INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Thursday, August 6, 2026**
Time:	3:00 pm Eastern Time
Location:	Zoom Teleconference
Institution:	Baptist MD Anderson Cancer Center, Jacksonville, FL
Principal Investigator:	**Lauren Hand, MD**
Protocol:	Precigen Inc., **PRGN-2009-201**
NCT Number:	NCT06157151
Meeting Type:	Initial Review of Protocol and Site
Title:	A Multicenter Phase 2 Study to Evaluate Efficacy and Safety of PRGN-2009 in Combination with Pembrolizumab in Patients with Recurrent or Metastatic Cervical Cancer.

1. Call to order:

The Meeting was called to order at 3:00 pm 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 six Institutional Representatives, the Principal Investigator, 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 PRGN-2009 since it consists of a genetically engineered gorilla adenovirus-based vector administered in a clinical setting.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of PRGN-2009** 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:

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. The Committee recommended that Biosafety SOP Section 5.1.4d be renumbered as Section 5.1.4b.
2. An Institutional Representative stated that disposable eyewash bottles are not available in the dosing areas since multiple plumbed eyewash stations are available. The Committee found this to be acceptable.
3. The Committee discussed notes from the certifier on the Biological Safety Cabinet certification, specifically that accurate traverse readings were not obtained. The Committee noted that these are required to verify safe containment, and product and operator protection. The Committee recommended that the certifier obtain the traverse readings in the future.
4. An Institutional Representative stated that non-sharps biohazardous waste containers are available in the dosing areas; the containers are yellow chemo bins located within cabinets. The Committee recommended that better photos of these containers be provided to IBC Services.
5. An Institutional Representative stated that the study agent specific biohazard sign will be posted at the entrance to the areas where the study agent is handled when the study agent is onsite.
6. The Committee noted that sponsor documents indicate that a maximum of two hours is allowed between thawing of the study agent vial and administration. An Institutional Representative stated that the vial and prepared syringe will be labelled with the appropriate expiration time.
7. An Institutional Representative stated that the preparation and dosing areas are located on the 9th floor within close proximity to each other.
8. An Institutional Representative stated that timers are used in order to adhere to the wet contact times for disinfectants.
9. An Institutional Representative stated that the soiled holding room used for biohazardous waste storage in the 9th floor pharmacy is not carpeted. The Committee recommended that a biohazard symbol be placed at the entrance to this room and that a photo of this be provided to IBC Services.

11. Site requirements:

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

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 3:20 pm Eastern Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 5.0, dated 01-26-2026
Investigator's Brochure, Version 4.0, dated 07-11-2024
Pharmacy Manual, Version 6.0, dated 03-21-2024
Biological Risk Assessment and Summary, dated 06-25-2026
Site Map, 9th Floor, dated 07-09-2026
Site Map, 9th floor, BMDA Pharmacy, dated 01-21-2026
Site Inspection Checklist, expires 01-28-2028, updated 07-14-2026
Photos, BMDA, dated 07-24-2026
Biohazard Sign, PRGN-2009, dated 07-07-2026

Biological Safety Cabinet Certification, dated 05-22-2026
SOP, Biosafety for PRGN-2009, dated 07-07-2026
Training, Shipping Certifications, expire 03-28-2027, 11-20-2026
CV, Hand, L., signed 11-18-2024