CRO
- Study File

ALL IBC-APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Report the following site-specific information to the IBC within 5 days:
 - a. Violations of the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines).
 - b. New information bearing on the NIH Guidelines.
 - c. Significant research-related accidents and/or illnesses.
 - d. Research-related spills, exposures, and/or laboratory-acquired infections.
 - e. Loss of containment.
 - f. Suspension or termination of the study by the sponsor, investigator, or institution.
 - g. Unresolved complaints related to biosafety.

2. Training:
 - a. Be adequately trained in good microbiological techniques and IBC-approved standard operating procedures.
 - b. Instruct and train the research staff in:
 - i. The practices and techniques required to ensure safety;
 - ii. The procedures for dealing with accidents, spills, and/or exposures.
 - c. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested.

3. Safety:
 - a. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed.
 - b. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken.
 - c. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
 - d. Remain in communication with the IBC throughout the conduct of the project.

4. Accountability:
 - a. Correct work errors and conditions that may result in the loss of containment of recombinant or synthetic nucleic acid molecules.
 - b. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules.
 - c. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
 - d. Notify WCG IBC Services and obtain IBC approval before making any changes to the protocol, facilities, practices, and key study staff associated with the research.

The NIH Guidelines require that the IBC conduct periodic reviews of approved research. You will receive Continuing Review Report Forms from WCG IBC Services. These reports must be returned in a timely manner, even if research at your site has not yet begun.



1019 39th Ave SE / Suite 120
Puyallup, WA 98374
855-818-2289
wcgclinical.com

April 23, 2025

Melanie Bergman, MD
Providence Sacred Heart Medical Center & Children's Hospital

Dear Dr. Bergman,

SUBJECT: INSTITUTIONAL BIOSAFETY COMMITTEE DETERMINATION

Sponsor: Imunon, Inc.
Protocol: **201-24-301**, Version 1.0, dated 12-19-2024
Protocol Title: A randomized phase III trial evaluating the safety and efficacy of intraperitoneal IMNN-001 (IL-12 Plasmid formulated with PEG-PEI-Cholesterol Lipopolymer) administered in combination with standard neoadjuvant and adjuvant chemotherapy in newly diagnosed patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer

The Institutional Biosafety Committee (IBC) for Providence Sacred Heart Medical Center & Children's Hospital has reviewed this research and made the following determination:

MEETING DATE: **April 23, 2025**

MEETING TYPE: **Initial Review of Protocol and Site**

IBC DETERMINATION: **Approved** **Disapproved**
 Conditionally Approved **Tabled**
Applicable Section of the NIH Guidelines: III-C-1

EXPIRATION DATE: **April 30, 2026**

Biosafety Level approved for this site: **BSL-1 plus Standard Precautions**
IBC Oversight Period approved for this site: **3 months after the last subject's final dose**

This IBC is administered by WCG IBC Services. If we can be of assistance, please contact us at IBCServices@wcgirb.com or by phone at (360) 252-2850.

If you have changes to your research to submit, please complete the "IBCS Change in Research Submission Form" on our website (<https://www.wcgirb.com/how-to-submit/ibc-forms/>), and submit the completed form with any other applicable documents to IBCServices@wcgirb.com.

cc: Jodie Mactagone, Providence Sacred Heart Medical Center & Children's Hospital
Joni Baxter, RN, BSN, CCRC, CCDS, Providence Sacred Heart Medical Center & Children's Hospital
Carissa Ubat, Providence Sacred Heart Medical Center & Children's Hospital
Louisa Meyer, Providence Sacred Heart Medical Center & Children's Hospital
Daniel B. Getz, MD, Providence Sacred Heart Medical Center & Children's Hospital
Hannah Egland, Providence Sacred Heart Medical Center & Children's Hospital
Lauren Musso, Imunon, Inc.
Study File

ALL IBC-APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Report the following site-specific information to the IBC within 5 days:
 - a. Violations of the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines).
 - b. New information bearing on the NIH Guidelines.
 - c. Significant research-related accidents and/or illnesses.
 - d. Research-related spills, exposures, and/or laboratory-acquired infections.
 - e. Loss of containment.
 - f. Suspension or termination of the study by the sponsor, investigator, or institution.
 - g. Unresolved complaints related to biosafety.

2. Training:
 - a. Be adequately trained in good microbiological techniques and IBC-approved standard operating procedures.
 - b. Instruct and train the research staff in:
 - i. The practices and techniques required to ensure safety;
 - ii. The procedures for dealing with accidents, spills, and/or exposures.
 - c. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested.

3. Safety:
 - a. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed.
 - b. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken.
 - c. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
 - d. Remain in communication with the IBC throughout the conduct of the project.

4. Accountability:
 - a. Correct work errors and conditions that may result in the loss of containment of recombinant or synthetic nucleic acid molecules.
 - b. Ensure the integrity of the physical and biological containment of recombinant or synthetic nucleic acid molecules.
 - c. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules.
 - d. Notify WCG IBC Services and obtain IBC approval before making any changes to the protocol, facilities, practices, and key study staff associated with the research.

The NIH Guidelines require that the IBC conduct periodic reviews of approved research. You will receive Continuing Review Report Forms from WCG IBC Services. These reports must be returned in a timely manner, even if research at your site has not yet begun.