National Black Church Initiative
Clinical Trials Education Awareness and Participation Program

The Benefits and Risks of African American Participation in Clinical Trials

An Interactive Booklet of Learning

NBCI Theme:

NBCI is ushering in a new era concerning African American participation in clinical trials and we are turning the corner on The Tuskegee Experiment and all other medical abuses with all lessons learned for the future.

NBCI Benefits of Clinical Trials Interactive Booklet

Visitor Information

Please tell us about yourself so we can better serve your needs.

1. First Name: _____
2. Last Name: _____
3. Gender: _____
4. Age: _____
5. Height: _____
6. Email Address: _____
7. Phone Number: _____
8. Home Address: _____
9. City/State/Zip Code: _____
10. Have you ever participated in a clinical trial? (Yes/No) _____
11. Please tell us what brought you to the NBCI Benefits of Clinical Trials Interactive Booklet:
    a. Research Needs/Interests
    b. General Information
    c. Pharmaceutical Partnership/Interests
    d. Other: _____

12. What are your specific interests regarding clinical trials?
    a. Research
    b. Pharmaceutical Interests
    c. General
    d. Other: _____

13. Do you have any suggestions or ways to increase African American participation in clinical trials?
    a. Increase education
    b. More advocacy for the participation
    c. An added incentive for participation
    d. Other: _____

Table of Contents

Click on any title below to navigate to that topic in the interactive booklet.

- **Introduction**
- **NBCI Clinical Trials Education Awareness and Participation Program (CTEAPP)**
- **Learning Objectives**
- **Chapter 1: History of African Americans in Clinical Trials and Medical Mistrust**
    - **How Are African Americans Being Protected?**
- **Chapter 2: Belmont Report and Common Rule: Safeguards and Lessons Learned**
- **Chapter 3: Permission - Informed Consent**
- **Chapter 4: Understanding the Fears of African Americans Around Clinical Trials**
- **Chapter 5: What is a Clinical Trial? (Fundamentals of Clinical Trials)**
- **Chapter 6: The Benefits and Risks of African Americans in Clinical Trials**
- **Three-Question Clinical Trial Survey**
- **Appendices**
    - **Dedication**
    - **NBCI Clinical Trial Field Trip Information**
    - **Glossary**
    - **Recap: Benefits of Clinical Trials**
    - **Additional Resources**
    - **NBCI Clinical Trial References**
    - **Quiz Answer Key**

Introduction

The goal of the NBCI Interactive Clinical Trials Booklet is to improve the health outcomes of the African American community by making African Americans aware of the critical features, benefits, and challenges of clinical trials. This study guide provides scientific facts that may positively influence African Americans' feelings about their participation in clinical trials. Additionally, this study guide attempts to provide an understanding of the complex relationship African Americans have had historically with clinical trials. They will also gain a deep understanding of the risks and benefits of clinical trials.

There is an unmistaken truth that the White American medical community has systematically abused African Americans since the early 1800s. However, in 2021, the Black community must make a major choice as it stands at the crossroads of risk and benefits. The first choice is to continue ignoring the health issues that impact the Black community daily while remembering the abuse visited on them. The second choice is to fight back by remembering the lessons learned from these medical abuses and changing our approach and cultural attitude toward clinical trials for the best possible outcomes in health disparities.

The Tuskegee Experiment is the only reference many African Americans have of clinical trials. The tragedy of this historic incident has tainted the views of most African Americans on clinical trials. Because of the medical abuse experienced by the Tuskegee Experiment participants and their families, African Americans have little understanding of the enormous benefits provided by clinical trials. Many do not know what a trial is.

This interactive booklet will provide enormous insights into the benefits of clinical trials.

The National Black Church Initiative (NBCI) is a coalition of 150,000 African American and Latino churches comprised of 37 denominations and 27.7 million African Americans working to eliminate racial disparities in healthcare, technology, education, housing, and the environment. NBCI has created the Clinical Trials Education Awareness Participation Program (CTEAPP), a groundbreaking initiative housed under NBCI's

Health Emergency Declaration (HED). This booklet is the primary source material for this new interactive learning program.

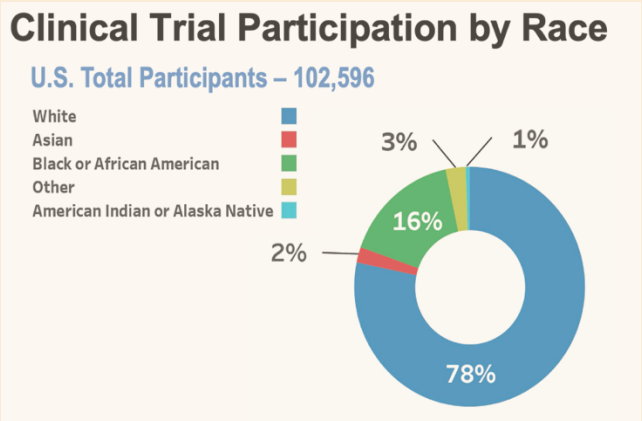
The theme for this booklet is that NBCI is ushering in a new era concerning African American participation in clinical trials and that we are turning the corner on the Tuskegee Experiment with all lessons learned for the future.

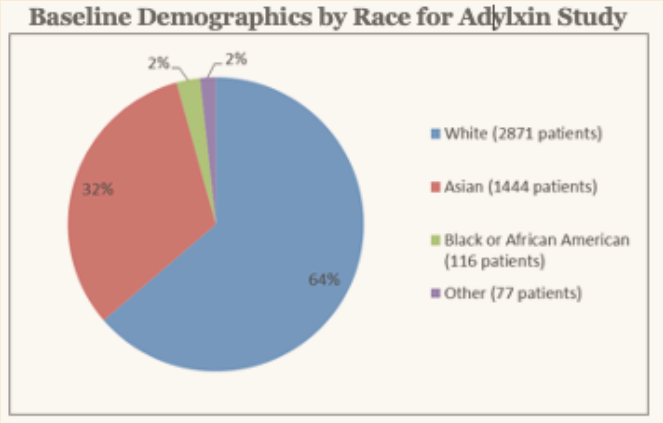
By refusing to participate in clinical trials, the African American community will give in to tragic diseases such as cancer, heart disease, diabetes, lupus, sickle cell disease, multiple myeloma, colon cancer, COVID-19, and other rare diseases that currently impact their health.

