

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: **Wednesday, December 17, 2025**
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: **Regina Stein, MD**
Protocol: BriaCell Therapeutics, Corp., **BC-IMT-04**
NCT Number: NCT06072612
Meeting Type: Continuing Review of Protocol and Site
Title: Randomized, open-label study of the BRIA-IMT regimen and check point inhibitor vs physician's choice in advanced metastatic breast cancer (BRIA-ABC).

1. Call to order:

The Meeting was called to order at 9:38 am Central 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 Institution's 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. Approval of previous meeting minutes:

Minutes Approved - YES: 6 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.

Point of Discussion:

1. The Committee noted that some sites may allow subjects to dose themselves at home. The Biosafety Officer was unable to confirm if subjects at the Institution are allowed to dose themselves at home.

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

The Committee previously determined that **BSL-2 containment facilities and practices** are required for SV-BR-1-GM, since it consists of human cells modified using a plasmid. 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 SV-BR-1-GM locally**, provided that all biosafety criteria for study closure are also 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: 6 NO: 0 ABSTAIN: 0

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10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Point of Discussion:

1. The Biosafety Officer confirmed that the Biological Safety Cabinets (BSCs) are certified every six months and forwarded the most recent BSC Certifications (September 2025) to IBC Services.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:44 am Central Time.