



# RECOMMENDATIONS TO THE FOOD AND DRUG ADMINISTRATION

## FROM THE NATIONAL BLACK CHURCH INITIATIVE

NATIONAL BLACK CHURCH INITIATIVE
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*"Bringing people together to serve humanity"*

July 5, 2017

Honorable Dr. Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

**Through:**

Church of God in Christ
African Methodist Episcopal Church
African Methodist Episcopal Zion Church
Christian Methodist Episcopal Church
Full Gospel Baptist Church Fellowship International
National Baptist Convention, USA, Inc.
National Baptist Convention of America, Inc.
Progressive National Baptist Convention, Inc.
Pentecostal Assemblies of the World, Inc.
The Union of Black Episcopalians
National Council of Churches
International Council of Community Churches
Unity Fellowship Church Movement
Mount Calvary Holy Churches of America
Greater Mount Calvary Holy Church
American Baptist Churches
Berean Missionary Baptist Church
The Potter's House

Dear Honorable Dr.Gottlieb,

Congratulations on your appointment as the Commissioner of the FDA. We are extremely pleased that you are willing to meet with us and consider recommendations of increasing African Americans in clinical trials. Let us pledge our entire support of 34,000 Black Churches behind your agenda during your tenure. We are committed to helping to produce safe and effective drugs, nutritious and disease-free food, and innovation in the process of these two industries that are now

under your regulatory control. We are committed to making your tenure the most successful in the history of the FDA.

Five years ago, the National Black Church Initiative Board and Denominational Leadership decided we needed to be a part of the coalition to improve our nation's health after the passing of the Affordable Care Act. We had a brainstorming session three years ago about what our approach would be in this endeavor. One of the first steps that we decided on was to tackle the regulatory issues surrounding the ACA to ensure on a regulatory level that African Americans were being treated fairly and equally, which we have a moral and constitutional right to and to create an environment and processes towards increasing African American access to care. We have worked with numerous policy groups around Washington, including PhRMA to make sure that the regulations that were being written were balanced and driven solely by hard science and not economics.

We also worked with pharmaceutical companies to create a comprehensive initiative to improve the participatory level of African Americans in clinical trials and bioresearch. We first sought to work with pharmaceuticals on the issue of the Affordable Care Act only to be rebuffed by the industry. So, we gathered again and offered a major push towards clinical trials using the full weight and might of our 34,000 churches and 15.7 million congregants. We wrote the Honorable Francis Collins a letter inquiring about the nature of what the government was doing around the *NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research*. We were then sent a cursory letter of no substance and felt that again we were being rebuffed by our own government inquiring about a regulation that they themselves created.

You can imagine the deep frustration that 34,000 clergy felt at that time. We also wrote a letter to President Trump about extorting the value and the benefits of clinical trials and research. At the same time we wrote to PhRMA on February 4th endorsing their bold initiative of explaining to the American public the value of research and drug intervention. Again, we are sad to report that we never got a written response from PhRMA and felt rebuffed by getting a call from a low-aid who felt as though they were not taking this initiative as serious as we had presented it. Recently we wrote PhRMA again, telling them about our deep disappointment. Considering the pushback, we have reached out to the Food and Drug Administration and we were hoping to work with you through regulations to compel the pharmaceutical industry to address the issues we set forth in the letter to the Honorable Francis Collins.

We look forward to future discussions with you and speaking in depth on how we can finally get this done after 25 years of deep frustration from 15.7 million African Americans who are citizens of this great country.

We initially sent a letter to the Honorable Francis Collins but never received a letter from him, though we did receive a letter from the Office of Minority Health which was insulting to 15.7 million African Americans who are trying to improve their health. They believe that a simple letter is sufficient from a community who struggles under the weight of health disparities. We do not.

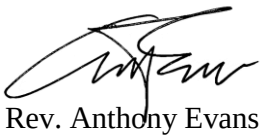
Through its innovative *Clinical Trial Education Awareness Participation Program (CTEAPP*), NBCI could be an answer to the industry's perplexing problem.

"Despite advances in literacy and education as well as major improvements in communication…in this period of unprecedented acceleration in the pace of scientific and technological advances, and the educational focus on Science, Technology, Engineering and Mathematics (STEM)…there will still be a great gap between medical (protective) knowledge and the public acceptance of it." - *Bailus Walker PhD, MPH*

The healthcare industry has a major problem, but neither the pharmaceutical industry nor the other major players in healthcare are not going to do anything about this problem until they are compelled by strong regulatory from the FDA. We are willing to work in a regulatory position or a substantive partnership to achieve the goals of these recommendations.

Let us make it very clear that the National Black Church Initiative is not going away. We will prosecute this issue across the proper channels and through the public if necessary. We should set up a meeting with the Chair of the oversight appropriation committee to drive home this point so we can refer to the meeting in this letter.

Sincerely,



Rev. Anthony Evans
President

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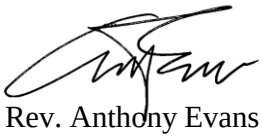

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Honorable Patty Murray
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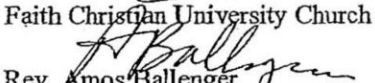
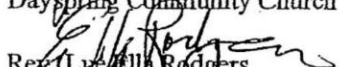
Rev. Edwin L. Jones, Ph.D.
Faith Christian University Church

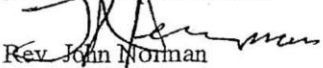
Rev. Dr. Cynthia T. Turner
Dayspring Community Church



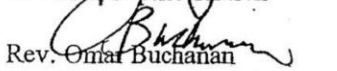
Rev. Amos Ballenger
Mt. Zion Baptist Church



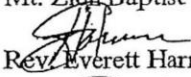
Rev. Lucretia Rodgers
Mt. Zion Baptist Church



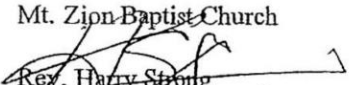
Rev. John Norman
Mt. Zion Baptist Church



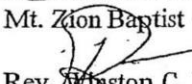
Rev. Omar Buchanan
Mt. Zion Baptist Church



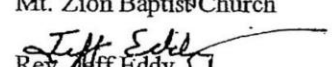
Rev. Everett Harris
Mt. Zion Baptist Church



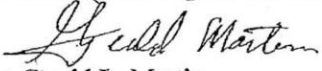
Rev. Harry Strong
Mt. Zion Baptist Church



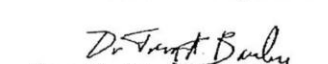
Rev. Winston C. Ridley, Jr.
The Greater First Baptist Church



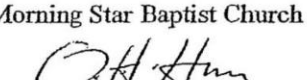
Rev. Jeff Eddy
National Lay leader



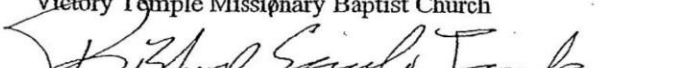
Rev. Gerald L. Martin
Morning Star Baptist Church



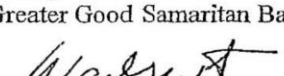
Rev. Dr. Tom A. Bailey
Victory Temple Missionary Baptist Church



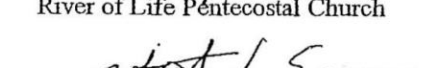
Bishop Ode H. Hines
Greater Good Samaritan Baptist Church



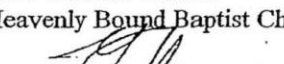
Bishop Scottie F Jackson
River of Life Pentecostal Church



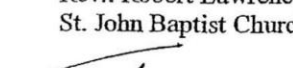
Rev. William Calvert
Heavenly Bound Baptist Church



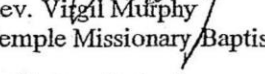
Rev.. Robert Lawrence Earls, Sr.
St. John Baptist Church



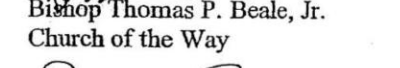
Rev. Virgil Murphy
Temple Missionary Baptist Church



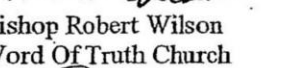
Bishop Thomas P. Beale, Jr.
Church of the Way



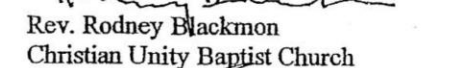
Bishop Robert Wilson
Word Of Truth Church



Rev. Rodney Blackmon
Christian Unity Baptist Church



Rev. Alex L. Lambert
St. Paul Baptist Church



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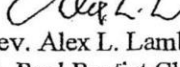
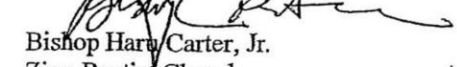
Zion Baptist Church



