YOU CAN MAKE A DIFFERENCE
LUPUS CLINICAL TRIALS AND AFRICAN AMERICANS

What Is A Clinical Trial?
Clinical trials are studies that research medications, vaccines, devices or procedures to determine if they are safe and work in people who have diseases such as lupus. These studies may show which medical approaches work best for certain groups of people. People who participate in clinical trials are always volunteers.

Why Participate?
Doctors and health experts agree that all medical treatments need to be studied in diverse populations to make sure that they are safe and effective. This includes African Americans, Latinos, Asians and other minority groups. Because lupus affects everyone differently, lupus clinical trials depend on the help of volunteers like you. Now and for future generations, it is important for African Americans to join studies that search for better treatments and cures for this complex disease.

What Are The Types Of Clinical Trials?
Clinical trials look at new ways to detect, prevent or treat disease. There are various types of trials:

- Screening trials focus on finding or improving a test that can find a disease or condition earlier.
- Diagnostic trials focus on finding better procedures or tests to diagnose or monitor a specific disease or condition.
- Prevention trials focus on vaccines, medications and even lifestyle changes that help prevent diseases.
- Treatment trials focus on testing new or existing medications, devices, interventions or treatments.
- Quality-of-life (or supportive care) trials focus on chronic diseases and look for ways to improve the mental and social impact a disease may have on patients.
Your full understanding of the clinical trial process, your safety, privacy of your medical records and your health are guiding factors of all clinical trials.

But Why Me? Why Should I — As An African American Be Part Of A Clinical Trial?

Participation in clinical trials — specifically lupus trials — is important for you because:

- Lupus is not only more common in African Americans, it is typically more serious.
- African Americans participate at lower rates in clinical trials than other groups.
- African Americans may respond differently to certain treatments than other racial groups. That's why it is critical that African Americans volunteer for clinical trials — to know these drugs will be safe and work in our population.

Are Clinical Trials Safe For Me?

Clinical trials follow a series of steps that are developed to protect YOU as a volunteer participant in the trial. Your full understanding of the clinical trial process, your safety, privacy of your medical records and your health are guiding factors of all clinical trials. There are rules that the government has put in place to protect patients and to make sure that they understand the clinical trial process. Informed consent is the process of providing potential participants with the key facts about a clinical trial before they decide whether to participate.  

THE APPROVAL AND OVERSIGHT

Before a clinical trial can begin, the study is typically approved by a group called an Institutional Review Board or “IRB.” An IRB is an independent committee with members who are physicians, scientists, other health professionals and members of the community. The purpose of the IRB is to make sure that the study is safe, that the risks are manageable and known and that the rights and safety of the participants in the trials are protected. The IRB’s role is to initially review and approve or deny the proposed trial and then to monitor all clinical trials.
It is important that you have an open discussion with the clinical research team anytime that you have a question or concern.

- **THE TEAM**
  Every clinical study is led by a principal investigator — often a physician. Clinical studies also have a research team that is led by a research/study coordinator and may include doctors, nurses, social workers and other health professionals. Clinical studies can take place in many locations, including hospitals, universities, doctors’ offices and in the community. The length of a clinical study varies, and volunteers are told how long the study will last before they enroll.²

- **THE RULES**
  The clinical trial team must develop and follow a step-by-step plan to carry out the study. This is called the protocol. The purpose of the protocol is to define and explain the specific research area to be studied (the medication, treatment, procedure, etc.) and the way that the research will be carried out. The protocol also focuses on protecting the health and welfare of participants in the study.

  The protocol describes:
  - Why the study is being conducted
  - Who may participate in the trial (eligibility)
  - Details about tests, procedures, medications and dosages
  - The length of the study and what information will be gathered
  - How the information will be used¹

- **THE KNOWLEDGE**
  Informed consent is very important in clinical trials. A clinical trial team works with the volunteer to provide as much information as possible. The informed consent process gives the volunteer the information needed to make a decision about participating in the study — information such as why the trial is being conducted, how long it will last, what the volunteer can expect, the risks and possible benefits of the trial and exactly who to contact with questions or concerns. The informed consent process occurs at the beginning of the trial and throughout the entire process. It is important that:
  - Volunteers understand what’s involved in the clinical trial and ask questions at any point during the clinical trial process.
  - The clinical trial team will explain the study, and volunteers will be given a document to sign stating that they understand the process.
  - Volunteers understand that they can withdraw from the study at any time, even after they sign the informed consent document.

- **THE RISKS**
  Clinical trials have potential benefits and risks. It is important to understand both before agreeing to participate in a clinical trial. Possible risks include:
  - The medication or treatment may not work in general and/or specifically in you.
  - You may not receive the “active” treatment, and instead a placebo.
  - There may be side effects.

Your time may also be a factor, as your participation will require frequent visits to the research center. It is important that you have an open discussion with the clinical trial team anytime that you have a question or concern.

**What Is Lupus?**
LUPUS is a serious disease that causes your body to “fight” against itself. Lupus is three times more prevalent in African American women, but people of all races and genders are diagnosed with the disease. To find out more about lupus visit Lupus.org.

Visit Lupus.org/Impact to find a lupus clinical trial near you.
LUPUS is a serious disease that causes your body to “fight” against itself.

IS A CLINICAL TRIAL Right for Me?

Here are a few important reasons to consider participating in a lupus clinical trial:

1. It is very important for African Americans to participate in clinical trials. Many of the medications and procedures that are currently being used to treat lupus have not been fully studied in African Americans. Participation in clinical trials helps doctors and healthcare providers understand how certain medications, vaccines and procedures work in our population.
2. Your participation in clinical trials can help increase medical knowledge and save or improve lives.
3. Participation allows you to take an active role in your own health.
4. You may be able to benefit from new or improved treatments before they are available to the general public. When you volunteer in a lupus clinical trial, you will have a team of lupus experts who will closely monitor you and are available to give advice, answer questions and provide support as needed.
5. Treatment may come at no cost to you. Be sure to discuss this with the clinical trial team and get a good understanding of what is and is not covered.
6. In some instances, you may be compensated for your participation.
7. Your participation in a clinical trial can also help the overall health of your community by making new drugs and treatments available faster and safer. Your voluntary participation in a clinical trial leaves a legacy to help future generations.

Citations:

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