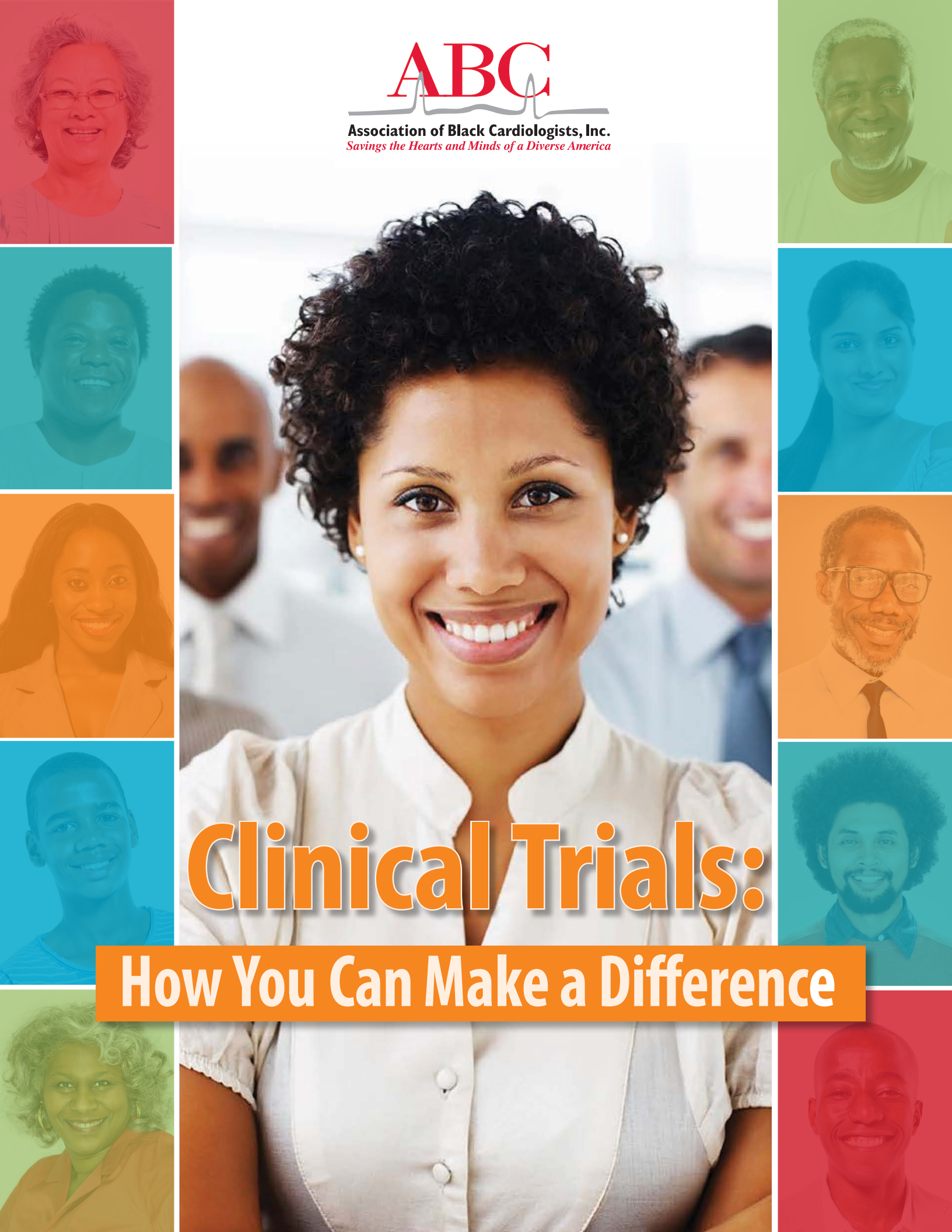
ABC

Association of Black Cardiologists, Inc.

Savings the Hearts and Minds of a Diverse America



Clinical Trials:

How You Can Make a Difference

The percentage of the U.S. population that is made up of people of color is growing, too.

In order to determine if there are different effects of new medical treatments based upon differences between racial or ethnic groups, we need to recruit all groups into clinical trials in order to have the best information available.

What are clinical trials?

Clinical trials are carefully controlled research studies that test new treatments in people with specific conditions such as high blood pressure, high cholesterol, and heart failure. Clinical trials are generally designed to test new treatments, new uses for existing treatments, or new combinations of treatments. The goal of clinical trials research is to find a better way to treat and help people.

Who can participate in clinical trials?

