Breaking the Barriers to Clinical Trials A Toolkit for Patients

Shifting the perspective from Experimental to Revolutionary – Shonte Drakeford

CLINICAL TRIALS | MEDICAL RACISM | PSYCHOLOGICAL & TRUST | FINANCIAL | LIFESTYLE | BLACK REPRESENTATION | MENTAL HEALTH | GEOGRAPHICAL | FEELING SEEN

A Toolkit Created With You in Mind

We see you. We hear you. We've got you covered.

TIGERLILY ANGEL ADVOCACY PROGRAM

ANGEL Advocate Approved

We have witnessed, heard, and personally experienced racial challenges due to both systematic and systemic racism within healthcare. People of color and other marginalized groups are often underrepresented in clinical trials. Black women in particular are among the most underrepresented populations, leading to a lack of or ineffective treatments for their bodies. We need to change this. For these reasons, we've crafted this toolkit with you in mind. Our goal is to help you feel empowered to make more informed decisions by providing you with the right tools and information to help you navigate clinical trials. Understanding clinical trials and getting access to trials is vital when seeking all avenues for treatment.

WHAT ARE CLINICAL TRIALS AND WHY ARE THEY IMPORTANT?

As a patient, it is important to know that clinical trials can be a potential treatment option. Clinical trials can extend life or be lifesaving for some people. Not only are they necessary to develop new treatments, but participation from people of all backgrounds helps researchers, patients, and advocates learn more about diseases and ensure that new treatments work safely and effectively in all people.

A clinical trial is a type of medical research study that determines whether an intervention – a new drug, medical device, or diagnostic tool – is safe and effective. The doctors leading a clinical trial, called investigators, develop a detailed document that describes how the study will be performed, called a study protocol. Trials are often designed to have a control group and a test group. The test group typically receives the new treatment being studied. The control group includes the group of patients who do not receive the new treatment but rather continue with their current or standard treatment, potentially with the addition of an inactive treatment or a 'placebo.' This allows medical experts to compare the effects of the new treatment versus the effects of the previous standard treatment.

Clinical trials are conducted by government agencies, universities, hospitals, and drug companies. They are necessary for a treatment or product to be approved as safe and effective for people to use.

Without the participation of the BIPOC population in clinical trials, we are limited in our understanding of whether or not a product is safe and effective for all people. Different races and ethnicities may have different responses to the same drug. With proper representation of all groups of people in a trial, researchers can be more confident about the effectiveness of their drug across populations, increasing the likelihood that it may truly be lifesaving for all.

CLINICAL TRIAL SAFETY

Empty promises and false pretenses were a consistent feature throughout early medicine, especially in clinical trials. The history of the Tuskegee Syphilis Study, the Stanford Prison Experiment, the Havasupai Diabetes Project, the utilization of Henrietta Lacks' cells, and many other events have led to the enactment of many laws and oversight groups that focus specifically on the safety of people as clinical research participants. Over the last 50 years, these protective measures have continued to expand to ensure that clinical trial participation is voluntary, well-informed, respectful, and beneficial for the participant. Read about some of the key developments that have occurred below to learn more about how clinical trials have been made safer.

- **National Research Act (1974)**
  - **What is it?**

    This law created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, required voluntary informed consent by participants, and required institutional review boards to oversee studies that include human participants

  - **What does it do?**

    The National Research Act ensures that all clinical trials are reviewed by a group of medical and ethical experts to confirm that the study is appropriately safe and ethical. This act also requires medical experts to review all of the details of the study with each participant before the participant can voluntarily decide to join the study.

- **Belmont Report (1979)**
  - **What is it?**

    This document established ethical principles to guide biomedical research, ensuring that the following are the underlying principles in every clinical trial: respect for persons, beneficence (prioritization of the participant's wellbeing), and justice.

  - **What does it do?**

    The Belmont Report requires informed consent of the participant in a way that is fully truthful and built on integrity; this report dictates that participants must be treated with courtesy and respect. The Belmont Report also confirms that all studies maximize benefit and minimize risk to the participants and that all procedures are reasonable, non-exploitive, and just.

