

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Friday, July 18, 2025
Time: 1:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Erlanger Health, Inc., Chattanooga, TN
Principal Investigator: Stephen DePasquale, MD
Protocol: Imunon, Inc., 201-24-301
NCT Number: NCT06915025
Meeting Type: Initial Review of Protocol and Site
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

1. Call to order:

The Meeting was called to order at 1:00 pm Eastern 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 three 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-1 containment facilities and practices plus Standard Precautions** are required for IMNN-001 since it consists of a plasmid vector complexed with a polymer to facilitate cellular uptake administered via intraperitoneal infusion.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of IMNN-001 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: 5

NO: 0

ABSTAIN: 0

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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 in the event of an eye exposure, the staff member will be escorted to the plumbed eyewash station and the affected eye will be flushed for 15 minutes.
2. An Institutional Representative confirmed that the main phone number for the Principal Investigator is monitored 24/7 and that [REDACTED] is the Main Pharmacy number which is also monitored 24/7. The Committee recommended that the Main Pharmacy number be added to the Biohazard Sign and that the sign be revised to reflect which phone numbers are monitored 24/7.
3. An Institutional Representative confirmed that the yellow waste containers in the preparation room are labeled with a biohazard symbol. The Committee recommended that an updated photo showing the biohazard label on the container be provided to IBC Services.
4. The Committee recommended that the biological safety cabinet (BSC) be labeled with a biohazard symbol.
5. An Institutional Representative confirmed that the Tennessee Board of Pharmacy does not allow any items to be kept inside the BSC, including sharps containers.
6. An Institutional Representative confirmed that the laminar flow clean bench pictured in the preparation room will not be used for study agent preparation.
7. An Institutional Representative confirmed that the plumbed eyewash stations are flushed weekly and a log of this action is maintained.
8. An Institutional Representative confirmed that the emergency eyewash sign is posted on the entrance door to the preparation room.
9. An Institutional Representative confirmed that biohazardous waste is disposed of in yellow waste containers and that black waste containers are used for disposal of trace hazardous waste.
10. An Institutional Representative confirmed that the red bag-lined container in the dosing room is not used for biohazardous waste.

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 1:19 pm Eastern Time.