Dr. A.H. Mark Dean
All For Jesus Scripture Art



Dr. Anthony Mays
Breakthrough Bible College

Rev Marcus Tillman
First Baptist Church

Elder Willie R. Hunt
New Community Church of God In Christ

Rev. Aubrey C. Lewis, Pastor
St. Luke Baptist Church

Rev. Dr. Rudolph White, Pastor
New Southern Rock Baptist Church

Rev. Queen Shepherd, Pastor
Powerhouse Ministry International

Rev. Darrell Lewis, Pastor
Family Fellowship Church

Rev. Elijah Sutton, Pastor
Guildfield Baptist Church

Rev. Lloyd Fennell, Assistant Pastor
Guildfield Baptist Church

Rev. Dr. Cleophus W. Atkins, Pastor
Restoration Christian Fellowship Church

Rev. Arafa Speaks
New African Church

Rev. Anthony White, Youth Minister
New Southern Rock Baptist Church

Rev. Edward Cole
Associate Minister

Rev. Milton R. Baker
Christian Faith Center Ministry, Inc

Rev. Ruth Sutton
Guildfield Baptist Church

Rev. Ronald Patterson
Guildfield Baptist Church

Rev. Lanier C. Twyman, Sr.
St. Stephens Baptist Church

Rev. Betty Crawford
Guildfield Baptist Church

Rev. Alan Horton
Guildfield Baptist Church

Rev. Antonio Lowery
Guildfield Baptist Church

Guildfield Baptist Church

Rev. Tommy Lee Gilbert
Guildfield Baptist Church

Rev. Denise Mills
Guildfield Baptist Church

Rev. Teresa Blanks
Guildfield Baptist Church

Rev. Richard Winston
Guildfield Baptist Church

Rev. Matthew Robinson
Guildfield Baptist Church

Rev. Eugene W. Wilson, Sr.
Wilson Ministries

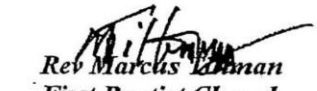
Rev. Walter A. Pettiford, Sr.
New Beginning Ministries

Rev. Wilbert & Dolores Gray
PG Sheriff Office Chaplin

Rev. Larry Phillip McCray
Mt. Calvary Missionary Baptist

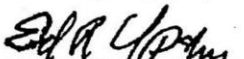
Rev. Jerome Williams
Williams Ministries

*Dr. A.H. Mark Dean*
*All For Jesus Scripture Art*

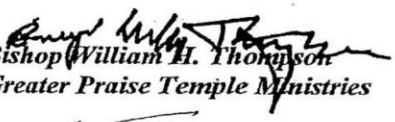


*Rev Marcus Lamman*
*First Baptist Church*

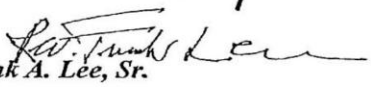
*Rev. L.D. Williams*
*Divine Prosperity Baptist Church*



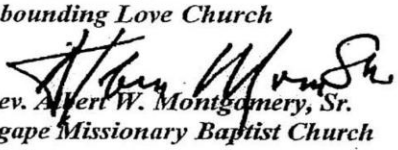
*Dr. Edrick R. Upshur*
*New Generation Baptist Bible Church*



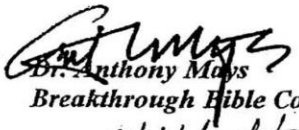
*Bishop William H. Thompson*
*Greater Praise Temple Ministries*



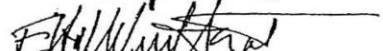
*Frank A. Lee, Sr.*
*Abounding Love Church*



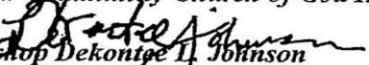
*Rev. Albert W. Montgomery, Sr.*
*Agape Missionary Baptist Church*



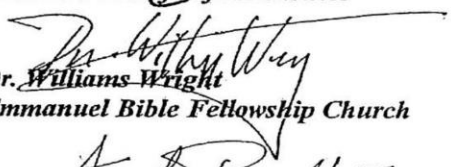
*Dr. Anthony Mays*
*Breakthrough Bible College*



*Elder Willie R. Hunt*
*New Community Church of God In Christ*

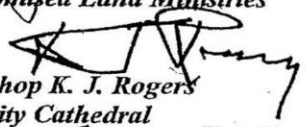


*Bishop Dekontee L. Johnson*
*Blessed Word of Life Ministries*



*Dr. Williams Wright*
*Emmanuel Bible Fellowship Church*

*Bishop Joshua Paul Logan*
*Promised Land Ministries*



*Bishop K. J. Rogers*
*Unity Cathedral*

*Bishop M. Preston Stancil*
*Providence Harvest Church*

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*"Bringing people together to serve humanity"*

February 4, 2017

Honorable Donald J. Trump
President of the United States
1600 Pennsylvania Ave NW
Washington, DC 20500

Dear President Trump,

The National Black Church Initiative is writing to congratulate you on your announcements concerning Health Care and particularly the concerns centered around drug pricing. We wanted you to know that we share some of the same concerns because of our vast membership, but we also want to share with you a different perspective that we are sure will add to the richness of your own perspective.

The National Black Church Initiative (NBCI) is a coalition of 34,000 African American and Latino churches comprised of 15 denominations and 15.7 million African Americans, working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to provide critical wellness information to all of its members, congregants, churches and the public. Our methodology is utilizing faith and sound health science.

The National Black Church Initiative has worked with a number of pharma companies around the issues of clinical trials over the part 20 years and we know first hand that the present pricings of the vast majority of Pharmaceutical companies seems just to us. Largely because of the enormous amount of money that is reinvested on research and development. We have met many of the researchers over the years who have such an unshakeable and unwavering commitment. Their perseverance gives us hope that the health disparity gap will someday soon be closed.

This is why whatever the formula going forward, it must include real science and research. It is our understanding that the reason why they are able to invest this large amount of resources is because of their tier pricing mechanism. We are sure that you are aware that the pharmaceutical industry offers assistance to low income families who cannot afford their prescriptions. Our members have benefitted from this and we are engaged in stepping up to qualify more of our members to take advantage of this important program.

We are still concerned that there are some companies that have taken advantage of the public when it comes down to pricing. We wanted to let you know that we have organized our members to be aware of

that in working with some national organizations like AARP, to identify those companies that are taking advantage of those who are poor and desperate. We will not allow it and we hope to work with you and your office on these issues.

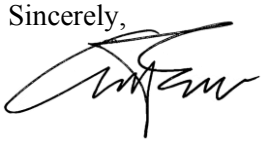
It should also be stated in this letter that we are not a part of the pharma marketing program to educate the public on what strides they are making in research and development. We just wanted to give you a first hand account on the issues that the Black Church and its members are involved in moving forward and we strongly believe that if there is a shift in funding that this can have dramatic impact on the ability of certain pharma companies to invest into innovative, new and exciting therapies around the issues of heart disease, cancer, lupus, multiple myeloma and diabetes just to mention a few of the major diseases that are having an adverse affect on the  African American program in the area of morbidity and mortality.

What we are asking is that when you go forth in developing your policy in this area that you would take into consideration the issues we have raised above. Issues surrounding research and development, pricing and the importance of doing this in a way that does not undermine nor cause large pharmaceutical and biomedical companies to cut back in the R and D area.

We look forward to working with you and your administration on these important questions but we also wanted to let you know that we are polishing off a letter to the National Institute of Health concerning their lack of engagement with the African American community around the issues of African Americans and clinical trials. We will carbon copy you on that important letter and your Health and Human Services designated Secretary concerning those issues we hope to address in the near future.

Thank you and we want you to know that you have our support on this issue.

Sincerely,



The Right Most Rev. Anthony Evans
President

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# Acknowledgements

The National Black Church Initiative would like to thank the following extraordinary physicians for their willing and passionate contributions in generating scientific and in-depth recommendations for the FDA:

Dr. James A. McCoy, MD, FACS — Morehouse School of Medicine, Professor

Dr. Owen Garrick, MD — Bridge Clinical Research, President & Chief Operating Officer

Dr. Evelyn L. Lewis, MD, MA, FAAFP, DABDA — Evelyn Lewis International, President & Founder

The National Black Church Initiative would also like to thank Alycia Hernandez and Selina Jones' contributions for without which this document would not be possible.

# Purpose

The purpose of this proposal is to compel the Food and Drug Administration to utilize its regulatory authority over the National Institute of Health and pharmaceutical and bioceutical industries to provide a substantive plan and framework to increase the numbers of African Americans in clinical trials. The piecemeal approach by both the government and industry concerning this effort is shameful in its application, given the history of clinical trials and African Americans.

This proposal is a concerted effort on behalf of 34,000 Black Churches and key African American health clinicians and institutions to move the ball forward concerning clinical trials in this country since African Americans first reached the shores of this great democracy. Never has a statistical comprehensive study on African American health issues been conducted in 400 years. In addition, African Americans have not been successfully incorporated into the advancement of medicine and research technologies as legitimate and natural born citizens of this country.

African Americans deserve every right under the Constitution and as Children of God to life, liberty and the pursuit of happiness, and they should not have ever been placed into this situation where their life expectancy has been fraught with no access to medical care, proper medicine, proper nutrition, physical exercise, and the many choices that exist in terms of drug therapy for all Americans.

The Black Church says clearly in this document that enough is enough. We demand change starting in 2017 and over the next 5 years introducing one of the most robust and sophisticated health clinical trial initiative that has ever been attempted by any organization to incorporate and motivate minority citizens for improving their quality of life which the Constitution guarantees in this country.

We find ourselves in this philosophical health predicament largely because of the choices and the mindsets of a few concerning the Tuskegee experiment, the Henrietta Lacks case, and other attempts by scientists and physicians who believe that African Americans were inferior and therefore they had the moral right to experiment on their person which in essence turned out to be a 400-year curse on the health of African Americans.

The National Black Church Initiative (NBCI) is a coalition of 34,000 African American and Latino Churches working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to provide critical wellness information to all its members, congregants, Churches and the public. Our methodology is utilizing faith and sound health science.

NBCI's purpose is to partner with major organizations and officials whose main mission is to reduce racial disparities in the variety of areas cited above. NBCI offers faith-based, out-of-the-box and cutting edge solutions to stubborn economic and social issues. NBCI's programs are governed by credible statistical analysis, science based strategies and techniques, and methods that work.

