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Lupus Research Action Network

by Lupus Foundation of America

LUPUS RESEARCH ACTION NETWORK: MEMBER TOOLKIT

This project is supported by Grant Number 1 CPIMP211305-01-00 from the U.S. Department of Health and Human Services Office of Minority Health.
Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the HHS, OMH.

This toolkit contains the following materials:

- You Can Make a Difference: Lupus Clinical Trials and African Americans
- Is a Clinical Trial Right for Me?
- Clinical Trials and Lupus: Frequently Asked Questions
- Helpful Resources for Lupus and Clinical Trials
- Patient Bill of Rights
- Notes

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:

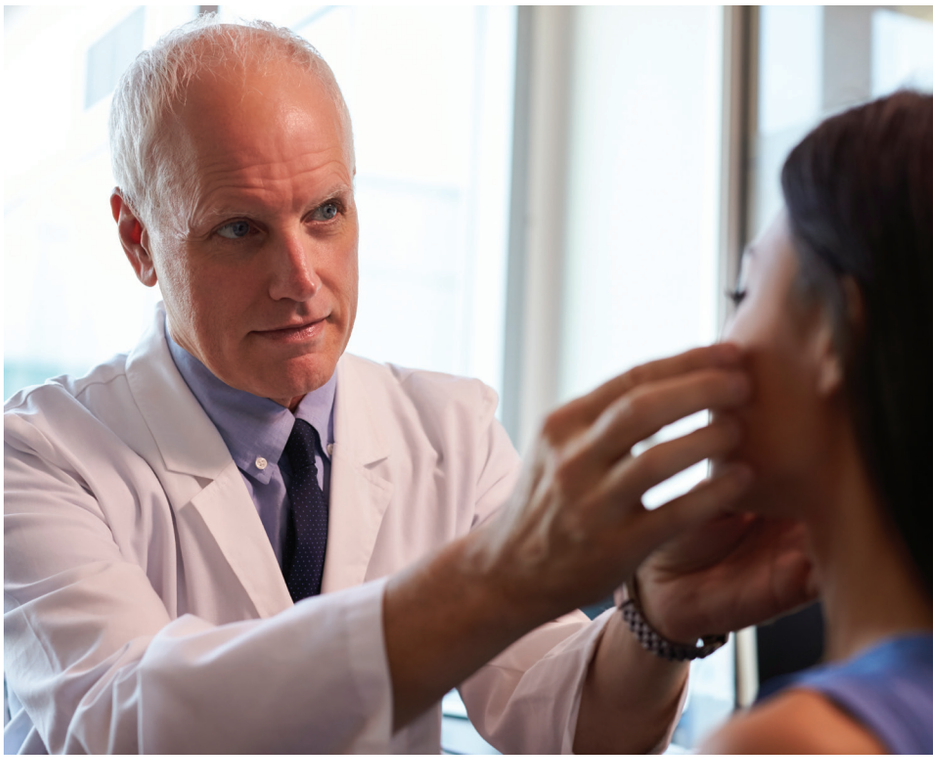
- Lupus is not only more common in African Americans, it is typically more serious.
- African Americans participate at lower rates in clinical trials than other groups.
- African Americans may respond differently to certain treatments than other racial groups. That's why it is critical that African Americans 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.[1]

- ### 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.[1]



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:
1. National Institutes of Health. www.nih.gov
2. Clinicaltrials.gov https://clinicaltrials.gov/ct2/about-studies/learn#WhoConducts

FOR MORE INFORMATION, VISIT LUPUS.ORG/RESOURCES

Help Us Solve
The Cruel Mystery

LUPUS™
FOUNDATION OF AMERICA

LUPUS.ORG

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.

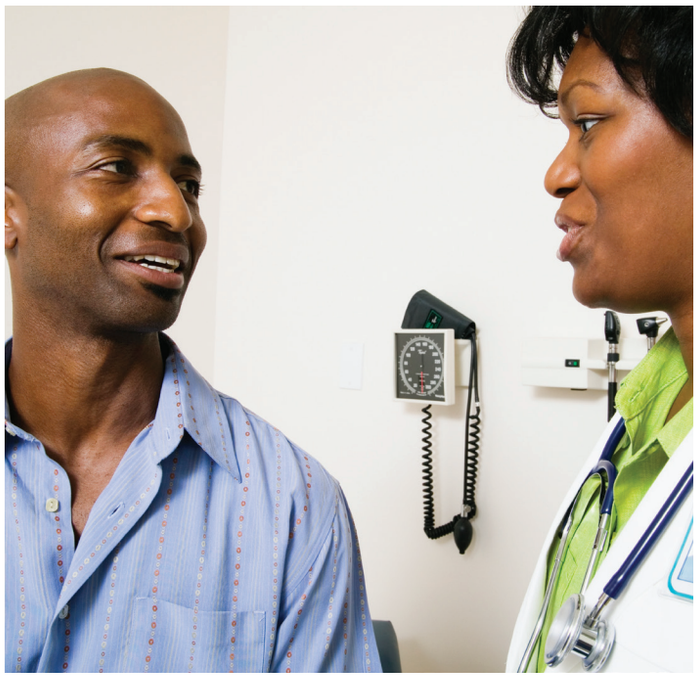
The protocol describes:

- 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 used[1]

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.

