Meeting Minutes

Institution:	Virginia Oncology Associates (VOA)
Meeting Date:	September 15, 2025
Meeting Time	11:30 AM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Ellis, Robert / Yes / Core Member: Biosafety Expert/HGT Expert Marz, Aylin / Yes / Local Unaffiliated Member Welch, Nancy / Yes / Local Unaffiliated Member Gobhardt, Wendi / No / Site Contact
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** None
Staff:	Hemmelgarn, Marian

Call to Order: The IBC Chair called the meeting to order at 11:29 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: The Site indicated that the Public Meeting Notice had not been posted prior to the IBC meeting. A Post-Meeting Public Meeting Notice will be sent to the Site for posting.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 6/5/25 were approved with no changes**.**

New Business:

PI:	Simmons, Gary DO
Sponsor:	Kite Pharma, Inc.
Protocol:	KT-US-499-0150 A Phase 1 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 is an open-label, multicenter Phase I 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. Both study agents are administered intravenously via a pre-placed venous line.

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, risks associated with handling KITE-363 and KITE-753 are similar to the risks associated with handling primary human blood and bodily fluids, including accidental exposure to the mucous membranes (e.g., eyes, nose, and mouth) from spills or splashes and percutaneous injury from needlesticks. 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.
  - In response to a question from the Committee, the Site noted that Biohazard Signs are posted on the entry room to the investigational pharmacy, outside the door to the Nursing area and on the door to the administration rooms. The Committee recommended that the Site provide representative photos of the posted Biohazard Signs.
  - The Site confirmed that the Biomedical Storage (outside bins) is temporary storage on the day of pickup.

Motion: A motion of Full Approval for the study at BSL-2 was passed by unanimous vote. There were 0 votes against and 0 abstentions.

- 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 12:02 PM.

Post-Meeting Pre-Approval Note: None