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*“Bringing people together to serve humanity”*

## **National Black Church Initiative National Clinical Trial Strategic Plan (NCTSP)**

The National Black Church Initiative (NBCI) is ushering in a new era of broadened engagement of Black and Latino communities in clinical trials. Particularly given the unethical and illegal behaviors involved with the Tuskegee Experiment and the intentional absence or lack of critical information for the involved subjects by governmental officials, the NBCI comprehensive approach utilizes important lessons learned from this historic medical abuse and ALL others experienced within Black and Latino communities for generating robust communication, demonstration, and education strategies toward substantially improving clinical trial participation.

Historical research and precedents have consistently suggested that African Americans have endured medical malpractices and injustices due to discriminatory behaviors (Public Broadcast Services, 2021). The documentary provides insights into how such behaviors have adversely influenced the overall quality of health and well-being. NBCI, too, recognizes that African Americans are not the only group who has suffered similar abuse – the Latino community has also been victimized in medical experiments that are now deemed unethical. This stems from institutional racism on the government, private companies, institutions, and individuals.

Notwithstanding, today, the Black community must make a significant 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. 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 and positively impact the health of Blacks and Latinos in this country in a systematic way, utilizing the government and the pharmaceutical industry as our partners.

To that end, in the 400-year history of the African American community, NBCI is launching an innovative, comprehensive, and science-based clinical strategic plan to promote clinical trials among African Americans. The NBCI National Clinical Strategic Plan touts a central goal of increasing the number of African Americans participating in clinical trials across all disease states. The mission of the NBCI clinical trials program is to increase the representation of

African Americans in clinical trials. African Americans' participation in clinical trials helps ensure that our population receives the benefits of cutting-edge drug therapies and modern medicine. The strategic plan addresses the African Americans' issues and clinical trials by increasing their understanding, education, and participation and thereby consists of three main objectives:

1. To launch a broad-based educational program to our 150,000 churches and online platforms, including web and social media;
2. To harness the deep wealth of African Americans and Latinos' medical knowledge through experts in the field and partners from the National Medical Association, the National Hispanic Medical Association, the National Black Nurses Association, and the National Association of Hispanic Nurses; and
3. To collect critical data on every aspect of African Americans' medical history and knowledge, utilizing its 27.7 million church members in the Black community, in addition to the Latino faith-based communities.

To accomplish the implementation of this approach, NBCI offers faith-based, out-of-the-box, cutting-edge solutions to stubborn economic and social issues. Our solutions are backed by statistical analysis, science-based strategies and techniques, and methods that work.

## **CONTEXTUAL FRAMEWORK**

The uniqueness of this NBCI comprehensive plan is that the leadership is not coming from the federal government, a pharmaceutical company, a predominantly white institution, or any other minority medical group or organization. The NBCI comprehensive plan comes directly from a faith-based organization that maintains a moral ethos and authority necessary to move the needle for achieving better health outcomes for its Black and Latino members. The NBCI comprehensive plan is not a top-down plan for institutions in which the African American community is told what is good for them. Instead, the NBCI comprehensive plan is one that is collaborative where we will involve community members in the implementation process. NBCI recognizes the power of the Black church for this health imperative as well as the powerful benefits of clinical trials and the impact on health outcomes in helping to eradicate health disparities. Given our dispositional and positional stance, this is a huge game-changer.

Twenty-five years ago, NBCI launched the Health Emergency Declaration (HED). HED serves to underscore that African Americans are in a health emergency due to the persisting illnesses within our community. According to health statistical data published in 2020, African Americans continue to have the highest mortality rate for all cancers combined compared with other racial and ethnic groups. One of the leading causes of death for African Americans also includes heart disease and complications from obesity<sup>1</sup>. Fast forward to today, our health status has not improved since the launch of [NBCI's HED](#). After eleven years of HED, NBCI's clinical staff concluded that we must raise the bar in African American health outcomes and begin to not only emphasize clinical trials participation but have faith-based communities advocate for them.

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<sup>1</sup> <https://www.americanprogress.org/issues/race/reports/2020/05/07/484742/health-disparities-race-ethnicity/>

NBCI realizes the need to lead and strengthen a care delivery structure that is sustainable and brings dramatic changes in African American and Latino participation in clinical trials in order to lead to positive health outcomes in these communities.

NBCI, as comprised of 27.7 million African American members plus the millions of Latino faith-based members as the foundation of our plan, constitute 109 million individuals and cover one-third of the country. NBCI has provided congregations with accurate health information, culturally sensitive literature, pre-screening tests, and encouragement of participation in data collection and protocols that emerged from the COVID-19 pandemic.

