BREAKING THE BARRIERS TO CLINICAL TRIALS

A Toolkit For Patients

Shifting the perspective from "Experimental" to "Revolutionary" – Shonte Drakeford

CREATED WITH YOU IN MIND

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

We have witnessed, heard and personally experienced racial challenges, specifically for Black women, due to both systematic and systemic racism within healthcare. For these reasons, we've carefully crafted this toolkit with you in mind. Our goal is to help you make more informed decisions by providing you with the right tools and information to help you navigate clinical trials.

People of color and other marginalized groups are more likely to be underrepresented in clinical trials, and Black women are among the most underrepresented groups. The goal of this toolkit is to provide you with the information that you need ahead of time to empower you and allow you to make the best decisions for your health. Understanding clinical trials and getting access to trials is vital when seeking all avenues for treatment.

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WHAT ARE CLINICAL TRIALS AND WHY ARE THEY IMPORTANT?

As a breast cancer patient, it is important to know about clinical trials. Clinical trials can be lifesaving for some. Not only are they a critical part of the development of treatments, but your participation helps researchers, patients and advocates learn more about diseases and advance scientific treatment options.

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/or effective. The investigators leading a clinical trial develop a protocol – a detailed document that describes how the study will be performed. A clinical trial recruits volunteer study participants to test the intervention. Trials are often designed to have a control arm. A control arm is the group of patients who do not receive the new treatment, but rather continue with their current treatment likely with the implementation of an inactive treatment. This is to allow researchers to study the responses to the treatment between the two groups; those who are receiving the treatment being tested by the trials and those who are not.[1]

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 effective for all people. Different races and ethnicities may have different responses to the same drug. With proper representation, researchers can be more confident about the effectiveness of their drugs across populations, increasing the likelihood of creating a solution that may be lifesaving for all.

PATIENT CONSIDERATIONS

Mistrust

While there have been great advances in medicine, the medical community is not without a dark past. The Black community were egregiously exploited during the Tuskegee trial and through experiences like those similar to Henrietta Lacks. 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 guidelines to protect patient's rights that have been created to help mitigate risks, including fully informed consent to participate so that you are aware of any and all potential impact. These strict ethical and scientific standards were put in place to prevent future exploitation and abuse by the medical and research community.

Check out our toolkit on Trust which provides you with tips and best practices to ensure you are safe.

Placebo

A common misconception is that you might get a placebo which may seem like a waste of time. Some cancer trials are not placebo-controlled trials, rather they are treatment based. You may just get a different treatment than another participant so that the scientists can compare to see which might be more effective.

If a trial does have a placebo, it can be in conjunction with another active drug or under close observation for care. But keep in mind that placebos are not always used in oncology trials.

It is important to keep in mind that clinical trials will always provide the standard of care treatment. A common misconception is that if you are getting a placebo you are not getting a treatment at all.

Access

Working with your healthcare provider 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 not, expressing interest or requesting additional information directly can help you gather details about trials to better understand what options may be available for you. Additionally, there are numerous databases with details on completed, ongoing, and upcoming clinical trial available through government agencies, hospitals and drug companies.

If you are interested in a clinical trial, review these steps below:

1. Be aware of your health and cancer type
2. Ask your physician about clinical trials and if they are right for you
3. Search https://clinicaltrials.gov/ to find private and publicly funded trials around the world
4. Reach out to the research team working on trials you're interested in to ask questions
5. Circle back with your healthcare professional to seek their recommendation
6. Make an appointment for pre-screening and to learn more directly from the trial site

Process

Here are the steps you will go through if you sign up for a clinical trial[1]:

1. The study team will explain the trial to you and also gather information about you.
2. They will give you an informed consent form to sign.
3. You will be screened to make sure you qualify for the trial.
4. If accepted, you will schedule your first visit (called the "baseline" visit). During this visit, the investigators will complete cognitive and/or physical tests to make sure it is safe and appropriate for you to participate.
5. You will be randomly assigned to a treatment or control group.
6. You will follow the procedures and communicate closely with the research team to report any issues or concerns. The investigators may schedule several visits to complete all the required assessments (usually a series of cognitive, physical, or other tests like imaging). During these visits, they will collect information about the effects of the intervention and your safety and well-being.
7. You will continue to see your regular physician for check-ups throughout the study.

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 choose to stop participation at any time throughout the clinical trial process.

Learn more about clinical trials by taking our ANGEL Advocacy Program

Cost

There are costs that are associated with participating in clinical trials. While some costs may be covered by health insurance, or the research sponsors, others may not be. Consult with your insurance provider and the trial's sponsor to understand which costs fall under coverage through insurance or trial participant support programs. Anticipated costs might include some of the following:

- Doctor visits
- Lab tests
- X-rays and/or other imaging
- Tests strictly for research purposes (an example of this is biomarker testing to help make future treatments more precise)
- Transportation for extra appointments
- Childcare
- Housing costs if you and your team think it is in your best interest to move closer to the medical center while you're undergoing your treatment, whether conventional or research related

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. Some nonprofit patient advocacy organizations may also help to cover and alleviate additional expenses such as childcare.