NBCI has generated a workable model that, according to respected members of the healthcare industry, may be a promising channel to increase African American participation rate in clinical trials from the dismal 1 percent to a possible 10-20 percent if fully funded and incorporated into the health system. The model referred to is the National Black Church Initiative Clinical Trials Education Awareness and Participation Program (See CTEAPP section on page 4)

The goals and objectives of this proposal are as follows:

# THE NATIONAL BLACK CHURCH INITIATIVE
# GOALS AND OBJECTIVES
# IN LIGHT OF
# RECOMMENDATIONS TO THE
# FOOD AND DRUG ADMINISTRATION

**Goals**

1) To create a 5-year framework for increasing African American participation in clinical trials to 10-20 percent while incorporating the existing efforts and approaches by both government and pharma.

2) To utilize the FDA and its authority to enforce the premise of the framework within the pharmaceutical and healthcare industry.

3) To institutionalize this 10-20 percent goal into the life of this country's healthcare system.

**Objectives**

1) To utilize this document and other documents within pharma and government as a powerful starting point to reach goals 1, 2 and 3.

2) To utilize African American healthcare experts and institutions as the main drivers to implement this bold principle as a tenant to American healthcare systems.

3) To fully fund this extraordinary and bold approach over the next 5 years for the purpose of institutionalization and sustainability with the whole objective of increasing access to care.

# Introduction

Since the National Institutes of Health Revitalization Act of 1993 mandating the inclusion of women and minorities in clinical research, research literature has well documented persistent barriers to clinical trial participation facing these groups. The lack of diverse representation in clinical trials reduces the generalizability of new therapies that can improve health outcomes for minorities, who often bear a disproportionate burden of disease. The need for increasing minority participation in clinical trials is particularly salient in diseases like HIV/AIDS, diabetes, heart disease, obesity, cancer, autism, and lupus, where the majority of those affected are women and minorities.

To inform the development of interventions addressing barriers to general clinical trial participation for racial/ethnic minorities, a full understanding of best practices and promising strategies of past clinical trial education and recruitment initiatives is critical. Since little published work on participation barriers for clinical trials among minorities exists, the purpose of this report is to summarize and distill approaches routinely used in clinical trial education and recruitment initiatives of minority or disadvantaged groups in other disease areas. Efforts targeting clinical trial participation barriers among minority populations can draw insight from the promising strategies outlined in this report. The key themes presented come from a review of 24 select studies identified from a larger literature review. Peer-reviewed published studies from the last ten years targeting participation, recruitment, education, or awareness barriers among racial/ethnic or disadvantaged populations in the United States were included in the initial review. Of the 32 studies that fit the inclusion criteria, 24 were identified as having shared themes and are highlighted in this report.

Twenty-five years ago, the National Black Church Initiative developed and implemented the faith medicine concept. For many years, various conceptualizations of this clinical trial model have been derived from the National Black Church Initiative Health Emergency Declaration (HED) Health Model *(The National Black Church Initiative, 1996)* and utilized by numerous institutions. NBCI is in a unique position in this realm considering that all the demographic groups within our faith communities, if fully funded, can substantially move the ball forward. We have amended their general concept to include relevant elements of this model for this grant. We have also developed the Clinical Trial Education Awareness and Participation Program (CTEAPP) (*The National Black Church Initiative, 2016)* which is now being implemented as a promising clinical trial model and has shown great progress in attracting more African Americans to clinical trials.

Despite this extensive background, many clinicians were unaware of the tremendous effort led by Reverend Anthony Evans. NBCI has pulled together some strong suggestions from many in the clinical community on how to effectively implement and incorporate the recommendations found in this document. One can imagine, that if both the clinician community and NBCI's *Clinical Trials Education Awareness and Participation Programs (CTEAPP)* approaches are applied, what results this partnership can provide.

# NATIONAL BLACK CHURCH INITIATIVE CLINICAL TRIALS EDUCATION AWARENESS AND PARTICIPATION PROGRAM (CTEAPP)

NBCI's mission is to provide critical wellness information to all its members, congregants, churches and the public. NBCI's methodology utilizes faith and sound health science.

The NBCI Clinical Trials Education Awareness Participation Program (CTEAPP) is another 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 clinical trials 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 for participants. In doing so, NBCI itself must be assured of the protections and the appropriateness of clinical trial protocols. Therefore, we have adopted a set of core principles that will govern our decisions regarding involvement in clinical trials:

## Principle 1

Education and awareness are key in getting African Americans to participate in clinical trials. The published literature is replete with studies that show the Black patients have similar to higher willingness to participate in clinical trials. As such, NBCI believes that there must be thorough education covering the potential risks and the 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 its relevance to African Americans
- Previous participation rates of African Americans in prior studies within the therapeutic area, the class of drug, or the specific program within the sponsor
- Why African Americans should participate in clinical trials, generally
- Why African Americans 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
- Resource accessibility 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 reach African American audiences concerning the trial. 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 adequate resources to launch and sustain a church/community based awareness program regarding all aspects of the trial.

## Principle 5

NBCI requires 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.

# NBCI/CTEAPP Partnership with Bridge Clinical Research

Bridge Clinical Research (BCR) provides recruitment strategies and solutions to address the unique challenges surrounding minority participation in clinical trials. BCR works directly with major pharmaceutical and biotech companies to provide a technology, service, and support solutions aimed at reducing clinical development timeframes and enhancing minority patient recruitment efforts. BCR provides the necessary training and certification to medical practitioners interested in participating in clinical trial research, and assists clinical research investigators and urban hospital and clinic systems with minority patient recruitment efforts. As part of our services, BCR communicates with investigators, sponsors, and clinical research personnel, resolves medical issues, provides medical input for regulatory documents, supports business development activities, and provides Serious Adverse Event (SAE) consultation. BCR clinical trials personnel maintain professional knowledge and skills, particularly in the areas of FDA/ICH guidelines and regulations. BCR also has core strengths in clinical operations, creative, marketing, messaging, and minority health to provide an end-to-end solution for recruitment of minority subjects into clinical trials.

## NBCI/CTEAPP Lecture Series

The National Black Church Initiative is initiating a ten-part nationwide lecture series that will highlight noted African American clinicians and to further NBCI Clinical Trials Education Awareness and Participation Program (CTEAPP). The lecture series is another important building block of creating an expansive clinical trials initiative to increase minority participation. The goal of NBCI/ CETEAPP is to assure 15 percent or more black participation in clinical trials.

*There are three goals of the lecture series*

1. Highlight the extraordinary partnership forged between Bridge Clinical and the National Black Church Initiative — combining science and faith.

2. Identify expert African American Clinicians who can serve as primary investigators in major clinical trial programs.

3. Build a list of 100,000 key African American stakeholders who are supportive of African American participation in clinical trials along with NBCI/HED Volunteer Health Corp.

We hope to galvanize and identify 2,500 key community stakeholders in each city of NBCI Churches who are in the health space and understand the historic importance of this movement by NBCI's Clinical Trials Education Awareness Participation Program. We plan to turn these individuals into clinical trial advocates. We will provide them with the training, education, and information they need. They will serve as our frontline advocates when we need to identify potential participants in a clinical trial. We plan to provide online training through a new website called www.blackchurchandclinicaltrials.com. This online educational portal for African American church members and their families will allow them to search for clinical trials of their choosing.

# Meeting of African American Clinical Trial Clinicians June 19th, 2017

The National Black Church Initiative, NBCI President Rev. Anthony Evans, and Dr. James McCoy of the Surgical Department of Morehouse School of Medicine convened an executive panel of African American experts on clinical trials to generate the following recommendations that would accompany Rev. Evans and two other representatives in meeting with the commissioner of the Food and Drug Administration in the next couple of months.

These African American clinicians are experts in their field in terms of clinical trials; they have served in distinguished positions throughout the healthcare industry and are well qualified to assist the Black Church in advocating for a new paradigm to create an inclusive environment where African Americans will feel freely to participate in clinical trials at the rate of thirty percent.

We called an all-day session of African American clinicians on June 19th whereby we generated the following recommendations and acceptable scientific language. This meeting included:

1) Rev. Anthony Evans, President of the National Black Church Initiative

2) Dr. Owen Garrick, President of Bridge Clinical

3) Dr. Evelyn Lewis, President of Evelyn Lewis International

4) Dr. James McCoy, Morehouse School of Medicine Surgical Department

# RECOMMENDATIONS TO THE FOOD AND DRUG ADMINISTRATION

Expanding and ensuring patient access to clinical trials is essential to improving and advancing high-quality, evidence-based care. Without clinical trials that accrue patients in a timely manner, the rapid diffusion of clinical advances into practice is hampered and interventions of questionable benefit may remain part of clinical practice without adequate evidence supporting their use. For example, in 1999, evidence for the lack of benefit of bone marrow transplantation for breast cancer was found, after several years of delay because of poor trial accrual (Bennett et al., 2001). While the trial was ongoing, many women received this treatment outside of the clinical trial, enduring the severe adverse effects of this therapy, including treatment related deaths, without evidence to guide the treatment decision.

Only 2 to 3 percent of adults with cancer participate in oncology clinical trials. Furthermore, elderly individuals, people who are members of racial and ethnic minority groups, low-income individuals, and people who reside in rural areas remain underrepresented in clinical trials (EDICT, 2008). This minimal participation has been attributed to several factors, including stringent eligibility criteria, physicians' perspectives and awareness of clinical trials (as described in the preceding sections), inadequate and uncertain insurance coverage, patient attitudes about and knowledge of clinical trials (as further delineated below), and complex social and institutional barriers delaying the implementation of clinical trials.