We can overcome these bad experiments, including the Tuskegee Experiment and other institutional racism that has occurred to African Americans since 1619, by listening to our medical experts like the **National Medical Association**, the **National Black Nurses Association**, Morehouse College of Medicine, Meharry Medical College, and Howard University School of Medicine regarding how to achieve better health outcomes for the entire African American community.

The rate at which African Americans participate in clinical trials compared to white Americans is disproportionately low. This booklet seeks to change that disparity.

The following graphs display the racial makeup of participants in all clinical trials and specifically for Adlyxin[i] (a drug that improves blood sugar control in adults with Type 2 diabetes). The graphs illustrate the crisis that we face because of the low participation rate of African Americans in clinical trials. This data illustrates the importance of this work.





This **interactive booklet** has been created for your benefit to help you understand how we can turn negative past experiences of African Americans with private and public health institutions a win for the African American community. This booklet will answer questions regarding clinical trials and give you reasons to consider participating.

Within this booklet, you will find the answers to the following questions:

- What is a clinical trial?
- How are clinical trials conducted?
- What safeguards have been put in place since the unethical experiments African Americans have experienced?
- What are the enormous benefits of a clinical trial?
- How would one participate in a clinical trial?
- Where would one go to find information about participating in a clinical trial?
- What is the role of my doctor in a clinical trial?
- What is the role of a hospital or pharmaceutical company in a clinical trial?
- How do clinical trial participation work to your advantage and that of the entire African American population?

We desire to achieve an exceptional level of **diversity** in clinical trials from the view of race, gender, and age.

African Americans can move beyond the traumatic Tuskegee experiment by recommending that all government agencies fund programs like Clinical Trials Education Awareness and Participation Program (CTEAPP) that focus on health outcomes for the African American community.

NBCI Clinical Trials Education Awareness and Participation Program (CTEAPP)

NBCI's big step toward advocacy for clinical trials in the African American community is the launch and facilitation of the NBCI Clinical Trials Education Awareness and Participation Program (CTEAPP). CTEAPP is a groundbreaking initiative, housed under NBCI's Health Emergency Declaration (HED). NBCI has always and will continue to hold itself to the highest ethical standards while advocating for clinical trial participation in our faith-based communities. The mission of the NBCI Clinical Trials Program is to increase the representation of African Americans in clinical trials. It is imperative that African Americans participate in clinical trials to assure that our population receives the benefits of cutting-edge drug therapies and modern medicine.

CTEAPP is a critical component of our work in eliminating health disparities. NBCI seeks to educate our member churches and their congregants of the value, benefits, protections, and promise clinical trials can offer to participants. In doing so, NBCI itself must be assured of the protections and safeguards of clinical trial protocols. Therefore, we have adopted a set of five core principles that will govern our decisions regarding involvement in clinical trials:

Principle 1

Education and awareness are key in getting Blacks to participate in clinical trials. The published literature is replete with studies that show that Black patients have a similar or higher willingness to participate in clinical trials than other patient populations. As such, NBCI believes that there must be thorough education covering the potential risks and benefits to patients in any clinical trial. We have found that an educational program that highlights the following can be done cost effectively and within the confines of a study's recruitment period:

- An overview of the disease in question and why it matters to Black people
- Previous participation rates of Blacks in prior studies within the therapeutic area, the class of drug, or the specific program within the sponsor
- Why Blacks should participate in clinical trials, generally
- Why Blacks should participate in clinical trials within this class (either generically or for a specific study)
- How patients are safeguarded
- Ongoing informed consent process
- Proper review and approval by a duly constituted and certified Institutional Review Board (IRB)
- Resource accessibility for answering all participants' questions in a culturally and linguistically appropriate manner

Principal 2

Culturally and linguistically appropriate literature, video, and web-based education modules are

critical to reach Black audiences concerning the available clinical trials. NBCI has regular success with the following approaches:

- Health Note
- Health Sermon
- Health-At-A-Glance

Principle 3

NBCI will advocate for patient participation in clinical trials with investigators who have been trained in Good Clinical Practice regulations, ethics, and cultural competence.

Principle 4

NBCI requires that there are adequate resources to launch and sustain a church/community-based awareness program regarding all aspects of the trial.

Principle 5

NBCI must have adequate resources for the completion of the clinical trial and for reporting the knowledge of benefits and risks for diverse populations participating in the trial.

After evaluating CTEAPP for five years, NBCI recognized the need to raise the bar again, which led us to developing NBCI's National Clinical Strategy Task Force (NCS):

- NCS is an independent group of health professional national experts in diverse disciplines
- NCS also provides guidance, clinical oversight, recommendations, scientific and technical support to NBCI
- They develop and/or approve the training and education for all healthcare providers, volunteers, Church Leadership, and Health Corp Members that have a role in any NBCI special programs/grants/contracts
- The task force will advocate for the being up to date in vaccinations available to Blacks and Latinos, especially the COVID-19 vaccine

In the beginning of 2022, NBCI will take its first comprehensive step of combining the principles set forth by the National Medical Association Project I.M.P.A.C.T. and CTEAPP with the full power of NBCI's 150,000 churches and 27.7 million members.

NBCI is launching the NBCI Online Clinical Trial Portal that will help direct our 27.7 million members to factual information on clinical trials and develop a path to increase African American participation in clinical trials in all disease states. The purpose of this portal is to not only increase numbers of African Americans participating in clinical trials to 20-25% from the current 16% (participation rate according to FDA (which could be as low as 3%), but also to collect African American health data and ensure diversity is present in clinical trials moving forward.

Learning Objectives

This booklet hopes to address **four major learning objectives:**

1. The history of African Americans participating in clinical trials

Learn how the history of African American participation in clinical trials has led to the protections that are now in place to ensure clinical trials are conducted safely and ethically.

2. What is a Clinical Trial

Discover how new drugs and treatments are tested in a clinical trial, what we can learn from a clinical trial, and why African Americans should participate in clinical trials.

3. How to Participate in a Clinical Trial

Gain an understanding of the process of enrolling in a clinical trial and how to determine if a clinical trial is for you.

