

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, September 2, 2026
Time: 9:00 am Central Time
Location: Zoom Teleconference
Institution: Northwestern University, Chicago, IL
Principal Investigator: Eric Ruderman, MD
Protocol: Sonoma Biotherapeutics, Inc., SBT777101-01
NCT Number: NCT06460844
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of SBT777101 in Participants with Rheumatoid Arthritis

1. Call to order:

The Meeting was called to order at 9:15 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 three 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 noted 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 SBT777101, since it consists of autologous T-reg 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 SBT777101 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: 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 previously confirmed that the biological safety cabinets (BSCs) in the MCCT are certified on a semi-annual basis. The Committee noted that the BSC certification reports provided by the certifier are marked as being certified on an annual schedule and recommended that future certification reports indicate the correct certification schedule.

11. Site requirements:

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

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:20 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Protocol, Version 9.0, dated 12-23-2025

Investigator's Brochure, Version 5.0, dated 12-23-2025

Investigational Product Manual, Version 3.0, dated 11-06-2025

Research Modification Evaluation, Protocol, Version 8.0

Research Modification Evaluation, Protocol, Version 9.0

Research Modification Evaluation, Investigator's Brochure, Version 5.0

Research Modification Evaluation, Investigational Product Manual, Version 3.0

Biological Risk Assessment and Summary, updated 04-20-2026

Site Map, Olson, 1st Floor, dated 01-23-2026

Site Map, Olson, 7th Floor, MCCT, Room 7-424, dated 02-27-2025

Site Map, Olson, 7th Floor, MCCT, Room 7-613, dated 02-19-2024

Site Map, Prentice, 16th Floor, dated 04-12-2024

Site Map, Feinberg and Olson Loading Docks, received 10-16-2018

Site Inspection Checklist, Cell Therapies, expires 03-05-2027, updated 08-24-2026

Photos, Olson Pavilion, Dosing, dated 05-01-2025

Photos, Olson Pavilion, MCCT, dated 06-05-2025

Photos, Prentice Hospital, dated 04-25-2025

Photos, Feinberg and Olson Loading Dock, dated 03-25-2026

Biohazard Sign, Dosing Areas, dated 08-24-2026

Biohazard Sign, Olson MCCT, dated 08-24-2026

Biological Safety Cabinet Certifications, Olson MCCT, dated 03-27-2026

SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026

SOP Addendum, Biosafety for Autologous Cells, dated 08-24-2026

Training, Shipping Certification, expires 06-05-2027

CRRF, dated 07-15-2026

Prior Meeting Minutes, Continuing, dated 10-08-2025