

## **VIDEO TRANSCRIPT**

### **Scleroderma: Cyclophosphamide Or Transplantation**

#### **WHAT IS A CLINICAL RESEARCH STUDY?**

**Length 9:34 minutes**

<p>SCOT logo</p> <p>Text on screen: What is a clinical research study? Length: 9:35</p> <p>Text across screen: SCOT 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).</p>	<p>Music</p>
<p>Dr. Shanahan, Duke University Medical Center</p>	<p>Dr. Shanahan: Hello. I am Joseph Shanahan, a rheumatologist and a clinical researcher at Duke University Medical Center. Have you heard or read about a clinical research study? Have you ever considered taking part in one? Let me briefly tell you about clinical research, and perhaps I can answer some questions that you may have.</p>
<p>Text on screen: What is a clinical research study?</p>	<p>Patient voice: What is a clinical research study?</p>
<p>Newspaper advertisement for a clinical research study. Physician speaking with male patient in an office setting. Medication capsule. Four people sitting at a table. Appear to be having coffee and/or orange juice.</p>	<p>Dr. Shanahan: A clinical research study is one way in which people help doctors find ways to treat disease and improve healthcare.</p> <p>Some studies are considered to be "investigational" because new drugs or interventions are tested on a small group of people before they are approved for the public at large.</p> <p>Other clinical studies are considered "observational" because no study drug or intervention is being tested. Instead, people's health habits are observed or they are asked to complete questionnaires about an important health issue.</p>
<p>Text on screen: Why do people participate?</p>	<p>Patient voice: Why do people participate?</p>

<p>Dr. Shanahan, Duke University Medical Center</p> <p>Female patient with healthcare providers</p>	<p>Dr. Shanahan: Sometimes people decide to take part in a clinical study because it might directly benefit them; that is, it might help them with a medical condition by giving them access to an intervention that they wouldn't otherwise be able to receive.</p> <p>Taking part in clinical research also gives people a chance to play an active part in their own healthcare. And, sometimes people agree to participate just so they can contribute to medical research, even though they themselves may not receive any direct benefit from that research.</p>
<p>Text on screen: Who can participate?</p>	<p>Patient voice: Who can participate?</p>
<p>Dr. Shanahan, Duke University Medical Center</p> <p>Female patient with healthcare providers</p> <p>Male physician reviewing medical records</p> <p>Female patient with female physician writing information</p> <p>Dr. Shanahan, Duke University Medical Center</p>	<p>Dr. Shanahan: Before anyone can take part in a clinical research study, they must first be "screened" to be sure that they are right for the study and that the study is right for them. All research studies will follow established guidelines, specific to that study, describing who should be included and excluded.</p> <p>Sometimes a study will be looking for people with a particular medical condition, and sometimes a study will want healthy volunteers.</p> <p>If you are interested in participating in clinical research, you'll be asked to provide information about yourself that will help the investigators determine if you are a good candidate for the study.</p> <p>These questions might concern your age, the condition being studied, treatment you've already received, and other medical conditions. Since this information is vital to your safety, it's very important that you answer all questions as accurately as possible.</p>
<p>Text on screen: What happens during a clinical research study?</p>	<p>Patient voice: What happens during a clinical research study?</p>

Dr. Shanahan, Duke University Medical Center	Dr. Shanahan: First of all, someone involved in the research will tell you all about the study. They will explain the reasons for the study and what would be required of you if you choose to participate.
Female speaking with female	
Female reviewing information with spouse next to her	Next, you'll be asked to review the study consent form. This form will spell out all of the potential benefits of the study, and, perhaps more importantly, the risks involved. It will describe all of the study procedures in detail. You should discuss the study with your family have them read the consent form as well.
Stethoscope, medications, medical records	As you review the form, you should ask any and all questions that you think of.
Female signing a form	If you decide to take part, you'll need to sign the consent form.
Picture of consent form	Signing the form means that you understand what's involved and that you are agreeing to take part. You always have the option to withdraw from the study even after you have signed the consent form.
Dr. Shanahan, Duke University Medical Center	Next, you'll be given a photocopy of the signed form, which will contain contact information in case you need to get in touch with a study staff member at any time during the study. Typically, the next step in clinical research is randomization.
Text on screen: What is randomization?	Patient voice: What is randomization?