4. The Risks, Benefits, and Complexities of Clinical Trials

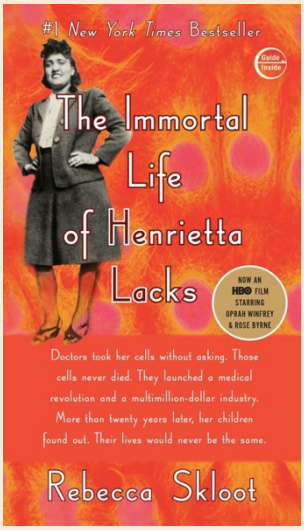
Find out how African Americans and the African American community can improve health outcomes by participating in clinical trials and understanding all clinical trials' risks and benefits.

Chapter 1
History of African Americans in Clinical Trials and Medical Mistrust

The history of African Americans in clinical trials is atrocious. It is a clear, cultural justification for African Americans and their fear of clinical trials. Their fear of clinical trials has led to a deep misunderstanding of the original intent and enormous benefits of clinical trials and how they can be conducted properly and ethically without racial or sexual bias.

Although our government has made strides in correcting medical abuse in clinical trials, it took them too long to acknowledge and address the unethical, illegal, and immoral experiments on African Americans and others.

Abuses on African Americans can be found as far back as 1619. In the 1800s, many enslaved African Americans were used in medical experimentation against their will. The founder of gynecology, Marion Sims, made many discoveries on enslaved women who were medically abused during his experiments.



New York Times 1619 Project

The 1619 Project is a long-form journalism project developed by Nikole Hannah-Jones. Writers from The New York Times and The New York Times Magazine "aim to reframe the country's history by placing the consequences of slavery and the contributions of Black Americans at the very center of the United States' national narrative."[1]

In the 1950s, Johns Hopkins University took cancerous cells from Henrietta Lacks, an African American woman, and used the cells for research without her knowledge or permission. Henrietta's family never received any financial compensation for her cells.

The most famous abuse case was the Tuskegee Experiment. In 1932, the Public Health Service (the forerunners to the Centers for Disease Control and prevention) withheld treatment for syphilis from African American males to study the disease. These men were lied to about the treatment received and were not asked for their permission before researchers experimented on them.

This trial lasted for 40 years, and the discovery of these abuses led to the creation of ethical guidelines that protect African American research participants in clinical trials today.

For the complete history of African Americans in clinical trials (1619-present), click here.

On May 16, 1997, in the East Room of the White House, President Bill Clinton issued a formal apology for the Tuskegee Study of Untreated Syphilis in the Negro Male, the "longest nontherapeutic experiment on human beings" in the history of medicine and public health. That study, conducted under auspices before at the U.S. Public Health Service (PHS) at Tuskegee Institute (now Tuskegee University) in Tuskegee, Alabama, was originally projected to last six months but spanned 40 years—from 1932 to 1972. The purpose of the study was to determine the effect of untreated syphilis in black men. The men in the study were never told that they had syphilis, a sexually transmitted disease. Instead, government doctors told the men they had "bad blood," a term commonly used to describe a wide range of unspecified maladies.

The study included 600 black men, 399 with syphilis, and a control group of 201 who did not have the disease. The men in the study were the sons and grandsons of slaves. Most had never been seen by a doctor. When announcements were made in churches and the cotton fields about a way to receive free medical care, the men showed up in droves, unaware of the high price over the next four decades. In the mid-1940s, when penicillin became the standard cure for syphilis, the Tuskegee subjects were not given the drug. Even as some men went blind and insane from advanced (tertiary) syphilis, the government doctors withheld treatment, remaining committed to observing their subjects through to the study's predetermined "endpoint"—autopsy. To ensure that the families would agree to this final procedure, the government offered them burial insurance—at most, $50—to cover the cost of a casket and grave.

The research project was finally stopped after Peter Buxtun, a former venereal disease investigator with the PHS, shared the truth about the study's unethical methods with a reporter from the Associated Press. On July 25, 1972, news accounts sparked a public outcry that ultimately brought the notorious experimentation to an end. Congressional hearings were

conducted, which led to federal legislation strengthening guidelines for the protection of human subjects in research. Fred Gray, a civil rights attorney, filed a class-action lawsuit on behalf of the men that resulted in a $10 million out-of-court settlement for the victims, their families, and their heirs. The study engendered among many African Americans a legacy of deep mistrust that hampered efforts to promote health and prevent disease in this population group. For more information on President Clinton's apology, please see the link below: https://www.c-span.org/video/?c4584112/bill-clinton-apologizes-tuskegee-experiment

Test Your Understanding

True or False: The participants of the Tuskegee Study gave their permission to participate in medical experiments for syphilis.

True or False: Henrietta Lacks gave permission for her cells to be used in research.

Resources

- ◊ This video depicts the sorrow that descendants from the Tuskegee Study still face today.
- ◊ This video provides a comprehensive overview of the Tuskegee Study.
- ◊ Miss Evers' Boys is a movie adaptation of true stories from the Tuskegee Study.

Chapter 2
Belmont Report and Common Rule – Safeguards and Lessons Learned

The Tuskegee Study of Untreated Syphilis occurred from 1932-1972. It took 40 years to stop one of the most inhumane human tragedies that ever happened. This study made it clear to the world the dire need for protection when using human subjects in scientific research.

The **National Research Act** was passed into law in 1974 to establish the National Commission for the Protection of Human Subjects Biomedical and Behavioral Research. This prestigious commission wrote and published the Belmont Report in 1979, which became a guiding document for performing clinical research studies safely and ethically.

The **Belmont Report** contains ethical human subjects' research principles, which require that clinical trials provide informed consent of study participants, maximize possible benefits, minimize possible harms to study participants, and benefit all people equally.[ii]

The **Belmont Report** details how research should be conducted on basic ethical principles:

- **Respect for Persons**
- **Beneficence**
- **Justice**

Respect for Persons

Research study teams must treat people as **autonomous**, respecting every individual's human right to make the best choices for themselves. The study team must not obstruct individual choice and provide individuals with all the necessary information to make the best, most informed decision about their health.

Researchers cannot withhold information about any study risks to convince someone to participate in the trial.