There are many factors that determine who can participate in clinical trials. Each trial is different. However, in general, any adult can participate in a clinical trial.

Historically, African Americans and other people of color have not been very eager to participate in clinical trials. Some of the reasons include lack of trust in the healthcare system, thoughts of being a human "guinea pig" for doctors to practice on, and fear of the unknown.

The purpose of this brochure is to provide you with information that will help you make an informed decision about whether you should participate in a clinical trial.

Should I participate in a clinical trial?

The most common reason to participate in a clinical trial is to find better treatments for current and future generations. While the new treatment being tested in a clinical trial may not immediately benefit you, it may benefit your children or grandchildren. Clinical trials provide the evidence that medical therapy is based on. It is essential that these new treatments are tested in all types of people who may be using them before they are introduced to the public.

While clinical trials provide knowledge that contributes to the fight against heart disease and other conditions, they may or may not always benefit you as a patient. The purpose of a clinical trial is to test a new treatment that may be better than current treatments. However, it may not be. The people talking to you about the study are obligated to clearly explain the potential benefits and risk, and your doctor should explain completely to answer any questions that may exist.

Only you can decide if the potential benefits to your health outweigh the risks. In fact, the law does not permit a person to claim that a clinical study is a treatment. It's important to talk with your doctor to ask questions about things that concern you and to weigh all of your options. After all, it's your health, and you should be comfortable with whatever decision you make.

Recipe for Healthy Living

1 Ounce of prevention (much better than a pound of cure)

5 Servings of fruits and vegetables each day

8 Glasses of water per day

½ Dozen good friends (relatives are okay, too)

30 Minutes of physical activity 3 times per week

4 Cups of laughter (no substitutions)

1 Mustard seed of faith

2 Tablespoons of patience (add more if you have children)

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ABC MISSION

To Promote the Prevention and Treatment of Cardiovascular Disease, including Stroke, in Blacks and other Minorities and to Achieve Health Equity for all through the Elimination of Disparities.

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How are people who participate in clinical trials protected?

Medical treatments such as drugs or vaccines must be tested before they can be sold by prescription or over the counter. Clinical studies are also needed for medical devices such as hip replacements, stents, pacemakers and in-home diagnostics like blood pressure or blood glucose testing machines. The **Food and Drug Administration (FDA)** sets very strict rules on how these treatments must be tested before they can be sold to the American public. Before doctors can conduct any research on human beings, they must have the research approved by an **Institutional Review Board (IRB)**. An IRB may include community representatives, scientists, clergy, physicians, and attorneys, whose sole purpose is to make sure that you, as a potential research participant, will not undergo any unnecessary or harmful tests and procedures. In addition to having the research approved by an IRB, your doctor must explain the study and ask your permission, known as informed consent, before you enroll in a clinical trial.

What is informed consent?

Informed consent is a process that protects you by guaranteeing that you are provided as much information as you need to ask questions and fully understand the possible benefits and risks associated with participating in the clinical trial. Because of informed consent, you don't need to worry about being in a research study of an experimental treatment without your knowledge. The FDA strictly prohibits such secret experiments and is very serious with respect to your safety.

Will participating in a clinical trial benefit or harm me?

Even with IRB review and informed consent, there is no guarantee that participating in a clinical trial will benefit you personally, or will not produce any undesirable effects. In fact, clinical trials should always be designed to give you the best therapy possible while testing a new therapy to see if it is better than what is currently being used. Before agreeing to participate in a clinical trial, be sure that you question your doctor to explain the study in detail. You should understand everything being asked of you and all of the potential risks. Also, if you decide not to participate in the trial, you will still have all the same treatments available to you and continue to receive the best care your physician has currently available.

How do clinical trials work?

Your doctor will closely follow the **protocol** for the clinical trial. A protocol is the term used for the "recipe" for a clinical trial. This tells your doctor exactly what study treatment to give you (ingredients), how much to give you (measurements), and when to give it to you (timing). The protocol also tells your doctor what tests to give you, and how often to give them to you. After the trial is complete, all of the information is collected and analyzed to determine if the new treatment is better, worse, or about the same as the standard treatment.

The medical researchers submit the data to the FDA and it is reviewed to ensure that the treatment is safe and effective. Only then is that new treatment offered to the general population, either over the counter or by prescription.

What else should I know about how clinical trials work?

Clinical research professionals monitor the treatment provided by your doctor to make sure your doctor does exactly what the protocol states.

Keep in mind that the study protocol may not allow your doctor to make substitutions in your treatment while you are participating in the clinical trial. Clinical trials are closely monitored and tightly controlled for your protection.