Clinical Trials and Lupus: Frequently Asked Questions

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.

Who Can Participate in a Clinical Trial?

All clinical trials have guidelines about who can participate. Researchers use inclusion/exclusion criteria to determine if someone is eligible to enroll in a clinical trial. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria".

These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead the criteria are used to identify participants and help ensure that researchers will be able to answer the questions they plan to study.

Are There Different Types of Clinical Trials?

Yes, types of clinical trials include:

- **Screening trials:** These trials test the best ways to detect certain diseases or health conditions.
- **Diagnostic trials:** These trials attempt to find better tests or procedures for diagnosing a disease or condition.
- **Prevention trials:** These trials look for better ways to prevent disease, lessen its severity, or avoid the complications associated with a disease.
- **Treatment trials:** These trials test new therapies, devices, combinations of drugs, or approaches to treatment.
- **Quality-of-life trials:** These trials evaluate ways to improve comfort and quality of life for people with chronic illness.

What Happens During a Clinical Trial?

The clinical trial process depends on the kind of trial being conducted. Clinical trials also have a research team that is led by a research/study coordinator and may include doctors, nurses, social workers and other healthcare professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed. Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. The clinical trial can only be successful if the protocol is carefully followed and there is frequent contact with the research staff.

What Are the Benefits of Participating in a Clinical Trial?

Clinical trials allow participants to:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care during the trial.
- Receive compensation, in some instances, for their participation.
- Help others by contributing to medical research.

What Are the Risks of Participating in a Clinical Trial?

There are potential risks to clinical trials.

- There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective for the participant.

- The protocol may require more time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

How is the Safety of the Participant Protected?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect the participants. The trial follows a carefully designed protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain private and will not be mentioned in these reports.

What is Informed Consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participant's native language is not English, translation assistance can be provided. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What Should I Consider Before Agreeing to Participate in a Clinical Trial?

You should know as much as possible about the clinical trial and feel comfortable asking the members of the research team questions about it, the care expected while in a trial, and the cost, if any, of participating in the trial.

The decision to participate in a clinical trial should not be taken lightly. If you would like to participate, you should have a clear understanding of the nature and aims of the study and your role in it. Ask the research team questions about anything that is unclear.

Can I Leave a Clinical Trial After it Has Begun?

Yes. You can leave a clinical trial at any time. When withdrawing from the trial, you must let the research team know about it and your reasons for leaving the study.

Where Can I Find Out About Upcoming Clinical Trials?

For more information about clinical trials in your area, visit the National Resource Center on Lupus: **Resources.Lupus.org/Entry/Search-For-Clinical-Trials**

Helpful Resources for Lupus and Clinical Trials

LUPUS FOUNDATION OF AMERICA RESOURCES

Lupus Foundation of America

Lupus.org

Lupus Foundation of America is the only national force devoted to solving the mystery of lupus, one of the world's cruelest, most unpredictable, and devastating diseases, while giving caring support to those who suffer from its brutal impact. About 1 in 250 African American women will develop lupus. Lupus is not only more common in African Americans, it is typically more serious. 9 out of 10 people with lupus are women, but men and kids get lupus too.

At the **Lupus Foundation of America**, we understand the physical suffering, emotional turmoil, and economic hardships caused by lupus. We collaborate with lupus medical experts to produce useful and relevant resources, programs and services to directly help people with lupus and their doctors better manage the disease.

Visit **Lupus.org** to learn more.

