INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, April 21, 2026**
Time:	1:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Children's Healthcare of Atlanta, Inc., Atlanta, GA
Principal Investigator:	**Muna Qayed MD, MsCR**
Protocol:	Wugen, Inc., **WUC007-03**
NCT Number:	NCT06514794
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 2 Study of WU-CART-07, an ANTI-CD7 Allogeneic CAR-T Cell Therapy, in Patients with Relapsed or Refractory T-Cell Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma (T-RRex)

1. Call to order:

The Meeting was called to order at 1:00 pm Eastern Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were one Institutional Representative and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

The Institutional Representative confirmed that the notice of the meeting was not publicly posted per Institutional policy.

6. Review of proposed research:

The Chair provided an overview of the protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for WU-CART-007, since it consists of primary human cells genetically modified via a CRISPR/Cas9 system and a replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of WU-CART-007 locally**, provided all other criteria for study closure are met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Institutional Representative confirmed that a red biohazard container on wheels is used to discard sharps but was unsure if non-sharps waste is also discarded into this container. The Committee noted that disposable of non-sharps waste in a sharps container increases the chance that an inadvertent needlestick injury could occur and highly recommended that separate containers be used for sharps and non-sharps biohazardous waste.
2. The Committee recommended that Slides 6 and 11 in the Photos document, dated 04-20-2026, be revised to replace the word “biohazardous” with “sharps”.
3. The Committee discussed the most recent photos available for review and recommended that the Institution follow-up with IBC Services about the following:
    a. Confirm what type of container non-sharps biohazardous waste is disposed of in the Lab where preparation of the study agent will occur.
    b. Submit a photo of the container used for non-sharps biohazardous waste.
    c. Submit a photo of the outside of the room used to store biohazardous waste in the Outpatient dosing location (should include a visible biohazard sign or symbol).
4. The Chair noted that the Institution recently provided IBC Services with a “24/7” phone number for the Biohazard Sign and that it will be revised to include this information.
5. The Committee recommended that the Site Map for the BMT Outpatient dosing area be revised as follows:
    a. Note that the dosing rooms are “highlighted in blue” and that “each room contains a sink”.
    b. Add an annotation specifically for the new plumbed eyewash located in this area, clearly showing its location.
6. The Committee recommended that study agent-specific information in the Biosafety SOP be transferred to the Main/Addendum Biosafety SOP format used for other similar genetically-modified human cell studies under IBC oversight. The Committee noted that the areas of handling are the same, as well as general practices and that it would be ideal to use the Main/Addendum format to maintain consistency for study staff training. The Institutional Representative agreed to this arrangement.
7. The Committee acknowledged that while plumbed eyewash stations are available in areas where the study agent will be handled, it is recommended that prefilled eyewash bottles also be readily available in rooms during study agent handling to allow for immediate use in the event of eye exposure
8. The Committee recommended that Site Inspection Checklist Item #22 be revised to note that plumbed eyewash stations and prefilled disposable eyewash bottles are available in the Inpatient and Outpatient dosing areas.
9. The Committee recommended that the Institution confirm that a small sharps container will be made available inside of the BSC during preparation and that Site Inspection Checklist item 11 be updated accordingly as applicable.
10. The Committee recommended that the Institution confirm if Sterility Testing will be performed on study agent samples. If the Institution does not perform sterility testing on the study agent, the Committee recommended that references to sterility testing in the Biosafety SOP be removed.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:26 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Amendment 02, dated 06-18-2025
Investigator's Brochure, Version 5.0, dated 02-09-2026
Investigational Product Manual, Version 3.0, dated 02-13-2026
Protocol, Clarification Memo, Amendment 02, signed 02-20-2026
Biological Risk Assessment and Summary, dated 04-06-2026
Site Maps, dated 11-18-2024
Site Inspection Checklist, Cellular Therapy Lab, BMT Inpatient Outpatient, expires 01-14-2027, updated 04-03-2026
Photos, dated 03-25-2026
Photos, dated 04-20-2026
Biohazard Sign, Genetically Modified Human Cells, dated 04-07-2026
Biological Safety Cabinet Certifications, Cell Therapy Lab, expires 09-2026
SOP, Biosafety for WU-CART-007, dated 04-06-2026
Training, Shipping Certifications, expire 10-2026, 12-2026
CV, Qayed, M., signed 02-27-2025