Meeting Minutes

Institution:	Case Western Reserve University		
Meeting Date:	April 10, 2026		
Meeting Time	10:00 AM Eastern Time		
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public		
Members in Attendance:	**Member**	**Voting**	**Member Type**
	Hauke, Caitlyn	Yes	Chair: Biosafety Expert/HGT Expert
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Wilson, LaKetta	Yes	Local Unaffiliated Member
	Yun, Yang	Yes	Local Unaffiliated Member
	Karlo, Colleen	Yes	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Young, Andrew	Yes	Biological Safety Officer
	Tepfenhart, Benjamin	Yes	Site Contact
Guests:	None		
Staff:	Smith, Jennifer		

Call to Order: The IBC Chair called the meeting to order at 10:00 AM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 2/13/26 were approved by the IBC with no changes**.** There were no votes against and no abstentions.

New Business:

PI:	Howard, Scott
Sponsor:	Inovio Pharmaceuticals, Inc.
Protocol:	RRP 331 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).
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: RRP-331 is a Phase 3 randomized, blinded, placebo-controlled clinical trial sponsored by Inovio Pharmaceuticals, Inc. designed to evaluate the safety and efficacy of INO-3107 with electroporation (EP) for the treatment of human papillomavirus (HPV)-6 and/or HPV-11-associated recurrent respiratory papillomatosis (RRP). INO-3107 consists of two synthetic DNA plasmids, one plasmid encoding for the HPV-6 and HPV-11 E6 and E7 antigens, and the other plasmid encoding for the human cytokine interleukin 12 (IL-12). The investigational product (IP) is administered by intramuscular (IM) injection.

Biosafety Containment Level (BSL): The investigational study agent INO-3107 consists of naked, purified recombinant DNA plasmids that are non-infectious, incapable of replication in human cells, and are not formulated in carrier molecules (e.g., lipid nanoparticles) that would enhance gene transfer. Therefore, BSL-1 may be considered as the minimum containment level for handling INO-3107. The Sponsor notes that standard biohazard safety precautions (Biohazard Safety Level 1) should be followed when working with INO-3107.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and

use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee stipulated that the Site confirm which waste receptacle is used for PPE in the OR and whether that waste is processed as biohazardous waste by 5/10/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP. The Committee reminded the Site that contaminated PPE should be disposed of as biohazardous waste.
  - The Site confirmed that the annual training includes BBP training.
  - The Site confirmed the array used to administer the study agent is disposed of in the red sharps container in the OR.

Motion: A motion of Approval with Stipulations for the study at BSL-1 plus Standard Precautions was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - The Committee stipulated that the Site confirm which waste receptacle is used for PPE in the OR and whether that waste is processed as biohazardous waste by 5/10/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:22 AM.

Post-Meeting Pre-Approval Note: None