

SAFETY Meeting Minutes
UAMS IBC

MEETING TIME RECORDS

Meeting start time: 12/5/2025 12:00 PM

Meeting end time: 12/5/2025 12:14 PM

Meeting type: Virtual

Name of Regular/Alternate Member	Status (Member or Alternate)	Present by Teleconference?
Ha-Neui Kim	Member	No
Matthew Jorgenson	Member	Yes
Robert Hunter	Member	No; electronic vote
Kimberly Murphy	Member	Yes
Lindsey Clark	Member	Yes
James Douglas	Member	Yes
Amanda Holloway	Ex Officio	No
James Bishop	Member	No
Youssef Aachoui	Member	Yes
Jia Liu	Member	Yes
Yuet-Kin Leung	Member	Yes
Melaney Gee	Member	Yes
Mark Manzano	Member	Yes
Christine Simecka Morgan	Member	No
Antino Allen	Member	Yes
KyoungHyun Kim	Member	No
James Townsend	Ex Officio	No
Shengyu Mu	Member	Yes
Kikumi Ono-Moore	Ex Officio	Yes
Zhiqiang Qin	Member	Yes

QUORUM INFORMATION

Number of SAFETY members on the roster: 17

Number required for quorum: 9

Quorum: Present

All members present via teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

ATTENDANCE STATUS AND VOTING KEY	
ABSTAIN:	Present for the vote but not voting “For” or “Against.”
ABSENT:	Absent for discussion and voting for reasons other than a conflict of interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflict of interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member serves as a substitute for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

GUEST NAMES
N/A

Previous Meeting minutes approved: Yes

REVIEW OF SUBMISSIONS

The review and discussion of the protocols listed below included the following elements: the agents involved and their characteristics; types of manipulations planned; the source(s) and nature of the nucleic acid sequences; the host organism(s) and vector(s) to be utilized; whether expression of a foreign gene is intended and, if so, the specific protein(s) to be produced; the containment conditions to be applied, including biosafety level and any special provisions; and the relevant sections of the NIH Guidelines.

All IBC members present were reminded to identify any conflicts of interest as each registration was reviewed.

For each protocol reviewed, it was confirmed that the Principal Investigator (PI) and laboratory personnel have received appropriate training in the safe conduct of research.

De Novo Review**1. Review of SPROTO202500000073**

Title:	ARC-112A
Investigator:	Carolina Schinke
Submission ID:	SPROTO202500000073
Description:	<p>This Phase II clinical study is evaluating CART-ddBCMA, an investigational BCMA-directed CAR T-cell therapy, in adults with relapsed or refractory multiple myeloma. The purpose of this study is to evaluate if the investigational CAR-T cell treatment is a safe and tolerable way to treat relapsed and refractory multiple myeloma. The study will also evaluate how well the investigational CAR-T cells kill tumor cells.</p> <p>Eligible participants will undergo leukapheresis for manufacture of the personalized CAR T-cell product. After receiving lymphodepleting chemotherapy, participants will be infused with CART-ddBCMA and monitored for safety, tolerability, and preliminary therapeutic activity.</p> <p>Blood, urine, and bone marrow samples will be collected at defined time points for standard clinical laboratory evaluations and exploratory biomarker analyses, including cytokine and immunogenicity assessments.</p> <p>Results from this study will contribute to understanding the safety profile and potential effectiveness of CART-ddBCMA in treating relapsed or refractory multiple myeloma.</p>
Agent Containment:	<p>Biological Containment Levels:</p> <ul style="list-style-type: none"> • Human Blood: BSL-2 • Urine: BSL-2 • Human Bone Marrow: BSL-2
Applicable NIH Guidelines:	<ul style="list-style-type: none"> • Section III-C • Section III-C-1

a. **Determination:** Modifications Required

b. **Required modifications:**

Modifications Required. Please respond to all comments and make any necessary changes. Thank you!

c. **Votes:**

For:	13
Against:	0
Recused:	0
Absent:	4

Abstained: 0

REVIEW OF OTHER AGENDA ITEMS

- Administrative approvals were acknowledged and approved.
- No safety incidents to report
- No inspection findings to report
- Dr. Liu asked for the committee's help to recruit a new community member. The committee is currently lacking 1 of 2 community members due to a recent resignation.
- Dr. Liu suggested that the January 2026 meeting be moved from Jan 2 to Jan 9. All committee members present agreed. We will next meet on Friday, Jan. 9, 2025, at 12:00pm.
- No other new business was discussed.