

lupusinitiative.org/MIMCT

WHAT YOU SHOULD KNOW ABOUT LUPUS CLINICAL TRIALS

MIMICT

Materials to Increase Minority
Involvement in Clinical Trials

AMERICAN COLLEGE
of RHEUMATOLOGY
Empowering Rheumatology Professionals



LUPUS CLINICAL TRIALS: A SNAPSHOT

Clinical trials test for new and better treatments for diseases. Clinical trial studies are important to the lupus community because they give information on how treatments effect people living with lupus.

African Americans are more likely to have lupus, but they are not often a part of clinical trial research.

African Americans make up about 12 percent of the U.S. population, but only 5 percent of African Americans are a part of important clinical trials.

There are about 400 lupus clinical trial locations in the U.S right now.



African American women are at a higher risk for developing lupus

While lupus affects women and men, it is much more common in women.

In fact, over 90 percent of people diagnosed with lupus are women, and most find out they have lupus between ages 15 and 44.

Studies show that lupus affects 1 in 406 young African American women.

African American women and men have more complications from their lupus than non African Americans.
It is really important to have African Americans be a part of clinical trials so that we know how treatments affect their lupus and lupus complications.

You've Got the Power!



National
Medical
Association

The following information is provided through the courtesy of the [National Medical Association](#) (NMA). NMA created an informational booklet called **"You've Got the Power"** to help individuals make informed and educated decisions about whether or not to participate in clinical trials.

We would like to thank the NMA for granting us permission to provide lupus patients with the following excerpt from **"You've Got the Power"**.

We want to help you and your family use medical science to lead a healthier, happier and longer life.

The words "clinical trials" can sometimes bring to mind negative and confusing images. These images include guinea pig, government mistrust, Tuskegee syphilis study, or fear of the unknown. We designed this pamphlet to provide you with basic honest information about clinical trials and how important it is for African Americans to participate in appropriate clinical trials. You will learn what they are, how they can help you, how your rights are protected and where to find additional information.

We trust the knowledge you gain from this pamphlet will help you in making an informed and educated decision about participating in a clinical trial. A decision that may benefit not only you, but others as well.

What's a Clinical Trial?

Want to know what clinical trials are all about? Open your own medicine cabinet! You can find all kinds of medicines and treatments that contribute to your health and well being. There are probably over-the-counter medicines like aspirin and cough syrup or maybe prescriptions for diabetes and hypertension.

If you have friends or family members who have survived a serious illness such as cancer, stroke, or a heart attack, it's very likely that they owe their lives to drugs developed in clinical trials.

What exactly is a clinical trial? It's a careful, step-by-step process that studies or tests a new procedure, drug or device for prevention, treatment, screening or quality of life.

There are many kinds of clinical trials. A trial can test a new device, for example, a new piece of equipment for diabetics. Some clinical trials evaluate the best way for finding a disease, such as the prostate specific antigen (PSA) test for prostate cancer. Other trials can test lifestyle changes, such as how a new diet or getting more exercise, affects your health.

What About Drug Trials?

Most clinical trials test a new drug or a new combination of drugs. **These trials are designed to make sure that new medicines work and that they are safe before they are approved for use by the general public.**

The group that receives the new drug is often compared with a control group to determine the drug's effectiveness. The control group might receive the current standard treatment or a placebo. A placebo is an inactive pill, liquid, or powder that has no treatment value. No patient with a serious or life threatening condition will receive a placebo if a known effective treatment is available.



What's in it for Me?

Every year thousands of people of all ages participate in clinical trials. In every clinical trial a question is being asked: "What is the best way to treat or to avoid a disease or condition?"

Some people fear clinical trials. They may not know the ways in which a trial can help them or someone close to them, such as access to new drugs before they become available in the marketplace. People may also think a clinical trial is their last hope to cure a disease. But nothing could be further from the truth. **Clinical trials are an important part of preventing disease as well as finding cures for disease.**

In fact, many people who benefit from clinical trials are not sick. But, if you are at risk for a disease such as arthritis or glaucoma, clinical trials might help you learn ways that may prevent you from becoming sick. **Every day researchers are trying to discover what medicines, diet, or lifestyle changes may improve your health and help you to stay healthy.**

Many of the treatments that save lives today are based on yesterday's clinical trials. For example, leukemia at one time killed nearly every child who developed it. Today most of these children live, thanks to clinical trials used to advance medical research.

Why Should I Care?

