

Meeting Minutes



Institution:	Case Western Reserve University		
Meeting Date:	February 13, 2026		
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
	Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
	Ellis, Robert	Yes	Core Member: Biosafety Expert/HGT Expert
	Wilson, LaKetta	Yes	Local Unaffiliated Member
	Yun, Yang H.	Yes	Local Unaffiliated Member
	Karlo, Colleen	Yes	Site Contact
	Young, Andrew	Yes	Biological Safety Officer
Invited Members Not in Attendance:	Member	Voting	Member Type
	Tepfenhart, Benjamin	Yes	Site Contact
Guests:	None		
Staff:	Smith, Jennifer		

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

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Previous Meeting Minutes: Minutes from 1/22/26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Deng, Changchun
Sponsor:	Estrella Biopharma, Inc.
Protocol:	EBUS22CD19AR100 An Open-Label, Dose Escalation, Multi-Center Phase I/II Clinical Trial of EB103 T-Cell Therapy in Adults with Relapsed/Refractory (R/R) B-Cell Non-Hodgkin Lymphoma (NHL)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: EBUS22CD19AR100 is an open-label, dose escalation Phase I/II clinical trial sponsored by Estrella Biopharma, Inc. and designed to assess the safety, tolerability, preliminary efficacy, and recommended phase 2 dose (RP2D) of EB103 in adult participants with relapsed/refractor B-cell Non-Hodgkin Lymphoma (r/r B-NHL). EB103 consists of autologous T-cells transduced with a lentiviral vector to express an antibody T-cell receptor (AbTCR) and a co-stimulatory molecule, both designed to recognize and bind CD19. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent EB103 consists of primary human cells transduced with a recombinant derivative of a Risk Group 3 lentiviral vector, BSL2 containment is the recommended minimal 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, or 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).

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- 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.

Motion: A motion of Full Approval 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: 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 10:17 AM.

Post-Meeting Pre-Approval Note: None