- **Federal Policy for the Protection of Human Subjects ("Common Rule", 1991)**
  - **What is it?**

    This policy unified regulations across federal departments and agencies and also conferred additional protections for vulnerable populations, including pregnant women, fetal and neonatal persons, children, and prisoners.
  - **What does it do?**

    Key features of this policy support the understanding of and compliance with human study participant protections by creating common principles around compliance, informed consent practices, and institutional review boards. This policy also increased protective guidelines for vulnerable populations.

- **National Bioethics Advisory Commission (1995), President's Council on Bioethics (2001), Presidential Commission for the Study of Bioethical Issues (2009)**
  - **What is it?**

    These three groups established expert-led councils to continually review regulations, policies, and procedures to ensure protection of volunteer clinical trial participants.
  - **What does it do?**

    These advisory panels identify and promote socially and ethically responsible policies and practices in clinical research and other scientific fields. The continued growth and expansion of these groups shows a continual effort to ensure that clinical trials are safe and ethical for human participants.

- **FDA Guidance on Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry (2022) and Consolidated Appropriations Act (2022)**
  - **What is it?**

    This FDA guidance and government law require clinical trial sponsors (most often pharmaceutical or medical device companies) to submit diversity action plans before their drug or device can be approved for the general public to receive.
  - **What does it do?**

    The diversity action plans that are required are documents that explain how sponsors will ensure the demographic makeup of the trial participants is appropriate for the demographics that bear the burden of disease; this means the new treatment will be studied in the people that need the treatment most. These documents specifically highlight the ways in which sponsors will include participants from historically excluded and underrepresented populations. The expected outcome is that medical experts will have a better understanding of how a new treatment works across all types of people, making it safer for all.

Acknowledging and understanding the previous failures and ethical errors in medicine allows us to identify ways to ensure that unethical activities are not repeated. With the help of these expert-led groups, guidelines, laws, and patients like you driving change and accountability, a framework has been established to ensure that clinical trials are ethical and just and that clinical trial participants are voluntary and well-informed. Safety and justice, especially for historically underrepresented and vulnerable populations, will continue to be a key underlying feature of all clinical trials.

THE CLINICAL TRIAL PARTICIPATION PROCESS

Here are the steps you will go through if you and your doctor agree that you should consider a clinical trial:

1. Your doctor will connect you with the study team who is running the trial at a nearby trial site, which may be the hospital or clinic you already attend or may be a different location in your area.
2. The study team, which often consists of a doctor (the 'investigator'), a study coordinator, and one or more clinical research coordinators, will explain the trial to you and also gather basic health information about you.
3. The study team will give you an informed consent form to sign; this form contains all of the information that they reviewed with you about the study and may be provided either electronically or as a paper document.
4. You will be screened to make sure you qualify for the trial. Screening often consists of collecting your health information and going through a checklist to make sure that you are eligible for the study based on your health conditions.
5. If you pass screening, the study team will schedule your first visit (the 'baseline' visit). During this visit, the doctor will complete cognitive and/or physical tests to make sure it is safe and appropriate for you to participate.
6. You will be randomly assigned to a group on the study; this will tell the study team which treatment you receive.
7. You will follow the procedures that were listed in the consent document and communicate closely with the study team to report any issues or concerns. The doctor or study coordinator working on the study may schedule several visits to complete all the required tests (usually a series of cognitive, physical, or other tests such as imaging). During these visits, they will collect information about the effects of the treatment and your safety and well-being.
8. You will continue to see your regular doctor for check-ups or other needs outside of the study-specific activities.

You will continue with the procedures and treatment of the trial for its duration or until you choose to withdraw from the trial. You can always choose to stop participation at any time throughout the clinical trial.