***Cited Scholarly Article:***

Bennett, C. L., J. R. Adams, K. S. Knox, A. M. Kelahan, S. M. Silver, and J. S. Bailes. 2001. *Clinical trials: Are they a good buy? Journal of Clinical Oncology* 19(23):4330–4339.

EDICT. 2008. *The EDICT Project: Policy Recommendations to Eliminate Disparities in Clinical Trials.* Houston, TX: EDICT Project.

## Recommendation 1

The FDA must develop a mandate for diversity in clinical trials for all drugs and devices before they can achieve final approval. A facet of this should include a recommendation towards branding and advertising whereby all marketed drug advertising should include the percentage of minorities that participated in their study with emphasis on women and African Americans, Latinos and other ethnic minorities as appropriate.

In 1993, the National Institutes of Health (NIH) Revitalization Act was passed by United States Congress and signed into law by President Clinton. The Act called for the NIH to require that all federally funded clinical research prioritize the inclusion of women and minorities and that research participant characteristics be disclosed in research documentation. When pivotal NIH-funded studies included large proportions of women by design, they made important and clinically relevant scientific contributions by identifying sex-specific differences in symptoms, pathologies, and treatment response.

This approach is in stark contrast to other government agencies (NCI, HHS, et al.,) who merely made spiritless recommendations regarding patient diversity and inclusion. Hundreds of meetings were held, but nothing has been accomplished, largely because no budgets or personnel have been appropriated to make any progress occur. This inaction persists for both the government and industry.

It has become obvious that the recommendation coming from the National Institute of Health, the *NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research*, has been voluntary in nature, and most pharmaceutical companies and biotech companies for a quarter of a century have completely ignored this policy due to lack of FDA reinforcement. Put simply, the pharmaceutical community is not going to improve minority participation in clinical trials until the FDA compels them to do so via regulations. Enrolling 1% of minorities is shameful and disrespectful a violation of the constitution of our country; this pitiful enrollment amounts to being more un-American than any other institution given the enormous profits that this industry possesses.

Minority enrollment in cancer clinical trials remains inadequate despite striking racial/ethnic disparities in cancer incidence and mortality. Similar incongruities between disease burden and representation in biomedical research exists for cardiovascular diseases and diabetes. These disparities have economic consequences: eliminating racial/ethnic health disparities would have reduced total medical costs during 2003–2006 by more than $1.2 trillion.

African American clinicians and religious leaders want the pharmaceutical and biotech industries to spend a minimum of $25,000,000.00 a year or 1% of their total profits as an industry for the next five years that will not exceed $25,000,000.00 - $40,000,000.00 to ensure enforcement of the 1993 National Institute of Health guidelines that were amended in 2001. *The pharmaceutical industry is believed to have spent $75,000,000.00 on lobbying in one month.* So, meeting any mandate from $25,000,000.00 - $40,000,000.00 a year in the clinical trials for including African Americans and women is achievable without question.

# Top 10 Pharmaceutical Companies 2017


*The global pharmaceutical market was estimated in USD 1.1 trillion in 2016. The global market is highly mature and consolidated. The top-10 pharmaceutical companies in this market had share of around 40% in 2016 and approximately 50% considering the top-15. A comparative analysis of the top-15 organizations was used to develop a ranking for these companies.*

***Cited Scholarly Article:***


Murthy VH, Krumholz HM, Gross CP. *Participation in cancer clinical trials: race-, sex-, and age-based disparities*. JAMA: The Journal of the American Medical Association. 2004;291: 2720–2726

Oh SS, Galanter J, Thakur N, et al. *Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled*. PLoS Med 2015;

Rathore SS, Wang Y, Krumholz HM. *Sex-based differences in the effect of digoxin for the treatment of heart failure*. N Engl J Med. 2002;347: 1403–1411

Sardar MR, Badri M, Prince CT, Seltzer J, Kowey PR. *Underrepresentation of women, elderly patients, and racial minorities in the randomized trials used for cardiovascular guidelines*. JAMA Intern Med. American Medical Association; 2014;174: 1868–1870

US Congress. *National Institutes of Health Revitalization Act of 1993: Act to Amend the Public Health Service Act to Revise and Extend the Programs of the National Institutes of Health, and for Other Purposes Public Law Washington, DC*; 1993. pp. 103–143.

## Recommendation 2

The FDA and its Office of Minority Health must work with African American and other ethnic minority clinicians and the National Medical Association:

1) To develop a CME accredited curriculum for clinicians at all stages regarding the stigma and historic fear African Americans have regarding participation in clinical trials. We are aware of many reasons to justify this fear; the Tuskegee experiments and the Henrietta Lacks' story are two classic and tragic examples of the corruption of the moral and ethical fabric of research. The goal is to increase clinician awareness, understanding, and sensitivity of these fears, apprehensions, and ethical concerns.

2) To address the need for an integrated multi-year National Campaign to ensure that the modern applications of clinical trials and their many safeguards is common knowledge.

***Cited Scholarly Article:***

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## Recommendation 3

The FDA must develop a matrix that will define and quantify adequate inclusion percentages of African Americans for various types of study, starting with population and noting that the percentage will differ with each disease category

## Recommendation 4

The FDA guidance and regulation enforcement regarding diversity and inclusion in clinical trials must be harmonized or aligned with the NIH, embedding a longitudinal process across the various approval phases for the drug or device would evaluate and ensure compliance.

## Recommendation 5

The FDA must increase funding and other resources for its National Institute on Minority Health and Health Disparities. The current National Institute on Minority Health and Health Disparities consists of a director and 1-2 FTEs.

## Recommendation 6

The FDA guidance and regulations around inclusion and enforcement in clinical trials must be harmonized or brought into uniformity with the NIH's own.

## BACKGROUND, SUPPORTING EVIDENCE, AND JUSTIFICATION

There appears to be minimal effort during the planning and designing of clinical trials regarding a solid strategy to recruit and retain minorities. For example, diabetes is a disease that is epidemic in the African American population yet they represented only 3% of trial participants for ADLYXINS as evidenced by the Drug trials snapshot 2016.

If the FDA were to require pharmaceutical and biotech companies to include their strategy, process, and budget for the recruitment and retention of minority participants. Budget items might include engagement and hiring of African Americans clinical investigators, education and outreach and advertisement through a minority owned and culturally appropriate media firms.

### Drug Trials Snapshots Report (2016)

| BRAND NAME | INDICATION | WOMEN | AFRICAN AMERICAN | ASIAN | WHITE | OTHER | AGE 65 and OLDER |
|---|---|---|---|---|---|---|---|
| ADLYXIN§ | Treatment of type 2 diabetes mellitus | 52% | 3% | 32% | 64% | 2% | 19% |
| ADLYXIN§§ | Treatment of type 2 diabetes mellitus | 31% | 4% | 13% | 75% | 8% | 34% |
| AXUMIN | Detection of prostate cancer recurrence | 0% | 4% | <1% | 31% | 64% | 66% |
| NUPLAZID | Treatment of hallucinations and delusions in patients with Parkinson's disease | 36% | 1% | 5% | 91% | 3% | 82% |
| TALTZ | Treatment of moderate to severe plaque psoriasis in adults | 32% | 2% | 4% | 93% | 1% | 7% |
| VENCLEXTA | Treatment of chronic lymphocytic leukemia (CLL) | 31% | 3% | <1% | 94% | 3% | 58% |

### Drug Trials Snapshots Report (2015)

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AVYCAZ | Treatment of complicated intra-abdominal infection (abbreviated as cIAI) | 26% | <1% | 27% | 60% | 12% | 11% | 8% | 4% |
| BRIDION | For the reversal of the effects of certain neuromuscular blocking agents | 52% | 3% | 12% | 84% | <1% | 29% | <1% | <1% |
| CHOLBAM | For treatment of peroxisomal disorders, including Zellweger spectrum disorders | 33% | 0% | 0% | 83% | 17% | N/A | N/A | N/A |
| CORLANOR | To reduce hospitalization from worsening heart failure. | 24% | 1% | 8% | 89% | 2% | 38% | 11% | 3% |
| COSENTYX | Treatment of moderate to severe plaque psoriasis in adults who do not respond well to medication applied directly to the skin | 30% | 1% | 22% | 68% | 9% | 8% | 1% | <1% |
| COTELLIC | Part of combination treatment melanoma | 42% | N/A | N/A | 93% | 7% | 27% | 9% | 3% |
| CRESEMBA | Treatment of invasive aspergillosis | 40% | <1% | 21% | 78% | <1% | 24% | 5% | <1% |
| ENTRESTO | Treatment of heart failure | 22% | 5% | 18% | 66% | 11% | 49% | 19% | 7% |

When pharmaceutical companies and the government organize clinical trials, the discussion concerning how we attract minorities is always the last discussion in organizing any clinical trial because they lack

African American clinical investigators. They are the last to be hired and asked as consultants onto the project, and they are treated as an afterthought.

Companies claim they cannot find African American clinical trial specialists or investigators to help consult them on how to better engage the African American community into signing up for clinical trials. Bridge Clinical Research is one of a few companies looking to help bridge the gap between pharmaceuticals and African American clinical trial experts.

We want every pharmaceutical and biotech company, as well as the government to commit to the practice of filing with the FDA a strategy on how they are going to attract minorities going forward and what percentage of the budget they intend to spend on this trial will be committed to this. Our recommendation is that $1/4^{th}$ of that budget should be committed to finding African Americans clinical investigators, education and outreach and advertisement through a minority owned media firm.

# TACTICS AND ACTIONS FOR THE RECOMMENDATIONS

## The Use of ReX in Education Awareness as a Self-Learning Health Platform

ReX Mission — solve a pressing human problem with technology, insights, and content with a robust digital health solution that advances patient engagement with sustainable, Human Health Enablement™.