Some people have reduced autonomy because they cannot make the best choices for themselves, often due to age, illness, mental disability, or incompetence. Respect for persons also requires that there are protections for people with reduced autonomy.

Justice

All clinical trials have possible benefits and risks. It is important that there is fairness in the distribution of research benefits and those who will bear the burden of risk.

To maintain fairness, it is important that researchers do not take advantage of vulnerable populations, so they bear all the risks from participation. For example, researchers cannot bribe vulnerable poor communities to participate in research, while rich communities reap all the benefits of the trials without participating in the studies. Similarly, prisoners are a vulnerable population and should not be coerced into participating in a clinical trial because of their compromised position in society.

Beneficence

Beneficence in clinical trials means that researchers must do no harm and make it their highest priority to optimize the well-being of every study participant.

Optimized well-being includes maximizing the benefits that participants receive from the clinical trial and minimizing all possible harm from the clinical trial.

The **Federal Policy for the Protection of Human Subjects** (more commonly referred to as the **Common Rule**) specifically details how research must include **Institutional Review Boards (IRBs), Assurances of Compliance, and informed consent**.[iii]

No research study will ever intentionally harm a participant. However, there may be possible harms because of treatment, such as unwanted side effects from a drug. It is the responsibility of the research team to determine whether the risks of potential harm from treatment are worth the possible benefits of the treatment.

An IRB must review all clinical trials before the research can start. The IRB will continue to review the data from the study as the research continues. An IRB has the authority to approve, deny, or request modifications to all research activities that fall under federal regulations.

All research institutions must provide **assurances of compliance** with federal regulations with continuous, supporting documentation to prove that their research activities are in line with the IRB-approved research protocols. In other words, researchers must prove they are performing ethical research by providing access to the data collected from all their studies.

Informed consent is the process of educating potential study participants on all the risks and benefits of a clinical trial, the requirements for participation, and documenting participants' consent to participate in the research once they have demonstrated understanding of the risks and benefits of participation. We will talk more about the informed consent process in the next chapter.

Safeguards and Lessons Learned

Even though there are now numerous and sufficient protections in place, we are still left with an important decision. Do we as African Americans refuse to participate in clinical trials, or can we use the history of this injustice to African Americans participate in clinical trials to realize their enormous benefits in dealing with health disparities and racial equity in health care?

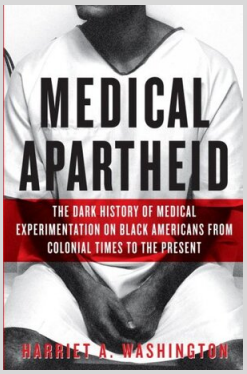
Test Your Understanding

- **True or False:** I should be worried about participating in a clinical trial because of what happened in the Tuskegee Experiment.

- **Which of the following ensure my safety in a clinical trial?**
  A. Federal laws that require my informed consent to participate in clinical trials
  B. Institutional Review Boards that monitor the safety of clinical trials
  C. Both A and B

Resources

- This video provides a brief overview of the Belmont Report.
- In 1997, President Bill Clinton delivered an apology to the survivors of Tuskegee. Watch the apology here.
- For more information about the protection of participants in clinical trials, please visit https://researchincludesme.com/trust
- Medical Apartheid: The Dark History of Medical Experimentation Black Americans from Colonial Times to the Present is a 2007 book by Harriet A. Washington.



Chapter 3
Permission – Informed Consent

Informed consent means that you must give your permission to researchers to participate in any medical experiment or clinical trial, especially when it involves personal biological data as well as taking any sort of specimen from your body.

The Tuskegee Experiment broke the principle of informed consent. The participants were never asked for their informed consent (permission) to participate. No risk-benefit assessment was ever given to the participants to make an informed decision about participation, and the researchers lied about the intent of the research. The experiment broke all the ethical rules in conducting a real scientific clinical.

We will spend a little time on informed consent by exploring what it is, what it is not, how it should be conducted, and how to ensure that the study is being conducted ethically by providing critical guidelines to ensure each critical protection is being implemented.

The following must be completed to help protect clinical trial participants' rights:

- Researchers must provide and follow a study plan called a "protocol" that outlines what will happen in the study.
- Participants must give permission by signing a document called the **Informed Consent Form (ICF).** If a participant cannot provide informed consent themselves, the consent must be provided by a Legally Authorized Representative (LAR).
- Participants must be allowed to withdraw from the trial at any time.

The three main components of the informed consent process include:

- Providing **sufficient information** to prospective subjects,
- Demonstrating **comprehension** of information by the prospective subjects, and
- Documenting the informed consent process, specifically recording the subject's **voluntary agreement** to participate in the study.[iv]

During the informational part of the **Informed Consent** process, the study team must explain the following:

- The purpose of the study and who is eligible.
- What to expect as a participant, and how many participants are expected?
- How will the study work?
- A description of any foreseeable risks.
- A description of any benefits that may be reasonably expected from the research.
- If you did not participate in the study, the alternative options for treatment might be advantageous to the subject.
- A description of the procedures to be followed and whether any of them are experimental.
- The schedules of tests and procedures, study medications, and dosages.
- The number of study visits required.
- What personal information will be shared as part of the study?
- Who to contact for more information about the study and who to contact if the subject is injured during the study?
- A statement of whether clinically relevant research results will be shared with the subjects.
- A comment on the voluntariness of the study and any consequences of a subject's decision to withdraw from the study.

Test Your Understanding

- **True or False:** I cannot drop out of the study if I provide my informed consent to participate in a clinical trial.

- **What information should you receive before providing your informed consent to participate in a clinical trial?**
  A. The benefits and risks of participating in the clinical trial
  B. What the trial does and does not include
  C. What tests and procedures you will need to undergo during the clinical trial
  D. All the above

Resources

◊ An example of an informed consent document and all of the elements it must contain can be found here.
◊ Click here for a video summarizing informed consent.

Chapter 4
Understanding the Fears of African Americans Around Clinical Trials

African Americans have fears and concerns about not participating in clinical trials. However, when African Americans are educated about the entire truth about clinical trials and their enormous benefits, many African Americans' fears can be reduced. It is a unique and challenging position to guide the African American community to trust the overall medical establishment, public health apparatus, and pharmaceutical industries; however, it is possible.

