Meeting Minutes

Institution:	Oklahoma Cancer Specialists and Research Institute LLC
Meeting Date:	April 02, 2026
Meeting Time	2:00 PM Central 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
Helm, Allen	Yes	Core Member: Biosafety Expert/HGT Expert
Fakhr, Mohamed	Yes	Local Unaffiliated Member
Maxey, Rhonda	No	Site Contact

Invited Members Not in Attendance:

Member	Voting	Member Type
Bender, Carol	Yes	Local Unaffiliated Member

Guests:	Street, Daron
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 2:00 PM. 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 5/8/25 were approved by the IBC with no changes.

New Business:

PI:	Street, Daron

Meeting Minutes

Sponsor:	TheraVectys
Protocol:	Lenti-HPV-07-CT01 An Open-Label Phase 1/2a Clinical Trial to Evaluate the Safety, Immunogenicity, and Preliminary Efficacy of a Lentiviral Vector-Based Therapeutic Vaccine Against Human Papilloma Virus (Lenti-HPV-07) in Participants with HPV-Associated Oropharyngeal Squamous Cell Cancer or Cervical Cancer
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: Lenti-HPV-07-CT01 is a Phase I/IIa clinical trial sponsored by TheraVectys and designed to assess the safety, tolerability, and preliminary efficacy of Lenti-HPV-07, a therapeutic vaccine against human papillomavirus (HPV)16- and HPV18-induced cancers, when administered to adult participants with HPV-associated oropharyngeal squamous cell cancer or cervical cancer. The investigational product (IP) is administered by intramuscular injection(s).

Biosafety Containment Level (BSL): Because the study agent Lenti-HPV-07 contains a recombinant, replication-defective form of a Risk-Group 3 lentivirus containing less than two-thirds of the native viral genome, BSL2 containment is considered the default biocontainment level under the NIH Guidelines.

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, splashes, and/or needlestick exposures of the IP during preparation and/or administration procedures. 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 Site confirmed the BSC recently passed recertification. The Committee stipulated that the Site send Sabai the updated BSC certification report by 5/2/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

Motion: A motion of Approval with Stipulations for the study at BSL-2 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 Site confirmed the BSC recently passed recertification. The Committee stipulated that the Site send Sabai the updated BSC certification report by 5/2/26. 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 2:22 PM.

Post-Meeting Pre-Approval Note: None