Meeting Minutes

Institution:	Virginia Oncology Associates (VOA)		
Meeting Date:	April 01, 2026		
Meeting Time	9:00 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
	Reed, Craig	Yes	Core Member: Biosafety Expert/HGT Expert
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Welch, Nancy Joined at 9:12 AM	Yes	Local Unaffiliated Member
	Gobhardt, Wendi	No	Site Contact
Invited Members Not in Attendance:	Member	Voting	Member Type
	Marz, Aylin	Yes	Local Unaffiliated Member
Guests:	None		
Staff:	Hemmelgarn, Marian		

Call to Order: The IBC Chair called the meeting to order at 9:00 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 1/29/26 were approved by the IBC with no changes.

New Business:

PI:	Simmons, Gary DO
Sponsor:	Wugen, Inc.
Protocol:	WUC007-03 A Phase 2 Study of WU-CART-007, an Anti-CD7 Allogeneic CAR-T Cell Therapy in Patients with Relapsed or Refractory T-Cell Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma (T-RRx)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: WUC007-03 is a Phase II, single-arm study sponsored by Wugen, Inc. and designed to evaluate the safety, tolerability and efficacy of WU-CART-007 in participants with relapsed or refractory T-cell acute lymphoblastic leukemia and lymphoblastic lymphoma (r/r T-ALL/LBL). WU-CART-007 is an allogeneic T cell product transduced with a lentiviral vector to express a CD7-specific Chimeric Antigen Receptor (CAR) and has also been gene edited to knock-out expression of endogenous genes to prevent fratricide and reduce risk of Graft-versus-Host Disease (GvHD). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent WU-CART-007 consists of gene-edited primary human cells transduced with a recombinant, replication-defective lentiviral vector derived from a Risk Group 3 virus. BSL-2 is the recommended biocontainment level under the NIH Guidelines. Furthermore, since the investigational cell product consists of primary human cells with the potential for transmission of bloodborne pathogens, compliance with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) is also required.

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 PI's credentials 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 noted there was no image provided of the agent storage room door and stipulated that the Site provide a photo of the agent storage room door with a biohazard sign by 4/30/26.
    - The Site confirmed that the study agent will be received in a dewar (just-in-time delivery) and will remain in the dewar until preparation. The photo's slide will be administratively updated to note this practice.
    - The Committee noted that biohazard symbols on biohazard waste containers in the preparation area were not visible in photos due to the positioning of the containers. The photos slide will be administratively updated to note biohazard waste containers have biohazard symbols.
    - The Committee noted that a photo of the spill kit was missing and stipulated that the Site provide a photo of the Spill Kit by 4/30/26.
    - The Committee noted the presence of a small refrigerator in the photos of the preparation area and reminded the site to ensure no food or drinks should be allowed in that area. The Site confirmed that the refrigerator is only used for clinical purposes and drinks and food items are not allowed in the area. The photo's slide will be administratively updated to note this practice.
    - The Committee discussed preparation methods for the agent, including safety practices to avoid aerosol generation. The Site noted that the Sponsor will provide necessary materials and recommendations for preparation at the upcoming Site Initiation Visit (SIV).
    - The Site confirmed that gravity infusion from the prepared infusion bag was the expected dosing method. The Site will inform Sabai of any changes in planned preparation methods once the SIV has been completed.
    - The Committee discussed best practices for ventilation, monitoring and storage of liquid nitrogen dewars.

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

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:

- The Committee stipulated that the Site provide a photo of the agent storage room door with a biohazard sign by 4/30/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
- The Committee stipulated that the Site provide a photo of the Spill Kit by 4/30/26. 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 9:43 AM.

Post-Meeting Pre-Approval Note: None.