African Americans understand the importance of all these entities, but many maintain historic fears take away from their ability to effectively understand the big benefits of clinical trials. This is a classic example of risk-benefit analysis. This booklet will provide the overall guidance of helping African Americans alleviate their fears of clinical trials and the pharmaceutical industry.

Test Your Understanding

- **True or False:** African Americans fear clinical trials due to their mistrust of the public health system and the lack of culturally sensitive education.

Resources

◊ This video explains the experience of racism by African American health professionals. Citation for each video

◊ This video describes the importance of African Americans participating in clinical trials despite the frustrating history of abuse.

◊ Find out how research partners can increase the trust of the African American community through safe clinical trials via https://researchincludesme.com/trust

Chapter 5
What is a Clinical Trial?

Throughout this booklet, you have learned about the history of African Americans in medical experiments and why this history has led to a deep distrust of medical institutions by the African American community. You have also learned how we can learn from this devastating history and what safeguards have been put in place to ensure that these medical institutions will no longer exploit African Americans during clinical trials.

Now we will go deeper into clinical trials themselves and how exactly the African American community stands to benefit from them.

What is a clinical trial?

- A clinical trial will tell us **whether a medicine will work**—the only way to find that out is to conduct an experiment.
- A clinical trial is also called a *clinical research study*. It is designed to investigate or study **potential new medicines and treatments.**

What questions can a clinical trial answer?

- Whether or not a Does the medicine works?
- Whether or not a Does the medicine works on African Americans?
- Is the study medication safe?
- Does it work better than medicines that are already available?
- How does it affect certain diseases or conditions?
- What are the side effects and reactions?
- Are there any differences in how the medicine acts due to gender, age, race, ethnicity, or other factors?

Who conducts clinical trials?

- Clinical trials are conducted by doctors, nurses, and other healthcare providers, and their goal is to find new and better ways to treat conditions and diseases.

- Every clinical study is led by a principal investigator - often a physician. Clinical studies can occur in many locations, including hospitals, universities, doctors' offices, and the community.

Test Your Understanding

- **What is another name for a clinical trial?**
  A. Clinical research study
  B. Survey

- **Why do we need clinical trials?**
  A. To figure out whether a medicine works
  B. To make pharmaceutical companies rich

- **Who is qualified to conduct a clinical trial?**
  A. Anyone
  B. Doctors, nurses, and other healthcare providers

Who ensures clinical trials are safe?

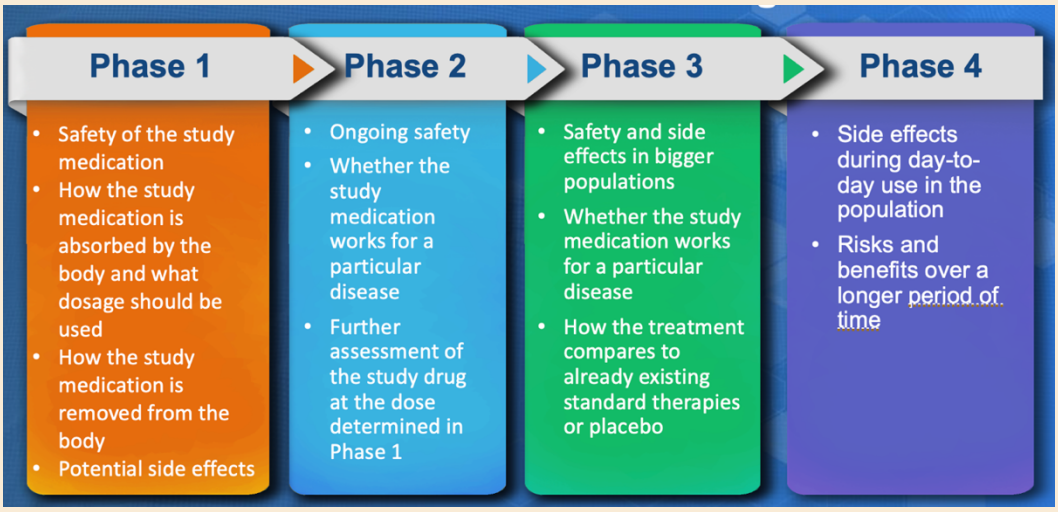
- Before a clinical trial can begin, the study is usually approved by a group of experts and a patient representative called an Institutional Review Board or “IRB.”

- An IRB is an independent committee of members who are physicians, scientists, other health professionals, and often members of the community.
- The purpose of the IRB is to make sure that the study is safe, that the risks are as low as possible and that the rights and safety of the volunteers in the trials are protected.
- The IRB's role is to review and approve or deny the proposed trial initially. Once approved, the IRB monitors the clinical trial to ensure they are following all protocols.

There are 5 Major Types of Clinical Trials:

- **Treatment trials** focus on testing new or existing medications, devices, interventions, or treatments.
- **Prevention** trials focus on vaccines, medications, and even lifestyle changes that help prevent diseases.
- **Diagnostic** trials focus on finding better procedures or tests to diagnose or monitor a specific disease or condition.
- **Screening** trials focus on finding or improving a test that can find a disease or condition earlier.
- **Quality-of-life** *(or supportive care)* trials focus on chronic diseases and look for ways to improve patients' mental and social impact.

A Clinical Trial is Made up of 4 Phases:



Each Phase of a Clinical Trial has a Different Study Population and Purpose:

Test Your Understanding

- **Which clinical trial phase has 20-100 people in it?**
  A. Phase 1
  B. Phase 2
  C. Phase 3
  D. Phase 4

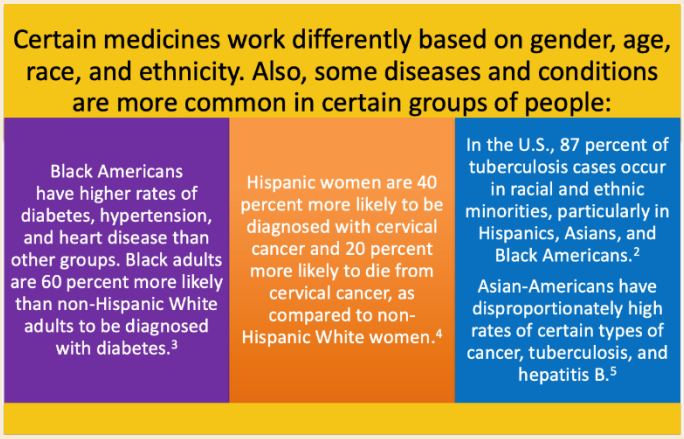
- **What clinical trial phase can African Americans participate in?**
  A. Phase 1
  B. Phase 2
  C. Phase 3
  D. Phase 4
  E. All of the above

- **Is it important for African Americans to participate in clinical trials?**
  A. Yes
  B. No, it does not make a difference if African Americans participate

Why Should African Americans Participate in Clinical Trials?

