INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Monday, July 28, 2025**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Old Dominion University, Norfolk, VA
Principal Investigator:	**Benjamin J. Rubinstein, MD**
Protocol:	Inovio Pharmaceuticals, Inc., **RRP-331**
NCT Number:	NA
Meeting Type:	Initial Review of Protocol and Site
Title:	A phase 3, randomized, placebo controlled, blinded trial of INO-3107 with electroporation (EP) in subjects with HPV-6 and/or HPV-11-associated recurrent respiratory papillomatosis (RRP)

1. Call to order:

The Meeting was called to order at 1:02 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 one local member unaffiliated with the institution and the institutional Biosafety Officer. 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. 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 the study agent INO-3107 since it is based on plasmids administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of INO-3107 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

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 discussed how biohazardous waste is disposed of. An Institutional Representative stated that hospital services removes the biohazardous waste containers from the storage area but was uncertain if a licensed waste hauler retrieves them from the hospital or if there is an onsite incinerator. The Committee recommended that the institution follow up with IBC Services on this and that site documents be revised accordingly upon receipt of the follow-up information.
2. An Institutional Representative confirmed that food is not stored in refrigerators, freezers, or cabinets used for study agent storage. The Committee recommended that Site Inspection Checklist (#5) be revised to indicate this.
3. The Committee recommended that the institution follow up with IBC Services on which company manages the site's insect and rodent control program. The Committee recommended that Site Inspection Checklist (#6) be updated upon receipt of the follow-up information.
4. The Committee noted that CaviWipes 2.0 are not effective against the study agent and recommended that a bleach-based decontaminating agent be used for work surfaces and spill clean-up. The Committee recommended that the institution provide IBC Services with the name of the bleach-based product(s) that will be used and that site documents be revised accordingly.
5. An Institutional Representative confirmed that the study agent storage room has carpeted flooring. The Committee recommended that the institution obtain a non-porous, wipeable plastic mat to place under the storage unit (over the carpet) while the study agent is stored and that a new photo, showing the plastic mat, be submitted to IBC Services.
6. An Institutional Representative confirmed that the floors in the dosing rooms are not carpeted.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the institutional Biosafety Officer.

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 1:17 pm Eastern Time.