Meeting Minutes

Institution:	Case Western Reserve University		
Meeting Date:	June 15, 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
	Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
	Yun, Yang	Yes	Local Unaffiliated Member
	Karlo, Colleen	Yes	Site Contact
	Young, Andrew	Yes	Site Contact
Invited Members Not in Attendance:	**Member**	**Voting**	**Member Type**
	Tepfenhart, Benjamin	Yes	Site Contact
	Wilson, LaKetta	Yes	Local Unaffiliated Member
Guests:	Deng, Changchun		
Staff:	Smith, Jennifer		

Call to Order: The IBC Chair called the meeting to order at 10:01 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

Meeting Minutes

Previous Meeting Minutes: Minutes from 4/10/26 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Ignatz-Hoover, James
Sponsor:	Kure Cells, Inc.
Protocol:	HEM02 A Phase 1, Single-Arm, Open-Label Study to Evaluate the Safety of UF-KURE-BCMA Cells in Patients with Relapsed or Refractory Multiple Myeloma
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: HEM02 is an open-label, single-arm, dose-escalation Phase I trial sponsored by Kure Cells, Inc. and designed to assess the safety and efficacy of UF-KURE-BCMA in adult participants with relapsed or refractory multiple myeloma (rrMM). UF-KURE-BCMA consists of autologous T cells engineered to express a Chimeric Antigen Receptor (CAR) against BCMA. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent consists of primary human cells engineered with a lentiviral vector, BSL-2 containment is the recommended 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 or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. 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 recommended that the Site additionally wear a disposable gown during administration.
    - The Site confirmed that sharps and non-sharps waste are segregated and confirmed that non-sharps waste is placed in the larger, red biohazard waste container.
    - The Committee recommended that the Site verify that an eyewash placard is placed above the plumbed eyewash and affix a placard if needed and send an updated photo to Sabai
    - The Site confirmed plumbed eyewash stations are located within the Lab where preparation occurs and on the administration floor. Due to the distance from the administration rooms to the plumbed eyewashes, the Committee recommended that the Site have disposable eyewash bottles available in the administration areas.
    - The Biohazard Sign will be administratively updated to remove the phrase "and any agent manipulation."

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 10:25 AM.

Post-Meeting Pre-Approval Note: None