

# You've Got the Power!

## Clinical Trials Fact Sheet



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## WHAT IS A CLINICAL TRIAL?

A clinical trial is the scientific term for the step-by-step process that studies or tests in humans a new procedure, drug, vaccine or device for prevention, treatment, screening or quality of life. The majority of clinical trials conducted in the United States test new drugs.

- **Prevention trials** look at drugs, vaccines or lifestyle changes that may help prevent disease.
- **Diagnostic trials** look at ways of detecting or finding out more about a disease.
- **Treatment trials** may monitor new drugs or evaluate new combinations of established treatments.
- **Screening trials** may be conducted to find out if a screening test (such as for prostate cancer) is useful in detecting the disease at an early stage and, as a result, reduce the number of deaths from the disease.
- **Quality of Life trials** may study the psychological impact of the disease and ways to improve a person's comfort and quality of life.

## WHY SHOULD MINORITIES PARTICIPATE?

In the past, most drugs were tested on white men. Groups such as African Americans, Hispanic Americans, Native Indians, Asian Americans, and women, had generally not been a part of drug clinical trials. Studies have shown that sometimes drugs work differently in people in these groups. It is important to make sure we understand how to use drugs to get the best results in all people.

## BENEFITS

- Opportunity to get a new drug before it's available to the general population.
- Possibility of being among the first to benefit from a new treatment or new information about a current treatment.
- Special care and close oversight by trial doctors.
- Possibility of free health screenings and exams.
- Opportunity to contribute to medical and scientific knowledge, possibly for your good and/or the good of future generations.

## PARTICIPANT PROTECTIONS

- Participant's own understanding of the process
- Informed Consent Process (where you learn about all the expected risks and benefits of a clinical trial)
- Institutional Review Boards (a group of scientists, doctors, clergy and consumers that review and approves the action plan for every clinical trial)
- Your Physician
- The Food and Drug Administration
- The National Institutes of Health
- US Department of Health and Human Services/Office for Human Research Protections

## RISKS

- The new treatment may not work well for you.
- It might be less effective than the standard treatment.
- The new drug may have known and unknown side effects.
- Sometimes side effects can occur after the trial stops.
- You may receive a placebo — (an inactive pill, liquid, or powder) that has no treatment value. However,

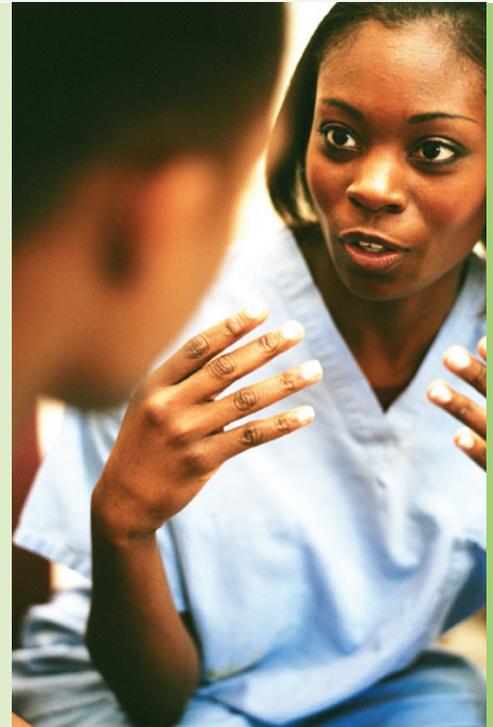
placebos are not used when doctors already have treatments that work or getting no treatment could put you at harm.

- For some trials, there may be expenses, such as for other medical tests, which may not be covered by your insurance or by a trial sponsor.

## QUESTIONS YOU SHOULD ASK

- What is the purpose of the study/trial?
- Who is sponsoring the study/trial?
- What about my safety? How is it monitored?
- What are the possible risks? (Present and long term)
- What are the possible benefits to me?
- Can I leave the trial at any time?
- What kinds of tests, procedures, or treatments might be performed? (How many and how often?)
- How long will the trial last? Will you continue to keep an eye on me after the trial is over? If yes, for how long?
- What is required of me in the trial?
- Will it cost me anything to participate in the trial?
- Who will have access to my name and records? How will you protect my privacy?

These are just a few of the questions you should ask and get answered.



## FOR MORE INFORMATION ABOUT CLINICAL TRIALS

Start and end with your healthcare provider. Other sources of general information include:

- **National Medical Association** Our website provides more information on clinical trials and links to other sources for clinical trial information ■ [www.NMANet.org](http://www.NMANet.org) ■ 202.347.1895.
- **The National Institutes of Health** Their website provides information on clinical trials for a wide range of diseases and conditions ■ [www.clinicaltrials.gov](http://www.clinicaltrials.gov) ■ 1.888.346.3656.
- **The Food and Drug Administration** Their website provides information on clinical trials and human subject protections ■ [www.FDA.gov](http://www.FDA.gov)

Use the space below to jot down any questions you may have on clinical trials. Take your questions with you on your next visit to the doctor.

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