Moreover, NBCI's big step toward advocacy for clinical trials in the African American community is launching and facilitating the NBCI Clinical Trials Education, Awareness, and Participation Program (CTEAPP) which was launched 8 years ago. CTEAPP is a groundbreaking initiative that is housed under NBCI's Health Emergency Declaration (HED). NBCI always has and will continue to hold itself to the highest ethical standards while advocating clinical trials participation in our faith-based communities.

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 promises clinical trials can offer participants. In doing so, NBCI itself must be assured of the protections and the 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:

## **GUIDING PRINCIPLES**

- **Principle 1**

Education and awareness are vital in getting Blacks to participate in clinical trials. The published literature is replete with studies showing that Black patients are more willing to participate in clinical trials than other patient populations. As such, NBCI believes in advocating the potential 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:

- 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.
- The importance of Blacks participating in clinical trials, generally.
- The importance of Blacks participating in clinical trials within this class (either generically or for a specific study).
- Patients being safeguarded during clinical trials.
- The ongoing process of informed consent.
- The proper review and approval by a duly constituted and certified Institutional Review Board.
- The accessibility of resources for answering all participants' questions in a culturally and linguistically appropriate manner.

- **Principle 2**  
Culturally and linguistically appropriate literature, video, and web-based education modules are critical to reaching Black audiences concerning the trial. NBCI has regular success with the following approaches:
  - Health Note;
  - Health Sermon; and
  - 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 adequate resources to launch and sustain a church/community-based awareness program regarding all aspects of the trial.
- **Principle 5**  
NBCI must be 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 develop NBCI's National Clinical Strategic 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 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 COVID-19 vaccine and the importance of getting vaccinated.

## **STRATEGIC APPROACHES**

At the beginning of 2022, NBCI will take its first comprehensive step of combining the principles set forth by the National Medical Association [Project IMPACT](#), CTEAPP, and our National Clinical Strategic Plan with the full power of NBCI's 150,000 churches and 27.7 million members plus the millions of Latino faith-based members.

NBCI's vision is complex to develop yet simple in its application. Our goal is to provide critical clinical trial education to 27.7 million African Americans through 150,000 faith-based communities and offer that same level of education to our Latino brothers and sisters through their faith-based organizations.

NBCI's National Clinical Strategic Plan includes the below strategies, moving into a new level of impact from CTEAPP:

- Appoint a dedicated Black Church Clinical Czar for the Black Church and a Deputy Clinical Czar for faith-based communities;
- Expand the NBCI National Clinical Strategic Task Force to serve on the NBCI Scientific Cabinet as the Black Church Clinical Czar Cabinet to include seven (7) members;
- Include the President of the National Medical Association and the President of the National Hispanic Medical Association, ex officio, non-voting members;
- Develop an advisory board to the NBCI National Clinical Strategic Taskforce, consisting of the four traditional medical schools: Charles R. Drew University, Morehouse School of Medicine, Meharry Medical College, and Howard University Hospital. We also plan to include other medical schools with large percentages of Latino students.
- Meld scientific and medical communities with African American churches and African American and Latino physicians to collaborate with a diverse group committed to bridging health equity insofar as a principal and co-principals investigator program.
  - NBCI will convene to Black, Latino, and other minority researchers on becoming principal investigators and how we can support them in that effort. We will create a nationwide data bank of African American and Latino researchers who have potential to serve as principal or co-principal investigators of clinical trials. These researchers will have to be members of the National Medical Association and the National Hispanic Medical Association. We will ask them what is needed from the industry perspective to keep them interested. To do so, the following will be done:
    - i. We will identify a total of 1,300-1,500 African Americans and Latino researchers who have an equivalent degree of a Ph.D. or an M.D.
    - ii. We will create an evaluation program for the identified researchers to verify their interest and qualifications.
    - iii. We will create an educational session to provide broad points on how to become a principal or co-principal investigator.
- Recruit over 300 African American and Latino primary care physicians to form a \$35MM African American and Latino Primary Care Clinical Program:
  - Turn these clinicians into co-investigators; and
  - Utilize their expertise to increase African American and Latino patient recruitment in clinical trials.

