INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Friday, June 27, 2025**
Time:	10:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Northside Hospital, Atlanta, GA
Principal Investigator:	**Melhem Solh, MD**
Protocol:	Kite Pharma, Inc., **ARC-112A**
NCT Number:	NCT05396885
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase II Study of CART-ddBCMA for the Treatment of Patients with Relapsed or Refractory Multiple Myeloma

1. Call to order

The Meeting was called to order at 10:00 am 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 two Institutional Representatives 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:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

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 CARTddBCMA since it consists of genetically modified primary human cells.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of CART-ddBCMA locally**, provided that other biosafety criteria for study closure are also 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:

Point of Discussion:

1. An Institutional Representative confirmed that the Principal Investigator's curriculum vitae (CV) is updated on a regular basis and agree to submit a more current one to IBC Services.

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. An Institutional Representative confirmed that used personal protective equipment (PPE) is disposed of into an appropriate container. The Committee recommended that the Institution confirm the specific type of container used and the Main Biosafety SOP Section 4 be updated accordingly.
2. The Committee recommended that the following language be added to the Main Biosafety SOP Section 5.2.4, "If a plumbed eyewash is not readily available, immediately start rinsing the affected eye using a prefilled disposable eyewash bottle, and escort the exposed individual to the closest eyewash station."
3. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to include the amount of time an eye must be flushed according to the Institution's policy.
4. The Committee recommended that the Main Biosafety SOP be revised to update the table on the first page to remove the 4th row.
5. The Committee recommended that the study agent be described as "CART-ddBCMA (also known as anitocabtagene autoleucel)" in the Biosafety SOPs and on the Biohazard Sign.
6. An Institutional Representative confirmed that the study agent will only be prepared on a countertop.
7. The Institutional Representatives expressed interest in maintaining a way to keep track of Biohazard Sign Versions and will look into the specific way they wish to do this.

11. Site requirements:

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

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 10:21 am Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 5.0, dated 06-21-2024
Investigator's Brochure, Edition 2, dated 04-09-2025
Cell Handling Manual, Version 7.0, dated 05-20-2024
Sponsor Memo, dated 06-28-2024
Biological Risk Assessment and Summary, updated 06-09-2025
Site Map, BMT Unit, 4th Floor, dated 01-29-2024
Site Map, HSC Laboratory, dated 01-29-2024
Site Inspection Checklist, GMHC, expires 02-10-2027, updated 06-11-2025
Site Inspection Checklist, Autoclave Addendum, dated 02-11-2025, updated 02-24-2025
Photos, HSC Lab, BMT Unit, dated 02-12-2025
Biohazard Sign, Genetically Modified Human Cells, dated 06-11-2025
SOP, Biosafety for Genetically Modified Human Cells, dated 06-18-2025
SOP Addendum, Biosafety for Autologous Cells, dated 06-11-2025
Training, Shipping Certification, expires 03-10-2026
CV, Solh, M., signed 04-08-2022