INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, November 4, 2026**
Time:	9:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Hoag Memorial Hospital Presbyterian, Newport Beach, CA
Principal Investigator:	**Raghuveer Ranganathan, MD**
Protocol:	Bristol Myers Squibb, **IM065-0002**
NCT Number:	N/A
Meeting Type:	Initial Review of Protocol and Site
Title:	A phase 1, multicenter, open-label study of BMS-986553, CD19 in Vivo Chimeric Antigen Receptor (CAR) T Cells, in participants with refractory autoimmune diseases

1. Call to order:

The Meeting was called to order at 9:01 am Pacific Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Four voting members were present, including one local member 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. 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-1 containment facilities and practices plus Standard Precautions** are required for BMS-986553 since it consists of lipid nanoparticle (LNP)-encapsulated circRNA molecules administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of BMS-986553 locally**, provided that all 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: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator qualifications:

The Committee reviewed the qualifications of the Principal Investigator and had no concerns.

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 Committee recommended that Biosafety SOP Section 3.3 be revised to specify that the study agent will be thawed at room temperature on the countertop and that the study agent will be withdrawn from the vial “into a syringe” using a non-safety needle.
2. The Committee recommended that Biosafety SOP Section 5.1.4b.i be revised to specify that spills greater than 25 mL will be treated with full-strength bleach, such that the final concentration approximates a 10% solution.
3. The Committee recommended that Biosafety SOP Sections 5.1.4a.ii and 5.1.4b.ii be revised to indicate that the surface will remain wet for a contact time of 10 minutes.
4. The Committee recommended that Biosafety SOP Section 5.2.4 be revised to indicate that in rooms without a plumbed eyewash station, individuals will be escorted to the nearest plumbed eyewash station after using the prefilled disposable eyewash bottles.
5. The Committee discussed whether the 10-minute aerosol settling time specified in Biosafety SOP Section 5.1.1 was required for spills and determined that the Institution may decide whether to retain or remove the requirement.
6. An Institutional Representative confirmed that needles will be directly discarded into a sharps container without recapping. The Committee recommended that Site Inspection Checklist, Item 13 be revised accordingly.
7. The Committee recommended that Site Inspection Checklist, Item 21 be revised to mark “N/A” for using hand sanitizer prior to exiting rooms when a sink is not available since all of the preparation and dosing rooms have sinks inside.
8. The Committee recommended that the Institution confirm whether Peridox RTU can be used to decontaminate reusable eye goggles and revise site documents as needed.
9. The Committee recommended that site documents be revised to include room numbers for the areas where study agent storage, preparation, and biohazardous waste storage will occur.
10. An Institutional Representative confirmed that the black biohazardous container, as shown in Slide 5 of the Photos document, is not used for biohazardous waste disposal. The Committee recommended that this photo be removed from the document.
11. An Institutional Representative confirmed that, in accordance with Institutional policy, a biohazard bag is brought into the dosing room for disposal of PPE and then carried to the soiled utility room on the same floor for disposal into a biohazardous waste container. The Committee noted that California Department of Health regulations prohibit carrying biohazardous waste in a bag from one location to the other and recommended that the Institution follow up to confirm this practice is in compliance with these regulations.
12. An Institutional Representative noted that there may be a plumbed eyewash station in each dosing room on the 8th floor. The Committee recommended that the Institution follow up with IBC Services regarding this and revise site documents as needed.

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: 4 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:27 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Original, dated 03-31-2026
Investigator's Brochure, Version 01, dated 04-02-2026
Pharmacy Manual, Version 1, dated 04-13-2026
Biological Risk Assessment and Summary, dated 06-01-2026
Site Maps, dated 10-19-2026
Site Inspection Checklist, expires 02-11-2028, updated 10-01-2026
Photos, dated 10-19-2026
Biohazard Sign, BMS-986553, dated 10-15-2026
SOP, Biosafety for BMS-986353, dated 10-15-2026
Training, Shipping Certifications, expire 04-2028
CV, Ranganathan, R., dated 11-10-2025