- **The number one reason why we should participate is that it can benefit African Americans.**
- We need to find out whether the proposed medicine will work on our bodies.

- Participation adds to the overall data to prove whether a medicine will be good for African Americans.
- Doctors and health experts agree that **all medical treatments need to be studied to ensure safety and effectiveness in diverse populations**. This includes African Americans, Latinos, Asians, and other minority groups. Both men, women, and children should participate in clinical trials. Minority populations often have more health challenges, so that's why minorities need to be included in studies that search for better treatments and cures.
- **Patients participating in clinical trials for new medicines and treatments are mainly White** — 80 to 90 percent in some cases. People of color, including Black/African Americans, Hispanics/Latinos, and other racial or ethnic minorities, are **lower**. [7]
- According to a 2014 study, among the 10,000 cancer clinical trials funded by the National Cancer Institute, fewer than 2 percent focused on a racial or ethnic minority.[7]



- **African Americans are more likely to suffer from respiratory conditions, like asthma, than White Americans**. Yet as of 2015, only 1.9 percent of studies of respiratory diseases included African American participants.[v]

Before you complete the next quiz, please visit https://researchincludesme.com/process for more information

Test Your Understanding

- **Which ethnic groups have more tuberculosis cases?**
  A. Whites
  B. Hispanics, Asians, and Black Americans

- **Which disease are African Americans more likely to be diagnosed with, compared to non-Hispanic whites?**
  A. Surgical cancer
  B. Diabetes

What happens after the clinical trial?

- Depending on the clinical trial's results, a healthcare authority, such as the Food and Drug Administration (FDA), may **approve** the medicine or treatment for public use.
- Medicines and treatments are approved when they are generally proven to be safe and effective. The benefits of using the medication or treatment outweigh the known risks for the intended population.

- Overall, only 14 percent of medicines and treatments get approved after a clinical trial.[9]
- Once approved, a doctor must prescribe these medicines and treatments. This means you may or may not have access to them after the trial is over.

A Day in the Life of a Clinical Trial Participant:

There are many steps in enrolling in and participating in a clinical trial, so there is no single day that is the same. The steps typically required for clinical trial participation and their associated demands are:[vi]

- **Pre-Screening**: research study staff will have an initial conversation with you over the phone or at the healthcare facility to determine whether you meet the high-level requirements of their clinical trial.
- **Informed Consent**: the research team will educate you about all aspects of the study to make an informed decision about whether the benefits of participation outweigh the risks. Your voluntary decision to participate will be documented via a signed informed consent document.
- **Screening**: the research team will ensure that you meet all the specified eligibility criteria, which vary from study to study. They may verify your eligibility via lab tests, physical exams, and questionnaires.
- **Enrollment and Randomization**: once your eligibility for the study has been confirmed, you will be assigned to one of the treatment groups, such as the control group, new treatment group, or placebo group.
- **Scheduled Study Visits**: The study protocol will determine how often you need to come into the facility for treatments or procedures. The frequency can range from daily visits to monthly visits to annual visits. The protocol will also dictate what will occur at each study visit to monitor how your body reacts to the treatment. This may be measured by lab tests, physical exams, or questionnaires.

Important Considerations to Determine Before Starting a Clinical Trial:

- Will you be able to fulfill the requirements of the trial in terms of the procedures and medications required?
- Will there-be a stipend or other compensation?—some clinical trials will compensate you for your time, but some will not. You must determine whether the payment (or lack of) is sufficient for your participation in the study.
- How often will you need to interact with the clinical staff or investigators?
- How much time will it take to participate (per week, per month)?
- Does the study provide childcare?
- Does the study provide transportation?
- Will your family be supportive?

- Will your spouse be supportive?
- Will participation interfere with your ability to work?

Test Your Understanding

- **Should you ask your minister or pastor to participate in a clinical trial?**
  A. Yes
  B. No

- **Should you research the nature of the study before you provide informed consent to be treated?**
  A. Yes
  B. No

Resources

◊ This video provides an overview of clinical trials.

◊ Find out how research partners can increase the trust of the African American community through safe clinical trials via https://researchincludesme.com/trust

Chapter 6:
The Benefits and Risks of African Americans in Clinical Trials

The healthcare field has come a long way in creating new medications and treatments for many human diseases. All this progress is due primarily to the work of clinical trials.

Every person should benefit from the billions of dollars poured into scientific research studies every year, including African Americans. African Americans must participate in clinical trials to obtain all the benefits that clinical trials provide us.

Many benefits come from participating in clinical trials[vii]:

1. Volunteers who participate in clinical trials help increase medical knowledge and save or improve lives.
2. Participation allows volunteers to take an active part in their health.
3. Volunteers will be able to increase their knowledge about their health conditions
4. Volunteers may be able to benefit from new or improved treatments before they are available to the public.
5. Volunteers get to meet with experts in the field of their current disease or condition.
6. Volunteers have a team of health professionals who are experts in their specific disease or condition. This team closely monitors volunteers and is available to give advice, answer questions and provide support as needed.
7. Treatment provided on the clinical trial may be more effective than the standard approach or have fewer side effects than the treatments currently available.
8. Many of the medications and procedures currently being used have not been fully studied in African Americans. Minorities who participate in clinical trials are helping doctors and healthcare providers understand how certain medications, vaccines, and procedures work in their population.
9. Researchers may provide volunteers with medical care and more frequent health check-ups as part of their treatment.
10. Treatment may come at no cost to the volunteer. Be sure to discuss this with the clinical research team and understand what is and is not covered.
11. Volunteers may be able to get information about support groups and resources.
12. If someone has been unable to treat their disease with approved medications, a clinical trial may be their only chance at a cure.