<p>Caduceus, universal medical symbol</p> <p>Healthcare providers taking blood pressure of patients</p> <p>Committee meeting, males and females reviewing and discussing documents</p> <p>Healthcare provider taking patient's blood pressure</p> <p>Family sitting together</p>	<p>Dr. Shanahan: The same legal and ethical requirements that govern any medical practice also apply to clinical research. Clinical research is very closely controlled and has built-in safeguards. By law, investigators have to follow very specific procedures.</p> <p>If you decide to participate, you'll be monitored frequently to check your progress and make sure there are no problems. If you feel you are having problems between your study visits, you should let a study staff member know as soon as possible.</p> <p>In addition, all clinical studies have to be approved by an institutional review board, known as an IRB. The IRB is made up of both medical experts and a member of the community. The IRB makes sure the study is as safe as possible and that participation by people is worth any risks involved.</p> <p>The IRB has to review and approve the study before it begins, to be sure it is ethical and that the rights of participants are being protected. The IRB will also review the study annually. Moreover, all serious side effects have to be reported immediately to the IRB, which has the power to stop the study if the IRB feels the study is doing more harm than good.</p>
<p>Text on screen: What about contact with my regular doctor?</p>	<p>Patient voice: What about contact with my regular doctor?</p>
<p>Female patient speaking with female physician</p>	<p>Dr. Shanahan: Your relationship with your regular doctor will not be affected by taking part in clinical research. Be sure to inform your doctor, though, so that any treatments or medications he or she may prescribe will not have a bad interaction with the study drug or interventions you may be receiving in the study.</p>
<p>Text on screen: Does it cost anything to participate in a clinical research study</p>	<p>Patient voice: Does it cost anything to participate in a clinical research study?</p>
<p>Female patient speaking with healthcare provider</p> <p>Female listening and holding form</p>	<p>Dr. Shanahan: In most clinical studies, the costs of services that are considered to be part of the research will be covered by the study, but routine medical care will not. Costs associated with your routine medical care will be billed to you and your insurance company.</p> <p>Depending on how many visits are involved, you may be reimbursed for expenses such as parking or travel, but reimbursement policies vary from study to study.</p>

<p>Text on screen: What should I consider before participating in a clinical research study?</p>	<p>Patient voice: What should I consider before participating in a clinical research study?</p>
<p>Dr. Shanahan, Duke University Medical Center</p> <p>Man thinking</p> <p>Female walking on the beach</p> <p>Healthcare provider talking to patient</p> <p>Female patient thinking</p> <p>Medications, pills</p> <p>Family members gathered together talking</p> <p>Man thinking</p> <p>Woman thinking</p> <p>Female patient with female physician</p> <p>Dr. Shanahan, Duke University Medical Center</p>	<p>Dr. Shanahan: Now that you have a better understanding of clinical research, you may be thinking seriously about taking part in a study. If so, here are some of the things you may want to consider:</p> <p>Before participating in a clinical research study you should ask yourself the following:</p> <ul style="list-style-type: none"> <li>* What is the purpose of the study?</li> <li>* Who will be in it?</li> <li>* What kinds of tests and interventions are involved?</li> <li>* Am I willing to be assigned randomly to either study group?</li> <li>* Do I have a strong preference to be assigned to one group over another? If you do, a randomized study may not be right for you.</li> <li>* Why do the investigators think the intervention being tested may be effective? Has it been tested before?</li> <li>* How do the possible risks and benefits compare with the treatment I am getting now?</li> <li>* Am I willing to risk developing the possible side effects that may be associated with the study?</li> <li>* Are there alternative treatments available instead of participating in this study? Would the alternatives be preferable in terms of the possible side effects or possible benefits?</li> <li>* How might this study affect my daily life?</li> <li>* How long will the study last?</li> <li>* Will hospitalization be required?</li> <li>* Who will pay for the interventions?</li> <li>* Will I be reimbursed for any expenses and/or time and effort?</li> <li>* What type of long-term care will I receive?</li> <li>* How will I know if the intervention is working? Will the results of the study be provided to me?</li> <li>* Who will be in charge of my care during the study?</li> <li>* Who should I contact if I have any questions?</li> </ul> <p>You should talk with your doctor, family, and friends before deciding to join a clinical research study. It's a decision that might have great impact not only on you, but on many people in the future. Thank you for your time.</p>

<p>Dr. Shanahan, Duke University Medical Center</p> <p>Text on screen: Produced by Duke Clinical Research Institute, 2005</p>	<p>Dr. Shanahan: At this point you may want to take a break and then you can return to watch the SCOT screening and study procedure videos.</p> <p>Music</p>
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