- Expand the HED Model of a broad-based program consisting of congregational volunteers and our Health Corps volunteers.
  - We will use 150,000 African American congregational volunteers, one volunteer for every church whose chief responsibility is to provide critical health information on clinical trials and other health information to church members and the community and to work with the senior pastor and its health ministry.
  - We will expand this volunteer base.
- Broaden the primary role of the 150,000 health corps volunteers is to collect a census of all African American healthcare professionals/providers who are part of our congregations to develop a directory of individuals who can help our congregation navigate the complexities of the current healthcare delivery system.
- Utilize NBCI's online interactive booklet to teach the basic understanding of clinical trials. The goal of this booklet is to provide basic information on clinical trials and collect participants' thoughts, suggestions, and attitudes regarding clinical trials. This data will be shared with our pharmaceutical partners. More information about the booklet: [https://blackchurchclinicaltrials.com/booklet\\_gen.html](https://blackchurchclinicaltrials.com/booklet_gen.html)
- Implement a Comprehensive Communication Plan, located in office of the President of NBCI which works closely with the Office of the Black Church Clinical Czar.
- Incorporate the NBCI Literature Review Committee.
- Implement a Comprehensive Patient Assistance Prescription Drug Program, a \$50MM Mental Health Initiative Program, and a \$25MM Oral Health Program.
- Establish of 25,000 Volunteer Clinical Outreach Educators.
- Develop of the NBCI Clinical Data Program.
- Develop of the NBCI Clinical Publishing and Peer Review Committee.
- Recruit 25-50 Clinical Program Outreach Workers for each of NBCI's Five Faith Commands.
- Utilize NBCI's train the trainer program to create 50,000 clinical trial educators in our churches to teach a basic curriculum on the risks and benefits of clinical trials to our members for the very first time.
  - The program projects to develop over 5 to 10 million clinical trial Black and Latino participants over the next five years we can compile into a directory based on age, weight, geography, medical conditions, and interest.

- Create a six-part educational video series on the risks and benefits of clinical trials notwithstanding the medical abuses on African Americans and Latinos that have taken place to date.
- Produce a one-page newspaper featuring all things clinical trials called Clinical News.

## **MOVING FORWARD**

- NBCI has created the most innovative educational approach called the NBCI Clinical Trial Field Trip. This approach allows our members to engage in a mock clinical trial before they enroll in a real one to give them a feel for what is required to be part of a clinical trial. They will get to meet principal and co-principal investigators, social workers, and other clinicians who look like them as motivation to participate in clinical trials. NBCI plans to work with every major teaching hospital to create a dynamic clinical trial educational apparatus for African Americans and Latinos.
- NBCI is engaged in an all-out, nationwide initiative to motivate more African Americans to participate in clinical trials in at least 50 cities where African Americans reside based on zip code and congressional districts.
- In 2021, NBCI launched the NBCI Clinical Trial Pavilion which is a live and virtual illustration of facts and principles of clinical trials utilizing tents in church site so that any churchgoer can take a tour of what it is like to be part of a clinical trial and the risks and benefits clinical trials.
- NBCI have developed over ten effective advocacy strategies to be employed at the launch of this plan in 2022 in which African Americans and Latinos are encouraged participate in clinical trials along with our pharmaceutical and university partners.
- NBCI plans to impact 5,000,000 – 10,000,000 African Americans and Latinos in the next 5 years through data collection.
- NBCI created over 25 health priorities including common and rare disease states that affect African Americans and Latinos, in collaboration with the Black and Latino medical and scientific communities and our pharmaceutical partners. These health priorities will come out of the Office of the Black Church Clinical Czar, once the appointment has been confirmed, supported by the National Clinical Strategic Task Force (his Scientific and Medical Cabinet). These health priorities will be released in 2022. NBCI will consult with our pharmaceuticals partners extensively in developing these health priorities in the next five years.

## **CONCLUDING REMARKS**

NBCI created over 25 health priorities including common and rare diseases that have been identified in the highest number of states where African Americans and Latinos reside. These health priorities have been developed in collaboration with the Black and Latino medical and



scientific communities and our pharmaceutical partners. These health priorities will be administered by the Office of the Black Church Clinical Czar which is fully supported by the National Clinical Strategic Task Force and the Scientific and Medical Cabinet. These health priorities will also be released in 2022. NBCI will consult with our pharmaceuticals partners extensively in developing these health priorities in the next five years. Alongside the development of health priorities and the strategies and goals listed above, the NCTSP prioritizes the collection, management, and protection of critical medical data as we implement the NCTSP. NBCI projects to impact 5,000,000 – 10,000,000 African Americans and Latinos in the next 5 years.

### **ABOUT NBCI**

The National Black Church Initiative (NBCI) is a coalition of 150,000 African American and Latino Churches with 27.7 million members working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. The NBCI's mission is to provide critical wellness information to its members and the public.

### **CITED REFERENCE**

Public Service Broadcast. (2021). With a history of abuse in American medicine, Black patients struggle for equal access. Retrieved from <https://www.pbs.org/newshour/show/with-a-history-of-abuse-in-american-medicine-black-patients-struggle-for-equal-access>