Meeting Minutes

Institution:	Virginia Oncology Associates (VOA)
Meeting Date:	December 08, 2025
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 Reed, Craig / Yes / Core Member: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Mars, 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
Guests:	None
Staff:	Hemmelgarn, Marian

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 10/23/25 were approved by the IBC with no changes.

New Business:

PI:	Simmons, Gary DO
Sponsor:	Lyell Immunopharma, Inc.
Protocol:	LYL314-101 A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of LYL314, a CD19/CD20 Dual-Targeting Chimeric Antigen Receptor T Cell Therapy in Participants with Aggressive B-Cell Non-Hodgkin Lymphoma
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: LYL314-101 (formerly MPCT-012L) is a Phase I/II multi-center, open-label study sponsored by Lyell Immunopharma, Inc. and designed to evaluate the safety, efficacy, and recommended Phase 2 dose (RP2D) of LYL314 (formerly IMPT-314) in adult participants with aggressive B-cell Non-Hodgkin Lymphoma (NHL). LYL314 is an autologous T cell product engineered to express a dual-targeting chimeric antigen receptor (CAR) targeting cluster of differentiation (CD)19 and CD20. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent LYL314 consists of primary human cells transduced with a recombinant, replication-defective form of a Risk-Group 3 lentivirus, BSL-2 containment is the recommended biocontainment level under the NIH Guidelines II-A-3.

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 needlesticks, spills or splashes 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 that the Bloodborne Pathogens (BBP) training will be due for recertification next month.
    - The Committee requested the Site map be updated to note all patient access points and doors.
    - The Committee stipulated that the Site add a plastic tray under the cardboard biohazard waste box in the Biohazard Waste Storage Room and an updated photo be provided by 1/7/26.
    - The Committee stipulated that a photo of the waterbath with a biohazard sticker/label be provided by 1/7/26.

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 Committee stipulated that the Site add a plastic tray under the cardboard biohazard waste storage box in the Biohazard Waste Storage Room and an updated photo be provided by 1/7/26. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
    - The Committee stipulated that a photo of the waterbath with a biohazard sticker/label be provided by 1/7/26. 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 10:30 AM

Post-Meeting Pre-Approval Note: None