PATIENT CONSIDERATIONS

Mistrust and Safety

While there have been great advances in medicine, the medical community is not without glaring missteps. The Black community has been exploited during a number of different studies that were managed in unethical ways. As a result, medical mistrust amongst the Black community is understandably high. Thankfully, medical, legal, and ethics professionals have worked hard to ensure that strict regulations and transparency is in place to ensure clinical trials are safer for everyone.

Extensive research is now conducted on the new drug before ever being given to humans. New measures have been put in place to protect people. There are many guidelines to protect patient's rights that have been created to help mitigate risks, including fully informed voluntary consent to participate so that you are aware of any and all potential impacts that may occur as a result of joining a study. These strict ethical and scientific standards were put in place to prevent future exploitation and abuse by the medical and research community. In the section titled 'Clinical Trial Safety,' you can review some of the guidelines that have been enacted to protect people during their participation in clinical trials.

Placebo

A common misconception when participating in a clinical trial is that you might get a placebo, which has historically been used as a term for an ineffective treatment that is used as a control for comparison against the investigative treatment. However, cancer trials are treatment based, meaning that all participants receive treatment. Some individuals may get to stay on their current treatment or will receive the 'standard of care' or most commonly used treatment and others will receive the treatment being studied.
You may just get a different treatment than another participant so that the scientists can compare to see which might be more effective.

Access

Working with your doctor or a nurse navigator to gain access to clinical trials is a great starting point! Your doctor may have previously mentioned clinical trials as an option to you. If your doctor has not mentioned clinical trials as a treatment option, you should feel empowered to ask your doctor directly! Additionally, there are numerous databases with details on completed, ongoing, and upcoming clinical trials available through advocacy groups, government agencies, hospitals, and drug companies that you can search for online.

If you are interested in a clinical trial try the steps below:

1. Know and understand your current health conditions and diagnoses
2. Ask your doctor about any clinical trials that may be recruiting or starting soon that you might qualify for
3. Search online to find potential trials near you

If there are trials nearby, reach out to the site or study team contact to make an appointment for pre-screening and to learn more directly from the trial site.

Cost

There are costs that are associated with participating in clinical trials. While some costs may be covered by health insurance or the study sponsor, others may not be. You may need to talk with your insurance provider and the study team at the clinical trial site to understand which costs are covered and how you will receive support.

Potential costs might include some of the following:

- Doctor visits
- Lab tests (such as biomarker testing or tests that may be required during screening)
- X-rays and/or other imaging
- Transportation for appointments
- Childcare or eldercare
- Housing costs if you and your study team think it is in your best interest to move closer to the clinical trial location while you're undergoing your treatment

While not all of the above costs may be covered, many clinical trials will offer cost coverage for lodging and travel, including airfare and ground transportation during trial visits. Many patient advocacy groups may also help to cover additional expenses that are not covered by insurance or the study team.

Transportation

Transportation may be a challenge when traveling to study appointments for clinical trials. Let the study team know if transportation is a barrier for you, as they may be able to provide ride services or reimbursement for gas and parking or they may have partnerships with organizations that can help mitigate this barrier.

Lodging

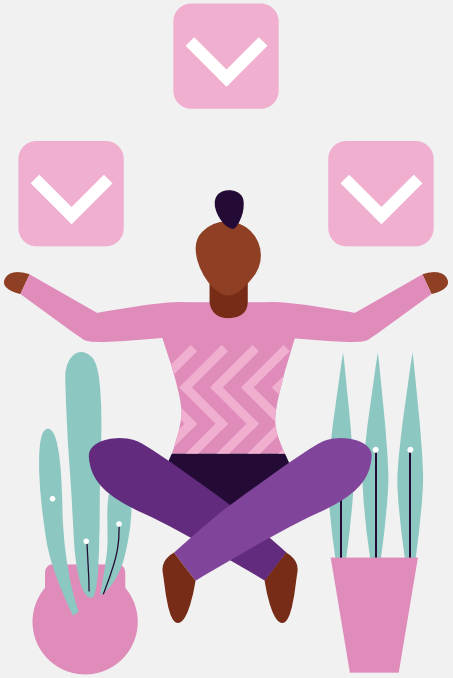
If your clinical trial is located in another city and traveling is required, discuss lodging options with your study team. They may know of hotels or other locations that offer free or discounted rates. The study team may also have funding set aside to cover this cost for you.