Transportation

Transportation may be a concern when getting to appointments for clinical trials. Communicate with those conducting the clinical trials about your need for transportation. They may have existing partnerships with organizations that can help with discounted or free transportation. Consider our partners over at Family Reach as they offer financial relief programs to assist with treatment.

Lodging

If your clinical trial is located in another city and traveling is required, discuss lodging options with the clinical trial provider. They may know of lodging sites that offer free or discounted rates or have funding set aside to cover this cost for you. Consider our partners over at Family Reach as they offer financial relief programs to assist with treatment.

Lifestyle

Trials, much like conventional treatment, may require a leave of absence from work or your daily responsibilities or make them a bit more challenging. Planning around childcare, increased costs, pet care, and work may be necessary. Planning in advance to find a replacement will help you to sustain a more normal life. Again, it's really important to communicate these concerns to your team because there may be funding and other supports available to help you.

QUESTIONS TO ASK YOUR HEALTH CARE TEAM

Clinical Trials

- What is a clinical trial?
- What trials are most appropriate for me?
- What type of trial should I consider?
- How can I find out if I am eligible to participate in a particular trial?
- Where can I learn more about clinical trials?
- Are they safe?
- Are they effective?
- What are the risks associated with the trial?
- What are the potential benefits?
- How are the trial benefits better than anything already tested that is available?
- Do you recommend trials to people who have a similar diagnosis as me?
- Why do you recommend these trials for me?
- What is the drug or drugs being tested? How do they work to target my cancer?
- What is the time commitment for me?
- How many people have participated / been enrolled?
- What evidence do we have that it works and how does it work?
- What are the safety concerns that have come up so far in the research?
- What do the appointments consist of (how long, frequency, tests included, etc.)?
- What will the cost be to me if I participate?
- Are there any patient support programs to offset financial burdens like travel, childcare or pet care?
- If the drug helps me, will I continue to have access to it after the trial?
- What type of side effects are typically experienced on a trial like this?
- What happens if I have a side effect?

- What happens if my tumors don't respond to the study drug?
- What if I change my mind about participating part way through the trial?
- Who do I call from the study team if I have a question or concern between appointments?
- Will the researchers be working with my oncologist?
- Where is the trial located?
- Do you offer discounted or free transportation to the trial site?
- Do you offer discounted or free lodging for trial appointments?
- Do you have any partnerships or offer any programs to help defray the costs of the clinical trials?
- Will I have to take days off from work to participate in the trial?
- Will I need someone to care for me?
- What do I need to do to get ready for the trial?
- What will I need to commit to once I am a part of the trial?
- Is there anything that I should not be doing during the trial?
- What does my diet look like during the trial?
- Can I exercise?
- Will I be able to continue my usual daily activities if I choose to participate in the trial?
- Will I be able to speak and connect with others that are a part of the trial as well?
- Will the researchers work with my doctor if I participate as a part of the trial? What is my responsibility? How will you coordinate with my doctor?
- When and how will I find out about the results of the trial?

TIPS AT A GLANCE

"Ask, ask, ask". We can't say it enough. Ask questions of both your health care provider and researchers conducting clinical trials

Be Proactive. Be knowledgeable about your health and cancer diagnosis. The more information that you know, the better it is when you are looking for clinical trials to participate in.

Do your research. Do your due diligence when it comes to finding clinical trials. Use the internet, telehealth, or physical visits to learn more about clinical trial opportunities.

WHAT THE LAW SAYS – KNOW YOUR RIGHTS

45 CFR 46 (The Common Rule)

These regulations exist for the protection of human subjects in research. The Common Rule (Subpart A) provides a set of protections for research subjects. Other subparts provide additional protections for certain populations in research.

Good Clinical Practice (GCP).

The Good Clinical Practice (GCP) course is designed to prepare research staff in the conduct of clinical trials with human participants.

Human Subject Protection (HSP)

This policy is for personnel involved in clinical research and clinical trials. It outlines trainings that are required federally before receiving funding for research.

Healthcare.gov

Keep in mind that you have a right to health insurance. According to healthcare.gov, healthcare law protects us by:

- Requiring insurance plans to cover people with pre-existing health conditions, without charging more
- Providing free preventive care
- Holds insurance companies accountable for rate increases
- Making it illegal for health insurance companies to cancel your health insurance just because you get sick
- Protecting your choice of doctors
- Protecting you from employer retaliation

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 our partners. Check out our Toolkit page to find additional resources available to you .