A Guide to Clinical Trials for Black and African American Communities

Finding Treatments Together

CISCRP
Center for Information & Study on Clinical Research Participation

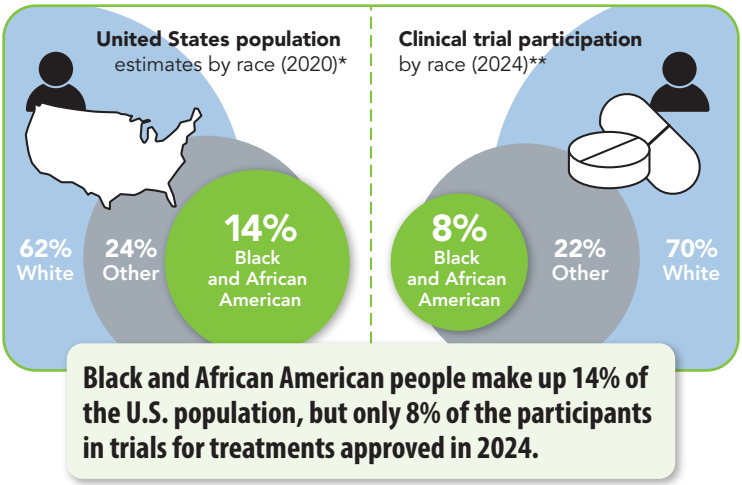
Clinical trials are the best way to find out if new treatments or vaccines work and how safe they are.

If clinical trials show that a new treatment works and is safe, then it can be approved to be used by the people who need it.

Not all clinical trials test a new treatment or vaccine. "Observational" studies collect information about people's health during their normal care. This helps researchers learn more about specific health issues.

Treatments or vaccines may affect people of different races, ethnicities, ages, genders, or sexes in different ways. It's important for everyone to be involved in clinical trials so we know how new treatments work and if they are safe for people from every community.

Black and African American people have been underrepresented in clinical trials.



*https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census.html

**Calculated from 2024 FDA Drug Trials Snapshot Summary Report

Many Black and African American people say they would take part in clinical trials if asked.

source: National Institutes of Health

Black and African American people are not always made aware of opportunities to participate in research. The research community is actively working towards including Black and African American participants in clinical trials to make sure that treatments work and are safe for people in these communities.

Tuskegee Study, 1932 to 1972

The Tuskegee study is an example of poor treatment of research participants. In this study, researchers withheld a treatment for syphilis from Black male participants. This unjust treatment led to changes in the way that clinical trials are run and how participants are protected.

The Tuskegee study is only one reason why some people may mistrust doctors or the research community. Unequal treatment of Black and African American people continues to exist in our modern healthcare system. By acknowledging these inequalities, researchers can take steps to correct them and to make sure that Black and African American people receive unbiased treatment.

Federal laws and guidelines protect the safety of clinical trial participants. Clinical trials must:

- Follow guidelines that make sure trials are ethical
- Include a process called informed consent to fully inform people about the trial before they can agree to be in it
- Be approved by an expert group called an institutional review board, also called an IRB, that makes sure the trial is fair and as safe as possible

When you sign an informed consent form to participate in a trial, you are not signing your rights away. Being in a trial is optional. **You can stop at any time and for any reason.** The trial staff will help you do this safely.

You can talk to the trial staff or the IRB anytime you have concerns.

Possible risks

- The treatment in the trial may not help you.
- You may have side effects from the trial treatment.
- You may have frequent testing or blood draws.
- You may need to set aside time for participation.

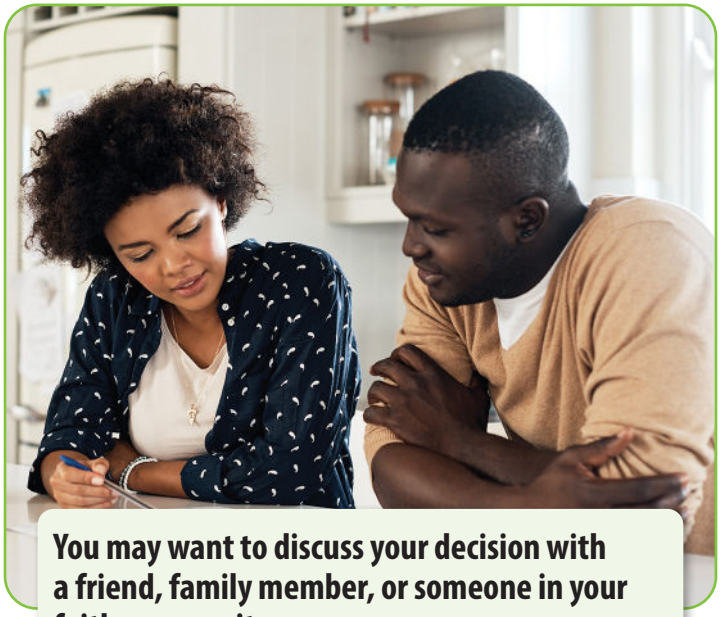
Possible benefits

- You will help researchers learn more about how a treatment affects your community.
- You may have early access to advanced treatments for your condition.
- You may have access to treatment when no approved treatment exists.
- Your health will be watched by the trial doctors and nurses.

If you are thinking about participating in a clinical trial, be sure to talk with your doctor about the risks and benefits that may apply to you.

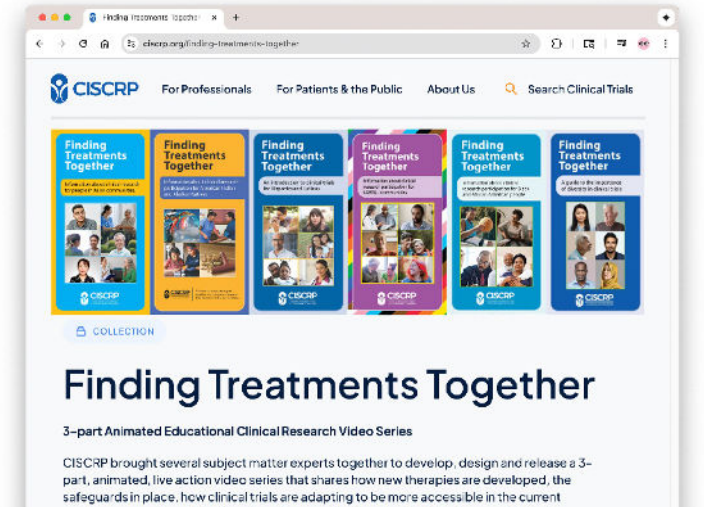
Joining a clinical trial that tests a new treatment for your illness or condition is only one way to participate in clinical research. Here are other ways to participate:

- Volunteer for an observational study that only collects health data.
- Join a trial as a "healthy volunteer" so researchers can collect data on how a new treatment acts in the body before giving it to patients.
- Sit on an institutional review board or a patient advisory board.
- Talk with your family and friends to raise awareness about clinical research in your community.



You may want to discuss your decision with a friend, family member, or someone in your faith community.

If you have a specific condition, the patient advocacy organization for your condition may have a list of clinical trials. Your doctor may also know about clinical trials for your condition. If you would like to learn more about current clinical trials, call **1-877-MED-HERO**.



For more information from CISCRP's *Finding Treatments Together* series and for translations of this brochure, go to: findingtreatmentstogether.org

CISCRP COMMUNITY COLLABORATION

This brochure was developed together with members of African American and Black communities and experts who work within those communities. It was also user-tested and reviewed with patients, the public, and health professionals. They all helped to make sure it is clear, non-biased, and culturally relevant.

CISCRP

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376

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