How are clinical trials conducted?

Clinical trials are conducted in phases. First, the research starts with a small group of people who may be healthy volunteers. If no major problems are seen, it is offered to a larger number of people, including those who have the illness to be treated. After the FDA approves the new treatment, it becomes available to even more people. Oftentimes studies are performed on the treatment even after the treatment has been released to the public. These studies are necessary to ensure the drug or device is safe and effective in a broader range of people in a real-world setting or to determine if the treatment could possibly have additional benefits. So, a good clinical trial program starts small and then expands.

What can I expect from participating in a clinical trial?

If you participate in a clinical trial, you will follow a specific treatment plan that your study doctor will give you. Your study doctor may be different from your primary care practitioner but they should communicate with each other throughout your participation in the study. There may be certain tests you must take to qualify to participate in a clinical trial. The screening tests are performed to exclude those who may not benefit or could possibly be harmed by the study treatment. The treatment plan is based on the protocol for the particular clinical trial. Depending on the study protocol, you may be randomly assigned, like flipping a coin, to either a group taking the new treatment (called the treatment group) or a group taking the standard treatment (the control group).

"Randomly" means that you have an equal chance of being assigned to either of the groups. By doing it this way, the study avoids being affected by human decisions about who gets assigned to which group. In addition, many trials are double-blinded. That means that neither your doctor nor you will know what group you are assigned to. However, in the event of an emergency related to your health and safety, the treatment you are taking will be made available to your care providers.

What if no standard treatment is available to compare to the new treatment?

If there is no standard treatment, in some cases a placebo may be used as the comparator. A **placebo** is a pill that looks like the pill received by the treatment group, but contains no active medication. In a clinical trial with one treatment group and one control group, you could have a 50% chance of being in the control group and receiving the inactive pill (placebo). You should ask your doctor what your chances of receiving the study treatment are if you decide to participate in the clinical trial.

All participants in a clinical trial *must* be told in advance whether a placebo will be used in the study.

What happens if the new treatment appears to be harming me?

In a clinical trial, your doctor will be closely monitoring you for any signs of harm and will stop the treatment if any signs of harm appear. Additionally, your doctor will be made aware to discontinue the study if a signal of harm is detected in other study participants or if more data (information) from the study is no longer needed, such as if the study is stopped early because overwhelming benefit is seen or if the study is halted because no benefit is seen. Your doctor is obligated to stop any treatment that appears to be harming you.

You also have the right to stop your participation in any clinical trial, for any reason, at any time. If you decide to stop participating in a clinical trial, you should talk with your doctor about your decision and the treatment options available to you. Remember, you must never stop a treatment without your doctor's guidance. Many study treatments must be switched back to standard therapy or weaned off to maintain the level of health you had before entering the study.

If you decide to stop participating in a clinical trial, you may be asked if you are willing to allow the information collected from you in the study so far to be used. The decision to allow use of information collected from you during the study is entirely up to you. You should discuss stopping your participation with your doctor before discontinuing treatment, since stopping a treatment abruptly can have serious side effects.

What questions should I ask if my doctor recommends a clinical trial for me?

The best way you can decide whether a trial is right for you is to ask questions. Here are some good ones to ask:

- What exactly is being studied in this clinical trial?
- Why do researchers believe the treatment being tested might be effective? Why might it not be effective?
- Has this treatment been tested before?
- How many people are participating in this study?
- What are the possible treatments that I might receive during the trial?
- How will it be determined which treatments I receive (for example, by chance)?
- Who will know which treatment I receive during the trial? Will I know? Will members of the research team know?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?
- What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic?
- Will hospitalization be required?
- How long will the clinical trial last?
- Who will pay for my participation or any study- related complications?
- Will I be reimbursed for any expenses?
- What type of long-term follow-up care is part of this trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will I be allowed to see the results of the study?
- Who will oversee my medical care while I am participating in the trial?
- What are my options if I am injured during the study?
- Will you communicate with my doctor about my participation in this study?

You Can Make a Difference!

By participating in clinical trials, you are helping researchers find better treatments for serious health conditions. These new treatments may enable you and other people of color to enjoy longer, healthier lives. **You can make a difference … please consider participating in a clinical trial.**

Would you like more information about research on cardiovascular and related diseases?

For general information or opportunities to participate in research:

- Contact your doctor
- Visit **www.abcardio.org** and click "Patient Resources"
- Send a note to **clinicaltrials@abcardio.org**
- Visit **www.clinicaltials.gov**