Other Potential Benefits[1]

- **Regular and careful attention from some of the best doctors.** The research team that conducts clinical trials usually include doctors and scientists from around the United

[11] https://www.breastcancer.org/treatment/clinical_trials/benefits_risks

States and the world, all of whom will work with you. Because of this close monitoring, any side affects you might have noticed and dealt with immediately.

- **Contributing to research that may save lives in the future.**
- **The feeling that you're taking an active role in your care.** Deciding to participate in a clinical trial can make some people feel as if they have more control over their situation, leading to a more positive outlook and better quality of life.

Your participation in a clinical trial can help the overall health of your community by making new drugs and treatments available faster and safer. You may have the chance to help others get better treatment for their health problems in the future. Your voluntary participation in a clinical trial helps leave a legacy and help future generations.

Potential Risks that Come with Being Part of a Clinical Trial:

- The new treatment may be uncomfortable or cause serious side effects.
- The new treatment may not work, or it may not be better than existing treatments—the only way you find out is to conduct clinical trials**. We do not know whether it works on African Americans until we participate.**
- There are always two groups, the control group and the placebo (no effect) group. You may not be part of the study group that gets the study medicine or treatment. Instead, you may be part of a "control group," which means you may get an existing standard treatment or a "placebo" (a drug that does not contain any medicine).

Given that there are both potential benefits and risks to participating in a clinical trial, you must complete a careful, comprehensive **risk-benefit analysis** of the clinical trial before providing your informed consent to participate

When weighing the risks of participation, one must consider both the chance of the harm happening (the probability) and the severity (or magnitude) of the possible damage that may result from participation. Potential harms include psychological harm, physical harm (like pain or injury), legal harm, social harm, and economic harm.

The consideration of risk should also include possible effects beyond the individual, for example, any impact on the individual's family.

Similarly, weighing the possible benefits of participation requires understanding possible uses and the magnitude of possible benefits. Possible benefits include psychological benefits, improved physical health, improved social health, and improved economic status.

Possible benefits from a study may also spread to the family. For example, an individual with improved health may be better able to take care of their family. In addition, benefits from a study

may also impact society, such as the data from the study proving that a particular drug works on African Americans will help the entire African American community and not just the clinical trial participant.

Other Potential Risks[2]

- **Not being able to choose which treatment you get.** In randomized trials, you are randomly assigned to get specific treatment. In some trials, you may be a placebo (sugar pill). In a randomized, double-blinded trial, neither you nor your doctors know which treatment you're getting (but if the information is needed, it's available).
- **The new treatment may not work for you**, even if it benefits other people in the trial. It also may turn out that the new treatment isn't as effective as what's currently available.
- **More severe side effects than current treatments.** This is more likely to happen with Phase I or Phase II trials. See Pages 20-21 for more information on clinical trial phases.
- **Your insurance company may not cover all the costs.** Be sure to talk to both your insurance company and one of the clinical trial coordinators, so you know exactly what you'll have to pay for BEFORE you agree to be part of a clinical trial.
- **More frequent testing and doctor visits.** Because you'll be closely monitored, you may have to undergo testing more often than you would if you weren't in the trial. This could mean more travel and time in the doctor's office or hospital for you.

Test Your Understanding

- **Which of the following are the benefits of clinical trials?**
  A. Medical Care and Increased check-ups
  B. Receiving more effective treatment than standard treatments
  C. Both A and B

- **Which of these groups are part of a clinical trial?**
  A. Control group
  B. Placebo group
  C. A & B

- **Will the drugs used in a clinical trial have side effects on African Americans?**
  A. No
  B. Maybe

[2] https://www.breastcancer.org/treatment/clinical_trials/benefits_risks

Resources

This video shows an African American woman whose participation in a clinical trial helped cure her sickle cell anemia.

This video depicts how researchers at the NIH helped an African American woman find treatment for lupus.

Three-Question Survey

NBCI will administer a comprehensive survey that you may take later.

- Are you interested in participating in a clinical trial because of this booklet? (Yes/No)
- Are you interested in becoming a certified trainer of trainers of clinical trials for the African American community? (Yes/No) (If yes, please click here to give us your information.)
- Are you willing to participate in a clinical trial field trip organized by the NBCI and participating research agencies? (Include the list of teaching hospitals) (Yes/No)
- Are you interested in participating in the comprehensive survey? (Yes/No)

NBCI Clinical Trial Field Trip

To further educate yourself on clinical trials, the NBCI is offering an opportunity for you to participate in a Clinical Trial Field Trip. This field trip will give you the chance to join a 3-4-hour experience at a teaching hospital. This will show you what it takes to participate in a clinical trial.

The field trip will start with a detailed educational session that will cover all the aspects concerning a clinical trial and the cultural, social, and personal results of being a part of a clinical trial.

You will then tour the clinical facilities and meet with research center staff principals and co-investigators of clinical trials.

You will have the opportunity to ask scientific and medical experts for their professional and cultural opinion on the risk-benefit analysis of clinical trials, the importance of increasing African American participation in clinical trials, and the safeguards to protect African Americans from being abused by the medical establishment.

The field trip will be purely informational, and there is no requirement that you commit to participating in a clinical trial at any time.

If you are interested in participating in this field trip, please contact NBCI.

Dedication

This booklet is dedicated to all African Americans who have suffered abuse and loss of loved ones because of institutional racism, unethical medical experiments, and tragic health disparities.