Unfortunately, the benefits of participation in clinical trials have been slow to reach our community. This is because in the past we were often not asked and when asked, most often we chose not to participate in clinical trials. Mostly white men volunteered for clinical trials. Medicines and treatments that have worked well for white men sometimes did not work well for women or African Americans. **It's important to make sure we understand how to use drugs to get the best results in all people.**

Clinical trials depend upon not only researchers, but on the help of volunteers just like you. To determine what is best for African American health and wellness now and for future generations, it's important for African Americans to join appropriate clinical trials. **When we don't participate we may deny ourselves the possible benefits.** Benefits such as:

- An opportunity to test a new type of treatment before it's available to the general population.
- Special care and close monitoring by the trial doctor.
- Free trial medicines.
- An opportunity to help researchers find answers and best medicines for us, our kids and their kids.

What's My Risk?

Prior to testing in people, drugs are extensively tested in the laboratory. However, there are always some risks in any clinical trial. These risks could be minor or they may be serious. They may include any one or more of these:

Before you agree to participate, the doctor or nurse should thoroughly explain to you the clinical trial, including any known risks, possible side effects and any potential expenses to you.

- The new treatment may not work well for you. It might be less effective than the standard treatment.
- The new drug may have unknown side effects.
- Sometimes side effects can occur after the trial stops.
- For some trials, there may be expenses, such as for other medical tests, that may not be covered by your insurance or by a trial sponsor.

No one can force you to participate in a clinical trial. You should carefully weigh the risks against any possible benefits. But, even if you decide to volunteer you can leave the trial at any time.

How Am I Protected?

Some African Americans may not trust researchers because we have a history of being exploited and abused in past medical research. One famous example was the Tuskegee syphilis experiment (The United States Public Health Service Study of Syphilis in the Untreated Negro Male) in which hundreds of black men were studied without their permission and were not treated for their illness.

This episode of abuse was a serious problem, but as a result of the Tuskegee outrage and other abuses, **federal laws now protect you from being taken advantage of in medical research.** When you discuss the clinical trial with the doctor or nurse, he or she must tell you the possible benefits, and all known risks. This process is called informed consent.

Also every clinical trial conducted in the United States must be approved and watched by an Institutional Review Board (IRB). An Institutional Review Board is a group of experts and people typically from your community. Its purpose is to make sure that volunteers like you will be told everything about the trial. **The IRB is there to protect your safety, privacy, and self-respect.**

However, your knowledge and full understanding of the clinical trial process is ultimately your best protection.



What Questions Should I Ask?

Before deciding to participate in a clinical trial make sure you fully understand the trial and what is expected of you. One of the best ways is ask questions and get answers. Talk with your health care provider and the researcher involved with the particular clinical trial. The following are some questions you may want to ask and get answered in advance of your decision.

1. What is the purpose of the trial?
2. Who is sponsoring the trial?
3. What about my safety? How is it monitored?
4. What are the possible risks? (Present and long term)
5. What are the possible benefits to me? Are the results of this trial likely to positively impact my own medical care or benefit members of my family?
6. What kinds of tests, procedures, or treatments might be performed? (How many and how often?)
7. How long will the trial last? Will you continue to monitor me after the trial is over? If yes, for how long?

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8. What is required of me in the trial?
9. Will it cost me anything to participate in the trial? Will I be compensated for my childcare, travel, or other incidental expenses?
10. Do I need to speak with my health insurance company before participating in this trial?
11. Who will have access to my name and records? How will you protect my privacy?
12. What happens if I'm injured by the trial? Who will pay for my treatment?
13. Whom can I contact if I have questions?
You may want to ask the following additional questions if you are considering a drug-related trial.
14. What are all my other treatment choices? What are their advantages and disadvantages?
15. Will the drug be available to me once the trial is over?
16. What's my chance of getting a placebo?

Should I Participate?

Participation in a clinical trial does not guarantee a successful outcome. **However, there can be benefit in volunteering.** Learn as much as you can about the clinical trial prior to deciding. Then talk it over with your healthcare provider and those close to you. **But remember the final decision is Yours!**



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For More Information About Clinical Trials

The first and most important step is to have a conversation with your doctor. Other good sources of information:

- » American College of Rheumatology's Lupus Initiative provides lupus resources for people living with lupus, including a tool that allows you to search for lupus clinical trials - lupusinitiative.org/MIMICT
- » National Library of Medicine/National Institutes of Health - niaid.nih.gov/clinical-trials/clinical-research-studies-systemic-lupus-erythematosus
- » Food and Drug Administration (FDA) - fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default
- » National Medical Association/Project I.M.P.A.C.T. - impact.nmanet.org
- » U.S. National Library of Medicine - clinicaltrials.gov

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