Establish the Alliance for Human Health Enablement™ of cross industry stakeholders who work independently, and with ReX to lead toward the next health enabled generation. Although research consistently demonstrates that patients who have higher levels of health literacy tend to be more engaged in their health and achieve better outcomes, only 12% of U.S. English speaking adults are health literate despite spending billions over decades (CDC).

Because of the engagement and knowledge demands placed on today's healthcare and wellness consumer driven by the highly technical integrated health environment, the ReX platform provides a pathway to achieve health knowledge and readiness at no cost to the consumer.

ReX is a self-learning health platform that connects everyone to an individualized education and motivational tool to content aligned with real-time need, culture, and preference. This connection occurs without intrusive advertising while the individuals read, listen or otherwise experience health and wellness content from trusted and approved sources.

ReX

- aggregates superior content assets from government, accredited licenses, associations, and leading health stakeholders into the ReX content library.
- curates individually relevant content aligned with interest, demographics, health history, behavior and culture. Moving from an indiscriminate information exposure to information precision.
- activates content by making it engaging (i.e., users can underline, save, tag, and book mark, etc.).
- integrates content into the individual's health life (individuals can link the content to their portals, calendars and other health and wellness activities).
- yields high value data (ensuring continuous process improvement for REX and individuals specifically and the health ecosystem in general).
- builds Trust. Through a group of "health stakeholders" known as the ReX Alliance of Human Health Enablement™*, the mission and vision of ReX is to ensure the next health enabled generation is re-enforced. (*See appendix for information)
- transforms in-effective "explosion" to "individually precise" communications.

— simplifies content search and use in a personalized and trusted environment without re-targeted marketing or click-bait.

— connects content to utilities and services, making ReX repeatedly useful while continuously advancing the experience.

— Funded by quality, sponsored content and services from health stakeholders needing a better, direct-to-patient access and monetizing valuable data.

— Valued for its inventory and curation where content is exponentially maximized by design, technology, and data at less cost.

— changes how we see and act in our world and how we understand use and VALUE resources.

— becomes the impact that changes way people see and act in their health world.

ReX is a first-of-its-kind, ad-free, digital health platform designed to advance health content delivery to an integrated human experience. ReX makes access to quality and trusted content better, smarter, and safer for patients that can be integrated into their health journey.

## Scientific Team

The scientific team will be composed of leading African American clinicians who can give a broad prospect on the roadblocks that this campaign may experience to recruit African Americans and minorities to clinical trials. We will work very specifically with the National Medical Association to compose this scientific team so that we will have the very best minds available to us to make this successful.

## Outreach to African American Clinical Trial Specialists

We need greater outreach to African American clinical trial specialists. When pharmaceutical companies and the government organize clinical trials, the discussion concerning how we attract minorities is always the last discussion in organizing any clinical trial because they lack African American clinical investigators. They are the last to be hired and asked as consultants onto the project, and they are treated as an afterthought.

Companies claim they cannot find African American clinical trial specialists or investigators to help consult them on how to better engage the African American community into signing up for clinical trials. Bridge Clinical Research is one of a few companies looking to help bridge the gap between pharmaceuticals and African American clinical trial experts.

We want every pharmaceutical and biotech company, as well as the government to commit to the practice of filing with the FDA a strategy on how they are going to attract minorities going forward and what percentage of the budget they intend to spend on this trial will be committed to this. Our recommendation is that 1/4th of that budget should be committed to finding African Americans clinical investigators, education and outreach and advertisement through a minority owned media firm.

## Inclusion of Dually-Diagnosed Patients

Many clinicians tell us that we can increase African American and women participation in clinical trials if the trial is not written so narrowly concerning a concern disease state and the condition of the participant. For instance, we recently participated in a lung cancer clinical trial in recruiting African Americans and our host company asked us to identify patients who had self-disclosed in the congregation. The problem was they could not be dually diagnosed with anything besides lung cancer so that the trial can determine and look at the relevant data that the trial was originally set to look at. So due to the fact that African Americans are dual diagnosed because of the lack of the access to care and the trial perimeters was so narrow, many

African American participants are dismissed form the trial even though their participation might bring about a new understanding that was not anticipated by the trial creators.

Our recommendation is that the clinical trial community broaden the definition and allow those who are dually diagnosed to participate once they control the trial to account for the other conditions the participants are diagnosed with.

***Cited Scholarly Article:*** The National Black Church Initiative, *The National Black Church Initiative Clinical Trial Education Awareness and Participation Program (CTEAPP).* Washington, DC: The National Black Church Initiative, 2016.

# Organizational Chart

# Three Perspectives of Leading African American Clinicians on Clinical Trials

## David Satcher, M.D., Ph.D. FAAFP, FACPM, FACP

*Former surgeon general of the United States*

A February 2014 article in the Washington Post by David Satcher, former surgeon general of the United States, discussed the importance of African-American participation in clinical trials. In the op-ed titled *"More African Americans need to participate in clinical trials,"* Satcher gives a brief history on the Tuskegee Experiment and the lasting effects it has had on the African-American community. "We participate in clinical trials at far lower rates than other ethnic groups, which helps to perpetuate the sort of disparities seen with diseases such as Alzheimer's," states Satcher. This disparity has not only impacted the physical health of the community, but has also negatively affected the financial health and overall quality of living." [1]

The Tuskegee study was an infamous clinical experiment in which researchers and the U.S. Public Health Service led African American men with syphilis to believe that they were receiving free medical care while, unbeknown to them, they were being left untreated so scientists could study the effects of prolonged syphilis. After the Associated Press exposed the truth, sparking a public outcry, the U.S. government ended the study in 1972, 40 years after it began. The 1974 National Research Act set new guidelines for the use of humans in clinical studies. In 1997, the Clinton administration worked with higher education institutions to usher in new training requirements and ethical standards for physicians, researchers, and medical students as part of an official apology President Bill Clinton issued on behalf of the nation to the victims of the experiments.

While these standards go a long way toward helping to prevent future such experiments, much damage was already done among African Americans. More than 40 years later, memories of the Tuskegee study have not faded, nor should they. But we should not allow the horrors of that study to loom over us to our detriment, and increasing African American enrollment in clinical trials is critical. We can start by better equipping physicians with easy-to-access information about the location and requirements of clinical trials so doctors may more easily refer their qualified patients. Without higher levels of participation among African Americans, we will never discover the root causes of the disparate impact of a disease such as Alzheimer's. Every day that African Americans continue to live in fear of such trials is another day that we fall further behind in the fight against Alzheimer's and other diseases.

Alzheimer's has major health implications for African Americans but also has a huge impact on families' financial stability. In 2012, African Americans accounted for one-third of the cost of care — around $71.6 billion — for Alzheimer's, despite accounting for less than 14 percent of the population, researchers at John Hopkins University found in 2013. While Medicare and Medicaid bear most of the costs of medical bills associated with Alzheimer's care, African Americans paid more than $3.45 billion out of pocket on care in 2012. Then there is the high toll of informal care, which is about 61 percent of the cost of Alzheimer's for African Americans. Sadly, this type of care can have even deeper economic repercussions as more and more African Americans drop out of the workforce or delay college to care for their loved ones.

Alzheimer's cases in the United States are projected to triple from 5.2 million to nearly 14 million by 2050. In other words, these problems are going to get worse before they get better. Researchers believe it is possible to stop Alzheimer's with investments in research equal to the size and scope of the disease. But funding can go only so far without a corresponding increase in patients willing to participate in innovative clinical trials. As one of the groups that has the most to gain from Alzheimer's clinical trials, African

[1] Satcher, *African Americans Must Begin to Participate in Clinical Trials,* (Washington Post, 2014)

Americans should lead by example. In doing so, we just might gain meaningful insight into the causes of the disparate impact of Alzheimer's and help speed our pace to a cure.

**Louis W. Sullivan, M.D.**
*Former Secretary of the U.S. Department of Health and Human Services*

According to an article published just last year by the Morehouse School of Medicine and written by the President Emeritus of the Morehouse School of Medicine, Chairman of the Sullivan Alliance, Chairman of the National Health Museum, and Former United States Secretary of Health & Human Services, Louis W. Sullivan,

*"Diversity in the scientific workforce is critical in order to address the many health challenges afflicting minority communities. Diversity of participation in clinical research is also necessary to gather accurate data regarding the efficacy of drugs on different populations.*

*Yet, clinical trial participation among minority groups remains troublingly low. Less than 20 percent of African-Americans, Hispanics, Asians and non-Hispanic whites say neither they nor anyone in their family has ever participated in a clinical trial, according to a survey commissioned by Research!America. But there's still hope. Altruism appears to be a motivating factor among non-white populations, with a majority expressing willingness to participate in a trial to improve the health of others."*

**James R. Gavin III, M.D., Ph.D.**
*Clinical Professor of Medicine at Emory University School of Medicine*

Dr. James Raphael Gavin III, MD, PhD, represents the quintessential scientist, educator, trailblazer, and type of leader most people aspire to become. The breadth and depth of his contributions to the scientific and medical community in the area of diabetes are unparalleled, while his passion has pushed him to unprecedented heights in American medicine. Dr. Gavin is a veteran clinical research professional with more than 40 years of scientific research experience with responsibilities spanning basic research in biochemistry, endocrinology, clinical monitoring, project management, safety surveillance, and international medical direction.