Lifestyle

Trials, much like conventional treatment, may require a leave of absence from work or may make your daily responsibilities more challenging to complete. Planning around childcare, eldercare, increased costs, pet care, and changes to your work habits may be necessary. Planning ahead of time for these challenges will be helpful for you, your family, and your colleagues while you are participating in a clinical trial. It is important to communicate these concerns to your study team because there may be funding and other support opportunities available to help you.

QUESTIONS TO ASK YOUR HEALTH CARE TEAM

- Are you involved in any studies or do you know of any that are happening nearby?
- Is there a study that is right for me?
- What makes me a good candidate for this study?
- What is the purpose of the study?
- Who can join the study?
- Are there any tests that I need to do before I can join the study?
- Where will the study be located?
- How will I know that the treatment is working?
- What happens if the treatment does not work?
- Who will be in charge of my care?
- What is the plan to make sure there is good communication between my regular doctor and the study team?
- Who do I call if I have questions about the study or my care?
- Has the drug, device, or treatment been tested before?
- What kinds of tests and treatments are part of the study?
- What are the possible risks, side effects, and benefits that could happen if I joined the study?
- How do the possible risks, side effects, and benefits that could happen during the study compare with my current treatment?
- Are there any safety concerns so far in this trial?
- How might this clinical trial affect my daily life?
- Do I need to change my diet and exercise while I am participating in this trial?
- Will I need to find someone to care for my children, elders, pets, or self while I am participating in this study?
- How long will the clinical trial last?
- What is the expected time commitment for me?
- What are the costs that I need to think about if I participate in this study?
- Who will pay for my treatment?
- Will I be reimbursed for other expenses?
- What kind of financial or other support resources are available for me?
- Is there a way for me to talk to other patients that are participating in this trial?
- If I decide to stop participating in the study, how do I do that and what happens to my treatment plan?
- Is there additional care included after the study ends?
- Will I have access to the clinical trial results?



TIPS AT A GLANCE

Just Ask. We can't say it enough: Ask questions to both your doctor as well as the study team in charge of the clinical trial. Be empowered to take charge of your health condition and your treatment options.

Be Proactive. Know and understand your health conditions and diagnoses. The more information that you know, the more empowered you will be to ask good questions and find a clinical trial that is right for you.

Do your research. Use all of the resources you have available when looking up information on clinical trials near you: use the internet, advocacy groups, telehealth visits, or in-person doctor visits to learn more

Be Unstoppable. Don't let fear stop you! There are many practices and policies that have been enacted to ensure the safety and well-being of trial participants. Don't let financial or logistical barriers stop you either – there are lots of supportive resources and advocacy groups like the ones noted below that can provide you a helping hand along the way.

RESOURCES

At Tigerlily, we are committed to providing you with the most up to date information along with resources to help you on your journey. We know that this is a challenging time and we want to provide you with resources not only Tigerlily offers, but also from our partners. Consider some of the below programs from Tigerlily and additional supportive resources from other advocacy groups. More resources can be found on Tigerlily's clinical trials webpage **here.**

- Tigerlily's RAISE Platform for Patients
- Tigerlily's Funds for Families Program
- Tigerlily's BREATHE Tv Series
- Tigerlily's HOPE Box Program
- Family Reach
- Lazarex
- Nancy's List
- Joe's House
- Cancer Support Community: Peer Support
- Cancer Care: Peer Navigation
- Patient Advocate Foundation: Financial Resources
- American Cancer Society: Patient Programs

Tigerlily Foundation

Beauty. Strength. Transformation.

1.888.580.6253
WWW.TIGERLILYFOUNDATION.ORG

@Tigerlilycares | tigerlily_foundation | @tigerlilyfoundation