INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Tuesday, June 30, 2026**
Time:	9:00 am Central Time
Location:	Zoom Teleconference
Institution:	Northwestern University, Chicago, IL
Principal Investigator:	**George Georges, MD**
Protocol:	Novartis Research and Development, **CYTB323K12201**
NCT Number:	NCT06655896
Meeting Type:	Continuing Review of Protocol and Site
Title:	A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis

1. Call to order:

The Meeting was called to order at 9:14 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:

The Biosafety Officer 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 YTB323, since it consists of autologous T 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 YTB323 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

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 noted that the Biological Safety Cabinet (BSC) Certifications were certified on March 27, 2026, with an annual certification schedule. The Biosafety Officer noted that these BSCs are typically certified every six months and that they will follow up with staff members to ensure they are aware that the BSC certifying company indicated these are due annually.
2. The Committee recommended that the expiration date of the BSC Certifications be revised to “expires 03-2027” to reflect the due date noted in the document.
3. The Committee noted that the sponsor instructions for decontaminating spills varies compared to the Institution’s policy. However, the Committee noted that the Institution’s policy is for decontaminating spills as outlined in the Biosafety SOP for Genetically Modified Human Cells is acceptable.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the 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 9:18 am Central Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda
Protocol, Version 03, dated 09-23-2025
Investigator's Brochure, Edition 10, dated 06-27-2025
Novartis T-Charge, Product Handling Manual, Version 2.0, dated 06-25-2025
Safety Summary Statement for Biological Entities, dated 12-10-2020
Research Modification Evaluation, Protocol, Version 03
Research Modification Evaluation, Investigator's Brochure, Edition 10
Research Modification Evaluation, Safety Summary Statement for Biological Entities, dated 12-10-2020
Research Modification Evaluation, Novartis T-Charge, Product Handling Manual, Version 2.0
Biological Risk Assessment and Summary, updated 02-17-2026
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 06-17-2026
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, Olson MCCT, dated 06-17-2026
Biohazard Sign, Dosing Areas, dated 06-17-2026
Biological Safety Cabinet Certifications, Olson MCCT, expires 09-2026
SOP, Biosafety for Genetically Modified Human Cells, dated 06-15-2026
SOP Addendum, Biosafety for Autologous Cells, dated 06-17-2026
Training, Shipping Certification, expires 06-05-2027

CRRF, dated 03-02-2026
Prior Meeting Minutes, Continuing, dated 06-11-2025