

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Tuesday, December 9, 2025**
Time: 2:00 pm Eastern Time
Location: Zoom Teleconference
Institution: Wayne State University, Detroit, MI
Principal Investigator: **Dipen Kumar Modi, MD**
Protocol: Janssen Research & Development, LLC, **90014496LYM1001**
NCT Number: NCT05421663
Meeting Type: Initial Review of Protocol and Site
Title: A Phase 1b/2 Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bispecific CAR-T Cell Therapy in Adult Participants with B-cell Non-Hodgkin Lymphoma

1. Call to order:

The Meeting was called to order at 2:00 pm Eastern Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution, and the Institutional Biosafety Officer. 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 JNJ-90014496, since it consists of autologous T cells modified by a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of JNJ-90014496 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: 6

NO: 0

ABSTAIN: 0

9. Review of Principal Investigator qualifications:

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

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices. The Committee had no comments or questions regarding these.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 2:07 pm Eastern Time.