Meeting Minutes

Institution:	Virginia Oncology Associates (VOA)		
Meeting Date:	August 27, 2026		
Meeting Time	9:30 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
	Welch, Nancy	Yes	Local Unaffiliated Member
Invited Members Not in Attendance:	Member	Voting	Member Type
	Marz, Aylin	Yes	Local Unaffiliated Member
	Ingram, Amber	No	Site Contact
Guests:	Vendt, David (Site Representative)		
Staff:	Hemmelgarn, Marian		

Call to Order: The IBC Chair called the meeting to order at 9:36 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 5/14/26 were approved by the IBC with no changes.

New Business:

PI:	Simmons, Gary DO
Sponsor:	Kite Pharma, Inc.
Protocol:	KT-US-499-0150 A Phase 1/2 Open-label, Multicenter Study Evaluating the Safety and Efficacy of KITE-363 or KITE-753, Autologous Anti-CD19/CD20 CAR T-cell Therapies, in Subjects With Relapsed and/or Refractory B-cell Lymphoma
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: KT-US-499-0150 (PALISADES-1) is an open-label, multicenter Phase 1/2 trial sponsored by Kite Pharma, Inc. and designed to evaluate the safety and efficacy of KITE-363 or KITE-753 in adult participants with relapsed/refractory (r/r) B-cell lymphoma. KITE-363 and KITE-753 are autologous anti-CD19/CD20 chimeric antigen receptor (CAR) T-cell products genetically modified using a replication-deficient lentiviral vector to introduce the anti-CD19 CAR and anti-CD20 CAR transgenes. KITE-753 is a rapidly manufactured version of KITE-363. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agents KITE-363 and KITE-753 consist of primary human cells transduced with a recombinant, replication-defective form of a Risk Group 3 lentivirus, therefore BSL-2 containment is the minimum 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 needlesticks 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 accuracy of the Annual Review Report.
  - The Site confirmed just in time delivery of the study agent.
  - The Committee discussed biohazard signage on sharps containers. The Site confirmed sharps containers have biohazard signage posted.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote.

- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:00 AM.

Post-Meeting Pre-Approval Note: None.