Glossary

Click Term for Definition

Adverse Reaction
Advocacy and Support Groups
Approved Drugs
Arm
Baseline
Bias
Blind
Clinical
Clinical Endpoint
Clinical Investigator
Clinical Trial
Cohort
Community-based Clinical Trial (CBCT)
Compassionate Use
Complementary and Alternative Therapy
Confidentiality Regarding Trial Participants
Contraindication
Control
Control Group
Controlled Trials
Data Safety and Monitoring Board (DSMB)
Diagnostic Trials
Dose-ranging Study
Double-blind Study
Double-masked Study
Drug-drug Interaction
DSMB
Efficacy
Eligibility Criteria
Empirical
Endpoint
Epidemiology
Exclusion/Inclusion Criteria
Expanded Access
Experimental Drug
Institutional Review Board (IRB)
Intent to Treat
Intervention Name
Interventions
Investigational New Drug
Investigator
Masked
Natural History Study
New Drug Application (NDA)
Off-label Use
Open-label Trial
Orphan Drugs
Peer Review
Pharmacokinetics
Phase I Trials
Phase II Trials
Phase III Trials
Phase IV Trials
Placebo
Placebo Controlled Study
Placebo Effect
Preclinical
Prevention Trials
Protocol
Quality of Life Trials (or Supportive Care Trials)
Randomization
Randomized Trial
Risk-benefit Ratio
Screening Trials
Side Effects
Single-blind Study
Single-masked Study
Sponsor
Standard Treatment
Standards of Care
Statistical Significance
Study Endpoint
Study Type
Subject
Toxicity
Treatment IND
Treatment Trials Volunteer (Subject)

Additional Resources

Harriet Washington, author and medical ethicist, wrote the first comprehensive social history of research on African Americans. She is the author of the well-cited book, ***Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present.*** Her research provides a pathway to ensuring we learn from our traumatic history as we work to increase African American participation in clinical trials.

Check out her interview here.

Everyone must be included in clinical research,
especially African Americans.
For more information, please visit
https://researchincludesme.com

Linda Villarosa's New York Times Article, "How False Beliefs in Physical Racial Difference Still Live in Medicine Today"

New York Times 1619 Project

The 1619 Project is a long-form journalism project developed by Nikole Hannah-Jones. Writers from The New York Times and The New York Times Magazine "aim to reframe the country's history by placing the consequences of slavery and the contributions of Black Americans at the very center of the United States' national narrative."[1]

- Janssen Pharmaceutical Clinical Trial Resource: Research Includes Me Website
- Charles R. Drew University Clinical Research Resource
- Morehouse School of Medicine Clinical Research Center
- Meharry Medical College Clinical & Translational Research Center
- Howard University Hospital Research and Clinical Trials
- National Medical Association Project I.M.P.A.C.T.
- American Medical Association Research Resources
- National Hispanic Medical Association
- ClinicalTrials.Gov
- Centers for Disease Control and Prevention Cancer Clinical Trials
- National Institutes of Health Clinical Trials Page
- U.S. Department of Health and Human Services Research Participation Page
- FDA Clinical Trials Resources Page
- Johns Hopkins Medicine Research Page

NBCI Clinical Trial References

- NBCI Clinical Trial Video Reference (*the below videos are embedded throughout the interactive booklet. Click on each link to revisit the content*):
  - President Bill Clinton's Apology to the Survivors of the Tuskegee Experiment
  - Descendants of Syphilis Study Still Fight Stigma
  - Voices of the Tuskegee Study
  - The Belmont Report (Part One: Basic Ethical Principles)
  - What is Informed Consent // Informed Consent Training
  - Black health care professionals experience racism
  - Sara Horton, MD - The Importance of African American Participation in Clinical Trials
  - What is a Clinical Trial?
  - Women in Clinical Trials: Juliana's Story
  - Nicole Jackson-Taylor / Lupus (SLE)
- NBCI Clinical Trials Education Awareness Participation Program (CTEAPP) Booklet
- http://impact.nmanet.org/downloads/power_booklet.pdf
- https://www.breastcancer.org/treatment/clinical_trials/benefits_risks

Quiz Answer Key

Test Your Understanding

True or False: The participants of the Tuskegee Study gave their permission to participate in medical experiments for syphilis.

True or False: Henrietta Lacks gave permission for her cells to be used in research.

Test Your Understanding

- **True or False:** I should be worried about participating in a clinical trial because of what happened in the Tuskegee Experiment.

- **Which of the following ensure my safety in a clinical trial?**
  A. Federal laws that require my informed consent to participate in clinical trials
  B. Institutional Review Boards that monitor the safety of clinical trials
  C. Both A and B

Test Your Understanding

- **True or False:** I cannot drop out of the study if I provide my informed consent to participate in a clinical trial.

- **What information should you receive before providing your informed consent to participate in a clinical trial?**
  A. The benefits and risks of participating in the clinical trial
  B. What the trial does and does not include
  C. What tests and procedures you will need to undergo during the clinical trial
  D. All the above

Test Your Understanding

- **True or False:** African Americans fear clinical trials due to their mistrust of the public health system and the lack of culturally sensitive education.

Test Your Understanding

- **What is another name for a clinical trial?**
  A. Clinical research study
  B. Survey

- **Why do we need clinical trials?**
  A. To figure out whether a medicine works
  B. To make pharmaceutical companies rich

- **Who is qualified to conduct a clinical trial?**
  A. Anyone
  B. Doctors, nurses, and other healthcare providers

Test Your Understanding

- **Which clinical trial phase has 20-100 people in it?**
  A. Phase 1
  B. Phase 2
  C. Phase 3
  D. Phase 4

- **What clinical trial phase can African Americans participate in?**
  A. Phase 1
  B. Phase 2
  C. Phase 3
  D. Phase 4
  E. All of the above

- **Is it important for African Americans to participate in clinical trials?**
  A. Yes
  B. No, it does not make a difference if African Americans participate

Test Your Understanding

- **Which ethnic groups have more tuberculosis cases?**
  A. Whites
  B. Hispanics, Asians, and Black Americans

- **Which disease are African Americans more likely to be diagnosed with, compared to non-Hispanic whites?**

A. Surgical cancer
B. Diabetes

Test Your Understanding

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- **Will the drugs used in a clinical trial have side effects on African Americans?**
  A. No
  B. Maybe

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[i] https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-adlyxin
[ii] Belmont Report and its Principles. Florida State University.
[iii] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
[iv] Hicks, Lorna. Duke University. Informed Consent.
[v] NHIS Asthma Prevalence Data. CDC Report https://www.cdc.gov/asthma/nhis/2015/table4-1.htm; 2015
[vi] https://prastudies.com/participating-in-clinical-research-studies/
[vii] https://www.nia.nih.gov/health/clinical-trials-benefits-risks-and-safety