As the Chief Medical Officer and CEO of the Healing Our Village (HOV) Clinical Research Network, in an extraordinary video that is easily accessible to the public through websites such as YouTube, Dr. Gavin underlined the importance of clinical trial research. These videos are part of a clinical research study to help encourage those in the African American community who still hold fear towards clinical trials and clinical research. [2]

[2] Elixa Clinical Trials DVD - https://www.youtube.com/watch?v=rdzbQWDWy-k, https://www.youtube.com/watch?v=o-Y9dF-RgcA

National Black Church Initiative
www.naltblackchurch.com
Clinical Trials

# What is a Clinical Trial?

## "Clinical trials benefit African Americans, too"

A clinical trial is a research study done by doctors to determine the effectiveness of a treatment or drug before it can be considered for approval. Once approved, the treatment or drug can be prescribed by doctors to administer to the public. African Americans should participate in clinical trials to determine whether new drugs are effective for African Americans

# Working Definition of a Clinical Trial

## Is a Clinical Trial for Me?

*Clinical Trials and African Americans*

**WHAT IS A CLINICAL TRIAL?**

Clinical trials are studies that research medications, vaccines, devices or procedures to determine if they are safe and work in people who have diseases. These studies may show which medical approaches work best for certain groups of people. People who participate in clinical trials are always volunteers.

**WHY PARTICIPATE?**

Doctors and health experts agree that all medical treatments need to be studied to make sure that they are safe and effective in diverse populations. This includes African Americans, Latinos, Asians and other minority groups. Men, women and children should participate in clinical trials. Minority populations often have more health challenges, minority inclusion in studies that search for better treatments and cures are imperative.

**BUT WHY ME? WHY SHOULD I AS AN AFRICAN AMERICAN BE PART OF A CLINICAL TRIAL?**

African American participation in clinical trials is important because:

- African Americans, Hispanics and Asians participate at lower rates in clinical trials than other groups. By participating, minorities help doctors better understand how a medication or treatment works in their population.
- African Americans may react differently to certain treatments than other racial groups. African American volunteers in clinical trials ensure that healthcare providers know these drugs will be safe and work in our population.

**WHAT ARE THE TYPES OF CLINICAL TRIALS? (WOULD put this in a Box)**

**Clinical trials look at new ways to prevent, detect or treat disease. There are various types of 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 the mental and social impact a disease may have on patients.

**ARE CLINICAL TRIALS SAFE FOR ME?**

Clinical trials follow a series of steps that are developed to protect YOU as a volunteer participant in the trial. Your understanding of the trial, your safety, privacy of your medical records and your health are guiding factors of all clinical trials. There are rules that the government has put in place to protect patients and to make sure that they understand the clinical trial process and agree to participate. This is commonly referred to as "Informed Consent."

**THE APPROVAL and OVERSIGHT:** 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 with 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 initially review and approve or deny the proposed trial and, then to monitor all clinical trials.

**THE TEAM:** Every clinical study is led by a principal investigator — often a physician. Clinical studies also have a research team that may include doctors, nurses, social workers and other health care professionals. Clinical studies can take place in many locations, including hospitals, universities, doctors' offices and in the community. The length of a clinical study varies and volunteers are told how long the study will last before they enroll. [(2)]

**THE RULES:** Doctors and the clinical trial team must develop and follow a step-by-step plan to carry out the study. This is called the protocol. The purpose of the protocol is to define and explain the specific research area to be studied (the medication, treatment, procedure, etc.) and the way that that research will be carried out. The protocol also focuses on protecting the health and welfare of volunteers in the study.

A protocol describes:

Why the study is being conducted
Who may participate in the trial (eligibility)
Details about tests, procedures, medications and dosages
The length of the study and what information will be gathered
How the information will be used

**THE KNOWLEDGE:** A clinical trial team works with the clinical trials volunteer to make sure they have as much information as possible. Informed consent is very important in clinical trials. The informed consent process gives the volunteer the information that he or she need to make a decision about participating in the study. It gives important information such as why the trial is being conducted, how long it will last, what the volunteer can expect, the risks and possible benefits of the trial and exactly who to contact with more questions or concerns. The informed consent process occurs at the beginning of the trial and throughout the entire process. It is important that:

- The volunteers understand the clinical trial and ask questions at any point during the clinical trial process. The clinical trial team will explain the study and volunteers will be given a document to sign stating that they understand the process.
- Volunteers understand that they can withdraw from the study at any time, even after they sign the informed consent document.

**THE RISKS:** Clinical trials have potential benefits and risks. It is important to understand both before agreeing to participate in a clinical trial. Possible risks include:

- The medication or treatment may not work in general and/or specifically in you,
- You may not receive the "active" treatment, and instead a placebo,
- There may be side effects

Your time will also be a factor, as your participation will require frequent visits to the research center. Anytime that you have a question or concern, it is important that you have an open discussion with the clinical research team.

**IS A CLINICAL TRIAL RIGHT FOR ME?**

Here are a few reasons to consider participating in a clinical trial:

1. African American participation is critical in clinical trials. Many of the medications and procedures that are 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.
2. Volunteers who participate in clinical trials help increase medical knowledge and save or improve lives.
3. Participation allows volunteers to take an active part in their own health.
4. Volunteers may be able to benefit from new or improved treatments before they are available to the public. Volunteers have a team of health professionals who are experts in their specific disease or condition. This team closely monitors volunteers and are available to give advice, answer questions and provide support as needed.
5. Treatment may come at no cost to you. Be sure to discuss this with the clinical research team and get a good understanding of what is and is not covered.
6. Your participation in a clinical trial can also help the overall health of your community by making new drugs and treatments available faster and safer. Your voluntary participation in a clinical trial helps leave a legacy and help future generations.

**Citations**


1. National Institutes of Health. www.nih.gov
2. Clinicaltrials.gov https://clinicaltrials.gov/ct2/about-studies/learn#WhoConducts

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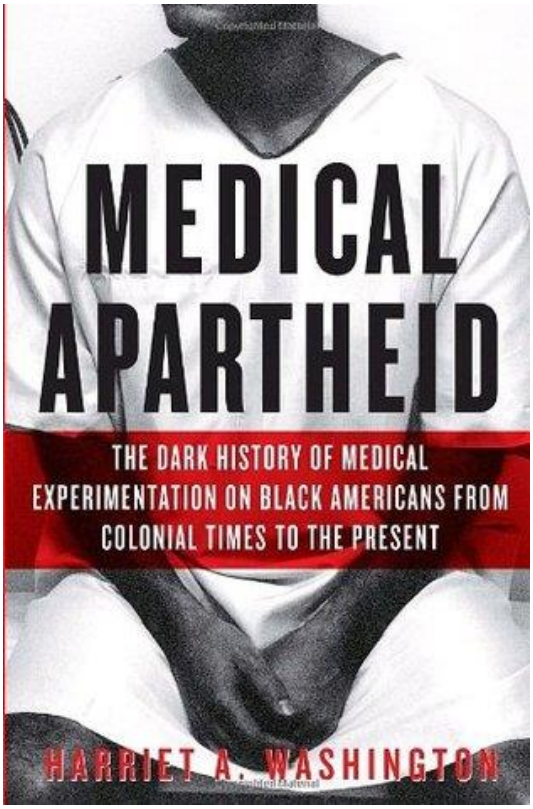
# Appendix A

***MEDICAL APARTHEID - The Dark History of Medical Experimentation on Black Americans From Colonial Times to the Present - By Harriet A. Washington***




The Tuskegee Syphilis Study remains an ignominious milestone in the intertwined histories of race and medical science in U.S. society. Initiated in 1932, this tragic 40-year long public health project resulted in almost 400 impoverished and unwitting African American men in Macon County, Ala., being left untreated for syphilis. Researchers wanted to observe how the disease progressed differently in blacks in its late stages and to examine its devastating effects with postmortem dissection.

A fresh account of the Tuskegee study, including new information about the internal politics of the panel charged by the Department of Health, Education and Welfare with investigating it in 1972, lies at the center of Harriet A. Washington's courageous and poignant book. The balance of *Medical Apartheid* reveals, with arresting detail, that this scandal was neither the first chapter nor the last in the exploitation of black subjects in U.S. medical research. Tuskegee was, in the author's words, "the longest and most infamous -- but hardly the worst -- experimental abuse of African Americans. It has been eclipsed in both numbers and egregiousness by other abusive medical studies."

Although medical experimentation with human subjects has historically involved vulnerable groups, including children, the poor and the institutionalized, Washington enumerates how black Americans have disproportionately borne the burden of the most invasive, inhumane and perilous medical investigations, from the era of slavery to the present day. (This burden has become global in the last few decades.) In 1855, John "Fed" Brown, an escaped slave, recalled that the doctor to whom he was indentured produced painful blisters on his body in order to observe "how deep my black skin went." This study had no therapeutic value. Rather, fascination with the outward appearance of African Americans, whose differences from whites were thought to be more than skin deep, was a significant impulse driving such medical trials.

Shielding whites from excruciating experimental procedures also proved a powerful motivation. J. Marion Sims, a leading 19th-century physician and former president of the American Medical Association, developed many of his gynecological treatments through experiments on slave women who were not granted the comfort of anesthesia. Sims's legacy is Janus-faced; he was pitiless with non-consenting research subjects, yet he was among the first doctors of the modern

era to emphasize women's health. Other researchers were more guilty of blind ambition than racist intent. Several African Americans, including such as Eunice Rivers, the nurse-steward of the Tuskegee study, served as liaisons between scientists and research subjects.

