

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, October 6, 2025
Time: 11:00 am Eastern Time
Location: Zoom Teleconference
Institution: Robert Wood Johnson University Hospital, New Brunswick, NJ
Principal Investigator: Vikram Bhise, MD
Protocol: Abata Therapeutics, 101-PMS-101
NCT Number: NCT06566261
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1 open-label, single ascending dose study of ABA-101 in participants with progressive multiple sclerosis

1. Call to order:

The Meeting was called to order at 11:00 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 five 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. Approval of previous meeting minutes:

Minutes Approved - YES: 5 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

The Chair provided an overview of changes since the last review.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for ABA-101, since it consists of autologous T cells modified by a lentiviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of ABA-101 locally**, provided all other criteria for study closure are met. The Committee reaffirmed this determination.

9. 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

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

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 one of the Biological Safety Cabinets (BSC) was recently certified and that this new Certification was submitted to IBC Services. The Committee agreed to allow an IBC Chair to evaluate the information in this document to confirm that it passed the required NSF/ANSI 49 tests for BSCs.
2. An Institutional Representative confirmed the plumbed eyewash stations are checked and flushed on a regular basis by the [REDACTED] and that a log is kept.
3. An Institutional Representative confirmed that washing hands in a sink with soap and water is the default method of hand hygiene.
4. An Institutional Representative confirmed that no subjects have yet been dosed.
5. An Institutional Representative noted that dosing of subjects will occur in the new [REDACTED] located across the street from the currently approved location. This building is accessible via a bridge and dosing of subjects will occur in one of several rooms on the [REDACTED]. This new unit contains several private rooms with positive pressure, and two rooms are set up under negative pressure. An Institutional Representative confirmed that these rooms are the same or similar in nature to what the IBC has previously approved.
6. An Institutional Representative confirmed that standard of care CAR T cell dosing is typically done in a positive pressure environment since those who receive these types of products are typically immunocompromised.
7. The Committee discussed dosing subjects in a positive pressure room with the study agent and found these to be acceptable as long as the exhausted room air is filtered and not recirculated. The Committee recommended that the Institution confirm that the exhausted air in these rooms is filtered.
8. The Committee found the description of this new dosing area to be acceptable.
9. The Committee recommended that the Institution update the following documents with the new area that will be used for dosing and that these documents be submitted to IBC Services: Site Map, Site Inspection Checklist, Biosafety SOP, and Photos.

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 11:28 am Eastern Time.