

For More Information

Dr. Maureen Mayes, from University of Texas—Houston Health Science Center, is the lead investigator for the Decliners' Registry. For more information about the registry and how to participate, please contact Dr. Mayes at (800) 736-6864.



The SCOT Decliners' Registry is sponsored by the National Institutes of Health (NIH) through its Division of Allergy, Immunology and Transplantation (DAIT) in the National Institute of Allergy and Infectious Diseases (NIAID).

SCOT (Scleroderma: Cyclophosphamide Or Transplantation) is a clinical research study comparing autologous stem cell transplantation and high-dose monthly Cytosan in participants with severe forms of scleroderma. To learn more, visit www.sclerodermatrial.org.



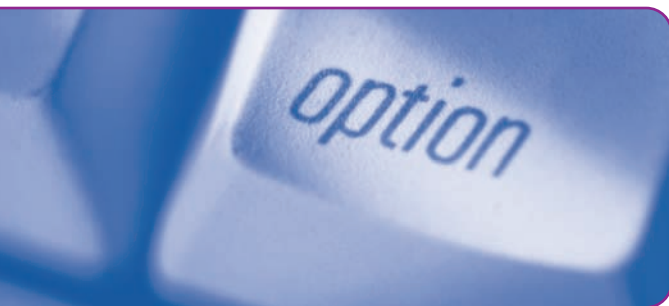
Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

An Observational,
Long-Term
Follow-up Study of
Eligible Individuals
Declining To
Participate in SCOT



The Decliners' Registry

Individuals who qualify for the SCOT study, but decide not to participate, should consider the SCOT Decliners' Registry.



Why is the Decliners' Registry Being Conducted?

Investigators in the SCOT trial and researchers from the NIH believe this registry will provide valuable information about current treatments for scleroderma.

With information from the registry, investigators will determine if the health and function of individuals in the registry are better, worse, or no different than those participating in the SCOT study.

Taking part in this registry will not influence the type of medical treatment you receive.

What's Involved?

If you decide to take part in the Decliners' Registry, you will receive a phone call from a study representative every 3 months for 44 months (approximately 3½ years). These phone calls will take about 20 minutes. You will be asked about your ability to perform usual activities such as vacuuming, eating, and going to the grocery store. This is sometimes referred to as a health assessment questionnaire. You will also be asked additional questions about your scleroderma, medication use, recent hospital visits and surgeries.

If you decide to take part, you may be asked to sign a medical release of information form. This may be requested so researchers can confirm specific details about your recent treatments and any hospitalizations you may have had.

Who Can Participate?

You may be eligible to take part in the registry if you have:

- Successfully completed the SCOT screen 1 evaluation but decline to progress to the screen 2 visit
- or**
- Successfully completed the SCOT screen 1 **and** screen 2 evaluations but decline to participate prior to study randomization
- **AND** signed the Decliners' Registry consent form

Individuals who are randomized and then decide not to participate in SCOT **are not** eligible for the registry.