The infringement of black Americans' rights to their own bodies in the name of medical science continued throughout the 20th century. In 1945, Ebb Cade, an African American trucker being treated for injuries received in an accident in Tennessee, was surreptitiously placed without his consent into a radiation experiment sponsored by the U.S. Atomic Energy Commission. Black Floridians were deliberately exposed to swarms of mosquitoes carrying yellow fever and other diseases in experiments conducted by the Army and the CIA in the early 1950s. Throughout the 1950s and '60s, black inmates at Philadelphia's Holmesburg Prison were used as research subjects by a University of Pennsylvania dermatologist testing pharmaceuticals and personal hygiene products; some of these subjects report pain and disfiguration even now. During the 1960s and '70s, black boys were subjected to sometimes paralyzing neurosurgery by a University of Mississippi researcher who believed brain pathology to be the root of the children's supposed hyperactive behavior. In the 1990s, African American youths in New York were injected with Fenfluramine -- half of the deadly, discontinued weight loss drug Fen-Phen -- by Columbia researchers investigating a hypothesis about the genetic origins of violence.

Washington's litany of experimental misdeeds done to African Americans is more extensive than can be described here. With such damning evidence, one wonders why she felt it necessary to include examples that, while clearly offensive, do not rise to the threshold of medical experimentation. For instance, supporters of slavery, to justify the peculiar institution, cited data from the 1840 census showing that free African Americans had poorer mental and physical health than enslaved blacks. Nonetheless, taking ideological liberties with questionable statistics is not, in and of itself, an example of medical experimentation, nor was circus impresario P.T. Barnum's display of black Americans as entertainment. While demonstrating the widespread exploitation of blacks, it confuses the thrust of Washington's argument.

But Washington also sheds light on how our understanding of what constitutes medical research requires broadening in the face of new developments in genetic science. Federal and state forensic DNA databases contain a disproportionate number of samples from African Americans, for example. Because genetic samples collected for this purpose carry information about a subject's health, blacks are particularly vulnerable to the exposure of sensitive medical information. And although experimentation with human subjects is less invasive than it once was, Washington cautions that it is no less injurious. Researchers still need to be mindful of the rights of their subjects.

Given the history presented in *Medical Apartheid*, it is no surprise that some African Americans continue to regard the medical system with apprehension, despite more stringent safeguards enacted by the federal government in the 1970s. Washington attributes this outlook, which she calls iatrophobia, to the seeds of distrust sown in black communities by the Tuskegee scandal and a history of lesser-known mistreatment.

Washington, a visiting fellow at Chicago's DePaul University, intends that *Medical Apartheid* serve a socially therapeutic -- if not cathartic -- function. Laying bare these atrocities,

her logic goes, will foster healing and frank but necessary conversation. Clearing the air may encourage a better informed African American public to participate in clinical trials.

Despite the author's best intentions, the scale and persistence of the "dark history" she delineates may well preclude such a development. Precisely because Washington's account of racially stratified medical exploitation is so gripping, it may be difficult for the public to muster enthusiasm to enter clinical trials, no matter their cultural background. And with the experimental research burden shifting from Americans of African descent to Africa itself (which Washington calls a "continent of subjects"), Asia, and Latin America, where some cavalier researchers are seeking more plentiful and pliant subjects, readers may be more convinced than ever of the durability of the medical color line. ·

*Alondra Nelson, an assistant professor of African American studies and sociology at Yale University, is writing a book, "Body and Soul: The Black Panther Party and the Politics of Health and Race."*

# Appendix B

***Tuskegee University National Center for Bioethics in Research and Health Care Journal of Health Care, Science and Humanities***

"Despite advances in literacy and education as well as major improvements in communication…in this period of unprecedented acceleration in the pace of scientific and technological advances, and the educational focus on Science, Technology, Engineering and Mathematics (STEM)…there will still be a great gap between medical (protective) knowledge and the public acceptance of it." - *Bailus Walker PhD, MPH*

In 2000, Healthy People 2010 identified limited health literacy as a public health problem based on several scientific evidence and systematic reviews of the literature on the effects of limited literacy on health outcomes and set national objectives for its improvement.

Inadequate or low health literacy significantly compromises an individual's participation in health education process, information-seeking practices, and navigation and accessing health care systems. People with poor health literacy may have problems communicating with their physician, reading instructions and labels on medicines, completing medical and insurance forms and understanding many other aspects of health care.

The impact of limited health literacy disproportionately affects lower socioeconomic and minority population groups. Furthermore, given the increasing link between health outcomes and health literacy, health issues arising from inadequate health literacy include problems understanding health concepts, informed consent documents, health-related tasks, the importance of adherence, prescription and appointment card usage, and compromised and adverse health outcomes.

Even with all that came out of the USPHS Syphilis Study at Tuskegee, with its impact on the field of bioethics, and with its legacy as defined by Art Caplan in his writings over the past quarter century, we still must watch over the system, ever prone to vulnerable persons being taken advantage of by others who see a moment of profit. And that's basically it. "Still," he says, "the real legacy of the U.S. Public Health Service Syphilis Study at Tuskegee is how hard it remains to admit to and respond to racism both in biomedical research and American society in general." "The legacy of the U.S. Public Health Service Syphilis Study at Tuskegee," he says, "is that racism fueled the study, shaped the response that evolved, and continues to frame how we think about research ethics in the U.S. and increasingly in other parts of the world as more and more clinical research is outsourced to the poor and developing nations."

Health education by its practice is directed towards improving health literacy, which in turn is linked to many other psychosocial issues. But, improvement in health literacy should be a clearly defined outcome of health education and health promotion efforts, not an after-thought or left to chance. Evidence-based strategies demonstrating that limited health literacy can be successfully addressed are emerging from the fields of communication, health care, public health, and adult education. Approaches to improve health literacy include simplifying targeted health education

materials (written, video, audio, and computer formats), improving patient-provider communication, plain language and pictogram medication sheets, and improving overall literacy. However, with increases in number of successful evidence-based interventions, important questions remain: What are the most effective strategies for improving health literacy skills? How can the health care system change to better meet the information and communication needs of all people? (DHHS ODPHP). Improving health literacy is critical to achieving the objectives set forth in Healthy People 2020 and, more broadly, key to the success of current national health agenda. In addition to the Healthy People 2020 initiative, there are many of initiatives by Federal agencies and national non-government organizations (NGOs) to address the problem of low health literacy at national, State and local levels.

The National Action Plan to Improve Health Literacy The Action Plan envisions a restructuring of the ways we create and disseminate all types of health information in this country. The plan also calls on us to ensure that all children graduate high school with health literacy skills that will help them live healthier throughout their lifespan. The plan sets forth achievable objectives and describes what is required to create and sustain a health literate Nation – while recognizing that actions are required to simultaneously address the multiple socio-political determinants of health. Some health professional organizations have rallied to answer the national call to action. For example, the oral health field produced agenda for health literacy in A National Call to Action to Promote Oral Health and research dentistry. The development of health policy, programs, and financing must address the need for increased usability of health information and services. The National Action Plan to Improve Health Literacy seeks to engage organizations, professionals, policymakers, communities, individuals, and families in a linked, multi-sector effort to improve health literacy.

The Action Plan is based on 2 core principles:

• All people have the right to health information that helps them make informed decisions

• Health services should be delivered in ways that are easy to understand and that improve health, longevity, and quality of life The vision informing the plan is of a society that: Provides everyone with access to accurate and actionable health information; delivers person-centered health information and services; and, supports lifelong learning and skills to promote good (optimal) health

The Action Plan contains 7 goals that, when achieved, will improve health literacy and strategies for achieving them:

1. Develop and disseminate health and safety information that is accurate, accessible, and actionable

2. Promote changes in the health care system that improve health information, communication, informed decision-making, and access to health services

3. Incorporate accurate, standards-based, and developmentally appropriate health and science information and curricula in child care and education through the university level

4. Support and expand local efforts to provide adult education, English language instruction, and culturally and linguistically appropriate health information services in the community

5. Build partnerships, develop guidance, and change policies

6. Increase basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy

7. Increase the dissemination and use of evidence-based health literacy practices and interventions

Many of the strategies highlight actions that particular organizations or professions can take to further these goals. It will take everyone working together in a linked and coordinated manner to improve access to accurate and actionable health information and usable health services. By focusing on health literacy issues and working together, we can improve the accessibility, quality, and safety of health care; reduce costs; and improve the health and quality of life of millions of people in the United States. (http://health.gov/communication/ initiatives/health-literacy-action-plan.asp)

# Appendix C

***Diversity in Clinical and Biomedical Research: A Promise Yet to Be Fulfilled – By Sam S. Oh, Joshua Galanter, Neeta Thakur, Maria Pino-Yanes, Nicolas E. Barcelo, Marquitta J. White, Danielle M. de Bruin, Ruth M. Greenblatt, Kirsten Bibbins-Domingo, Alan H. B. Wu, Luisa N. Borrell, Chris Gunter, Neil R. Powe, Esteban G. Burchard***

In 1993, the National Institutes of Health (NIH) Revitalization Act was passed by United States Congress and signed into law by President Clinton. The Act called for the NIH to require that all federally funded clinical research prioritize the inclusion of women and minorities and that research participant characteristics be disclosed in research documentation . When pivotal NIH-funded studies included large proportions of women by design, they made important, clinically relevant scientific contributions by identifying sex-specific differences in symptoms, pathologies, and treatment response. In continuation of this effort, the NIH announced new measures to enhance gender equity. Herein, we evaluate the impact of the Revitalization Act's other stated aim: diversifying study populations by race/ethnicity. We also make suggestions on what we believe will bolster the Revitalization Act's effect in shaping clinical and biomedical research and thereby provide guidance for President Obama's new Precision Medicine Initiative (PMI).