For lupus news and information follow us here:

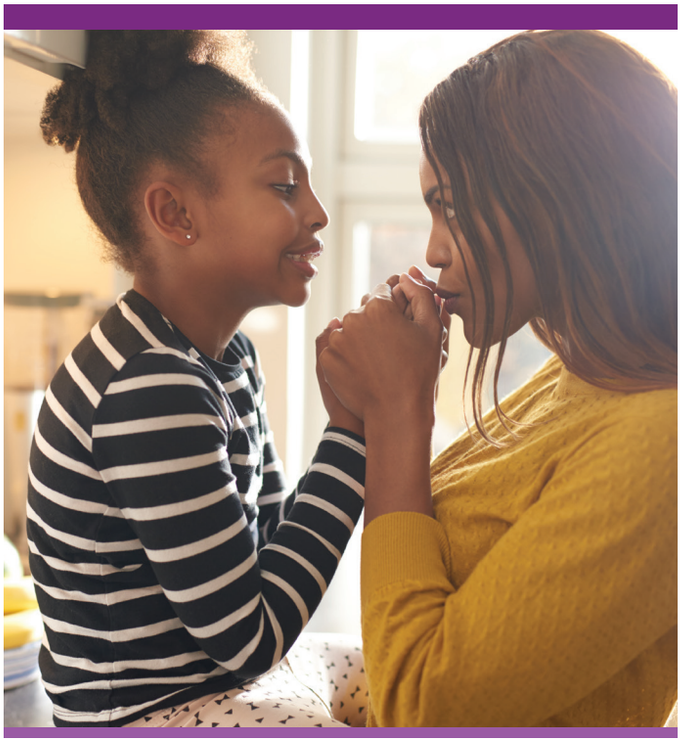
- **LupusFoundationofAmerica**
- **@LupusOrg**
- **@LupusOrg**

National Resource Center on Lupus

Resources.Lupus.org

Developed by Lupus Foundation of America, the **National Resource Center on Lupus** is a one-stop resource for all things lupus, from treatment to living and relationships. The Resource Center is updated on a regular basis to ensure that you are up-to-date and well-prepared to manage your lupus.

The Resource Center aims to empower, educate and connect people with lupus through reliable resources that provide emotional support and clear, accurate health information.



Anyone affected by lupus, including people diagnosed with lupus, children and teens, caregivers, health care professionals and the general public can find tailored information on the Resource Center. Visit **Resources.Lupus.org** to learn more.

National Health Educator Network

Lupus.org/HealthEducator

Lupus Foundation of America's health educators are available to answer questions and provide caring support to people with lupus, their families and their caregivers.

Call 1-800-558-0121 or visit **Lupus.org/HealthEducator** to contact a health educator today. (*Questions are answered in English and Spanish.*)

LUPUS CLINICAL TRIALS DATABASES

National Resource Center on Lupus

Resources.Lupus.org

For more information on Clinical Trials in your area, visit **Resources.Lupus.org/Entry/Search-for-Clinical-Trials**

For a listing of Frequently Asked Questions on Clinical Trials, visit **Resources.Lupus.org/Entry/Frequently-Asked-Questions-Clinical-Trials**

Research.forMe™ Lupus Registry

Resources.Lupus.org/Registry

A registry is a place to store detailed information about individuals with a specific disease and their families. The **Research.forME™ Lupus Registry** is for individuals with a diagnosis of lupus. This registry will help researchers and clinicians better understand the disease, and registry participants will receive tailored information on available studies and research opportunities.

Visit **Resources.Lupus.org/Registry** to learn more.

The Center for Information & Study on Clinical Research Participation (CISCRP)

CISCRP.org

The CISCRP Education Center offers individuals information and resources on clinical research participation.

Visit **CISCRP.org/Education-Center** to learn more.

Search Clinical Trials

SearchClinicalTrials.org

Search Clinical Trials is a public service that compiles clinical trial listings from multiple sources. You can also request a free search for clinical trials in your area.

Visit **SearchClinicalTrials.org** or call 1-877-MED-HERO to learn more.

ClinicalTrials.gov

ClinicalTrials.gov

ClinicalTrials.gov is a registry and database of publicly and privately supported clinical studies conducted around the world. ClinicalTrials.gov provides in-depth information on clinical studies including relevant history, policies, and laws.

Visit **ClinicalTrials.gov** to learn more.

What You Need to Know Before Participating:
PARTICIPANT BILL OF RIGHTS

Any volunteer who gives his or her consent to participate in a clinical trial or who is asked to give his or her consent on behalf of another has the following rights:

- To be told the purpose of the clinical trial.
- To be told all the risks, side effects or discomforts that might be reasonably expected.
- To be told of any benefits that can be reasonably expected.
- To be told what will happen in the study and whether any procedures, drugs or devices are different than those that are used as standard medical treatment.
- To be told about options available and how they may be better or worse than being in a clinical trial.
- To be allowed to ask any questions about the trial before giving consent and at any time during the course of the study.
- To be allowed ample time, without pressure, to decide whether to consent or not to consent to participate.
- To be told of any medical treatments available if complications occur during the trial.
- To receive a signed and dated copy of the informed consent form.
- To refuse to participate, for any reason, before and after the trials started.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Help Us Solve The Cruel Mystery
LUPUS FOUNDATION OF AMERICA

Notes

You now have
the Power
and the Knowledge!