NATIONAL MINORITY QUALITY FORUM

LIFTEVERYVOICE PATIENT NETWORK

What You Should Know About Clinical Trials

This resource gives a comprehensive overview of clinical trial participation, patient rights, and a snapshot of successful trials that have advanced care for Black populations.

From HeLa to Healing

Building Faith and Trust in Clinical Trials

The history of medical mistrust among Black Americans stems from centuries of unethical medical practices, including **experimentation without consent, such as the Tuskegee Syphilis Study and the non-consensual use of Henrietta Lacks' cells.**

The unethical manner in which Ms. Lacks' cells (now known in research as 'HeLa' cells) were used highlights a legacy of exploitation and inequity in medical research, fueling deep-seated mistrust among marginalized communities, particularly Black Americans. This mistrust persists today, often showing up in hesitancy to join clinical trials. Yet, through faith, hope, and collective action, we can begin the journey toward healing, increased medical advancement, and improved health outcomes for Black populations.

Conversely, Black scientists have made profound contributions to the advancement of medicine, often overcoming systemic barriers and racism to achieve breakthroughs that have transformed healthcare and saved countless lives.

Black American scientist and Assistant Professor of Immunology and Infectious Diseases at Harvard T.H. Chan School of Public Health, Dr. Kizzmekia Corbett played a vital role in the creation of the Moderna COVID-19 vaccine. As a viral immunologist and senior research fellow at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases, her work was central to the design and testing of the COVID-19 vaccine that became a key tool in fighting the global pandemic.

Dr. Corbett was heavily involved in overseeing and analyzing data from the clinical trials. Her work ensured the vaccine was effective in getting strong immune responses with minimal side effects. Her work reminds us that through perseverance and divine purpose, transformative change is possible.

Accountability in Clinical Trials

Accountability in clinical trials has changed drastically over the past few decades, driven by an increasing focus on ethical standards, participant protection, and transparency. Modern day clinical trials follow strict rules to keep participants safe and ensure that past mistakes don't happen again.

These include:

The Belmont Report
This is a key document in research that sets ethical guidelines, emphasizing respect, beneficence or maximizing societal and individual benefits while minimizing risk, and justice. The report was created in response to past unethical studies.

Institutional Review Boards (IRBs)
These are committees full of experts that review and approve the ethical standards of all clinical trials to protect participants. These experts often include doctors, scientists, and community members, all of whom ensure that clinical trials are safe and participants are treated with respect.

Informed Consent
Researchers must provide clear, detailed, easy to understand information about the study. This information includes the purpose of the study, all expected procedures, risks and benefits, and that their participation is entirely voluntary. This information is usually shared through a written document and verbal discussion with researchers to make sure participants can ask questions and make an informed choice

Embracing Transparency
Today, medical trials are set up to protect the people involved, and continuous efforts are made to build trust by being open about the process. For Black people, taking part in these studies is an act of empowerment, faith, and stewardship. By joining, they ensure that research includes their voices, paving the way for greater equity in healthcare.

> *It is motivating to know that **treatments are tested thoroughly** to ensure they are effective.*
>
> **-Alicia**

How are participants protected during clinical trials?

Participants are protected through rigorous testing standards and processes designed to keep them safe, respect their rights, and ensure their well-being.

Participant Rights and Informed Consent

As a clinical trial participant, you have rights designed to ensure your safety and independence. Informed consent is a key component, requiring that researchers provide all the information you need to make an educated decision about your involvement. You also have the right to withdraw from a trial at any time.

Oversight and Monitoring

To maintain safety and ethics, trials are reviewed and approved by IRBs to ensure that studies minimize risk and are respectful of participants. Trials must follow strict regulations set by the U.S Food and Drug Administration. Participants are closely monitored for adverse effects during the study. Data and Safety Monitoring Boards oversee ongoing trials to ensure participant safety, and they can adjust or halt studies if any major issues arise.

Safety Specific to Black Communities

Because of historical injustices, today's researchers focus on building trust and collaborating with community organizations to ensure safety and accountability. More Black researchers and knowledgeable staff are taking part in clinical trials, helping connect participants with the study.

Why Black people should participate in clinical trials?

1. **Improving Health Outcomes for Black People**

Black people are more likely to have lupus and face its toughest symptoms, but they often don't take part in the studies that create treatments for this disease. When Black people join these studies, it helps researchers learn how the treatments affect them. This can lead to better and more effective care just for them.

2. **Addressing Health Disparities and Building Health Equity**

Taking part in a clinical trial can have good benefits. You might get to try new treatments that aren't available to everyone yet. Plus, while you are in the study, healthcare providers will continuously monitor your health, giving you extra care and support.

3. **Being Part of the Solution**

By participating in clinical trials, Black people can make healthcare more equitable. Participation is an act of love and service, benefiting future generations.

*Knowing that I could be part of **innovative and groundbreaking research** would absolutely motivate me to participate in a clinical trial.*

-Gail

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*I believe clinical trials are important because they help contribute to medical advancements. When I think about joining a clinical trial, I feel intrigued because I could possibly be **helping with the launch of a new treatment plan.** I need to know the full details of the clinical trial. The reward is greater than the risk. **Trials can truly help those who are experiencing a specific medical condition.***

-Angelica

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*Even though I am terrified to participate in a clinical trial, I do **believe that they are beneficial to those they give wanted outcomes to.** It is a possibility that I may join a clinical trial; it just depends on the research, data, risks, etc. of the trial itself.*

-Aaliyah

Clinical Trials Successfully Advancing Black Care

Historically, Black people have been underrepresented in clinical trials due to systemic barriers, medical mistrust, and other factors. Their participation in clinical trials has proven to be critical in addressing diseases and developing groundbreaking treatments and therapies.

BiDil (heart failure medication)

BiDil, a heart failure medication, was the first "race-specific" drug approved by the FDA targeted towards Black Americans. Although the research faced negative criticism for excluding other races, it was highly effective in Black people with congestive heart failure (CHF). Further research was conducted later on to see differences among Black and white patients which indicated small effects in white patients, but great effects in Black patients to help with their CHF.

REPRIEVE (Randomized Trial to Prevent Vascular Events in HIV)

The REPRIEVE trial aimed to address increased cardiovascular disease risk among individuals living with HIV. With 44% of participants being Black, this was important given the higher rate of Black people living with HIV. A diverse group of participants was crucial for ensuring the results were useful and beneficial to Black populations disproportionately affected by both HIV and cardiovascular conditions.

> *I like knowing that the **clinical trial will help improve the health of others.***
>
> **-Angelica**

By participating in a clinical trial, you can answer the call to be agents of healing and justice and help ensure medical research reflects the diverse needs of your community, leading to treatments and therapies that are safer and more effective for everyone. You may even gain access to treatment not yet readily available to the public. By contributing to research, you are helping to address historical inequities and improve trust and representation in the healthcare system. Each step forward in research is a testament to faith, hope, and love in action.

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