## Disease Pattern, Clinical Presentation, and Therapeutic Response Can Vary Dramatically by Race/Ethnicity and Ancestral Background

Race is a social construct rooted in cultural identity and shaped by historic and current events, which influence an individual's behavior and place of residence. Genetic variation correlates with self-identified race, and this genetic variation also correlates with clinical presentation and therapeutic response. Thus, while not every study needs to examine racial differences or include all racial/ethnic groups, we feel that the group(s) included should be representative of their larger population(s) such that including an adequate proportion of racially/ethnically diverse groups in clinical and biomedical research can provide meaningful opportunities to examine the complex relationship of ancestral influences, environmental exposures, and social factors. In turn, understanding the interaction between the social and environmental milieu with an individual's genomic profile and genetic ancestry can extend our understanding of disease pathology and expand therapeutic options for everyone. For example, up to 75% of Pacific Islanders are unable to convert the antiplatelet drug clopidogrel into its active form and are at higher risk for adverse outcomes following angioplasty.

## Past Research Has Under-Studied Minorities

The US has been regarded as a "global lead" and "exemplar" in biomedical and clinical health research since the end of the Cold War. Yet, few US biomedical studies focus recruitment efforts on attaining adequate minority representation, nor do they focus their research attention to factors most relevant to minority health. Since the passage of Revitalization Act in 1993, less

than 2% of more than 10,000 cancer clinical trials funded by the National Cancer Institute included enough minority participants to meet the NIH's own criteria and goals. Moreover, less than 5% of NIH-funded respiratory research reported inclusion of racial/ethnic minorities. Minority enrollment in cancer clinical trials remains inadequate despite striking racial/ethnic disparities in cancer incidence and mortality. Similar incongruities between disease burden and representation in biomedical research exist for cardiovascular diseases and diabetes. These disparities have economic consequences: eliminating racial/ethnic health disparities would have reduced total medical costs during 2003–2006 by more than $1.2 trillion. Some NIH reviewers have argued that the inclusion of diverse groups will increase the financial costs of clinical and biomedical research. However, it is generally agreed upon that the long-term financial benefits outweigh short-term expenses. The social, biomedical, and economic costs of inaction are ameliorated by a new appreciation for the clinical and biomedical benefits achieved through precision medicine when applied to all populations. The proportion of taxpayers who have not gained optimal benefit from scientific discoveries they are funding continues to grow with the changing US demographics. Therefore, ensuring that diverse populations are adequately included in scientific research is imperative not only in terms of scientific integrity and fiduciary responsibility but also as a matter of social justice.

## Barriers to Diversify Research Need Concerted Attention

While US minorities may be as willing to participate in health research as non-Hispanic whites, barriers to participation among minority populations must be addressed and will require buy-in from stakeholders: funders, academic institutions, investigators, and potential research participants. Minority populations often have limited access to specialty care centers that serve as referral sources for clinical studies, resulting in a lack of an effective referral base. Other barriers include, but are not limited to, fears of exploitation in medical research, financial constraints, competing demands of time, lack of access to information and comprehension about research, unique cultural and linguistic differences, fears of unintended outcomes, stigmatization, and health care discrimination.

Highly feasible changes can increase minority participation despite the challenges described. Ideally, investigators would reflect the communities being studied. Given the tremendous disparities in our biomedical workforce, we must seek out other realistic solutions. For example, some participants prefer studies that include research staff who share their same culture and with whom they can communicate in their own language. Potential contributors are also more likely to partake when recruited by research staff they personally know or with whom they identify. Town hall meetings and study newsletters can be adapted to the language and reading level requirements of target groups; these can describe how collected data will be used, ensuring transparency and allaying fears stemming from lack of information. Challenges of transportation, childcare, work hour considerations, and meals can be addressed via payment, travel support, flexible recruitment hours and locations, provision of food during study visits, and positioning study sites in areas with diverse residents. To compensate for the limited internal referral base, tertiary care centers can partner with community health care providers. Targeted advertising

(e.g., on public transportation) can reach potential participants at a moderate cost. Nonetheless, outreach and external partnerships introduce costs and effort that can raise recruitment budgets. The Revitalization Act specifically prohibits cost considerations from being a reason to exclude minorities, and NIH study sections are instructed to disregard budgetary requests in evaluating a project's scientific merit. However, our experience in grant reviewing has been that in practice, the size of budgetary requests can bias reviewers. Grant applicants, in turn, react by submitting proposals with inadequate budgets to recruit minority participants so as not to "raise eyebrows" of reviewers.

Minorities would likely to be as willing to be involved in research as whites if problems of diversity could be better addressed. Some of these problems may stem from issues within the research community and its own profound diversity gap. Minority physicians and scientists are more likely to conduct research in minority populations and are often best suited to gain the trust of minority communities, but they are also significantly underrepresented in medical and scientific communities. For example, blacks or African Americans and Hispanics, respectively, represented only 4.3% and 7.2% of doctorate degree awardees in biomedical sciences in 2013, although they represented 13.9% and 17.2% of the US population during the same period. Moreover, less than 2% of NIH principal investigators on research project grants are black, a proportion much lower than in the general US population (10.2%). Similar disparities were observed for Latinos (3.4% versus 12.5%), American Indians and Alaska Natives (0.4% versus 0.7%), and Native Hawaiians and other Pacific Islanders (1.2% versus 10.2%).

To further complicate the picture, an NIH study of research grant awards found that the proportion of applications funded was 13% lower for blacks or African Americans and 4% lower for Asians than among whites. According to demographic information provided by the NIH's Office of Extramural Research under the Freedom of Information Act, the award rate for R01 or equivalent grants has been consistently lower among non-white applicants (Pacific Islander, Native Hawaiian, African American, American Indian, and Asian) than white applicants (42.1% versus 48.6% in 1985 and 19.3% versus 23.3% in 2013).

Contributors to funding disparities arise throughout the research application review process. The NIH has commented on reviewer bias, acknowledging that the probability of funding after peer review does not differ by race, but that minority investigators tend to receive lower priority scores from peer review, indicating that the review process is biased against applications from minority investigators. The relative absence of minority participants throughout the research application evaluation process may contribute to this problem, since underrepresented minorities comprised 10% of NIH study section reviewers in 2000 and only 10.9% in 2013. Increasing minority representation within the research community could in itself promote better science. Diverse research teams are more likely to have diverse ideas, which may explain why manuscripts authored by multi-ethnic research teams are more likely to be cited than publications authored by authors of the same ethnicity. However, since study section members are drawn from the pool of successfully funded researchers, funding disparities have a self-perpetuating effect and functionally eliminate scientists best suited to respond to the call to action we describe.

**How Can the NIH (Re)catalyze Diversity in Research?**

The Revitalization Act intended to re-catalyze diversity in biomedical research by increasing minority representation. President Obama's Precision Medicine Initiative plans to enroll a cohort of 1 million or more Americans that will provide the platform for expanding our knowledge and benefit the nation for many years to come. It is time to heed the President's call to action, given the changing US demographics. The NIH should be empowered to set and enforce recruitment of diverse research populations as the default and require scientific justification for limited or selected study population enrollment, as they have just created policies to do for sex balance. Other US government agencies (e.g., Centers for Disease Control and Prevention, Food and Drug Administration, Agency for Healthcare Research and Quality, Patient-Centered Outcomes Research Institute, Department of Defense) should be similarly empowered. Recruitment approaches should be formally included as criteria for scientific merit scoring, rather than the current application of such criteria after scoring.

In this vein, the NIH should include race/ethnicity as a criterion for assigning priority scores to ensure that well-characterized cohorts and clinical trials not only answer questions relevant to the growing diversity of the US population but are also appropriately statistically powered. The same techniques for monitoring sex/gender inclusion should be used to explicitly review minority accruals over the course of the award, and adjust funding levels accordingly. We believe this would prompt researchers of all racial/ethnic and cultural backgrounds to incorporate understudied populations in their research studies.

To their credit, the NIH is actively addressing many of the issues we have mentioned. Following President Obama's PMI announcement during his 2015 State of the Union address, the NIH has actively solicited feedback to help guide creation of a diverse research cohort of 1 million or more Americans. The NIH has since hosted several workshops to develop a vision for building the national PMI cohort, and maximizing cohort diversity (across socioeconomic standing, geography, sexual orientation, education, and age, in addition to race/ethnicity) has been an ongoing topic at these workshops. In particular, participant and public engagement, diversity and inclusion, and health disparities considerations for the development of a national research cohort were among the topics discussed at a workshop dedicated to participant engagement and health equity.

We applaud and encourage the NIH's focus on diversifying the makeup of the forthcoming PMI cohort. To build on these efforts, an administrative supplement for currently funded research to investigate racial/ethnic differences in health and therapeutics should be created, similar to efforts by the Office of Research on Women's Health to promote discovery of sex differences. This supplement would be hypothesis-generating and show the NIH's commitment to diversify study populations throughout all Institutes. The NIH should also incentivize collaboration amongst groups with similar approaches and data elements so that adequately powered analyses can examine racial/ethnic differences.

Applications from minority-serving institutions should be judged on their capacity to conduct research rather than relying on the institutions' research track records. In our experience, applications from institutions with strong community ties are better equipped to enroll and retain

subjects in clinical and biomedical research. The importance and novelty of studies focused primarily or solely on minority populations should be recognized for their validity and worth, as these may be the only studies to recruit sufficient minority participants to determine whether research findings can be generalized to these populations.

Given the systemic bias against minority scientists, the solution does not lie in simply increasing the number of competitive applicants. To this end, the NIH is actively funding investigations to understand and eliminate discrepancies for minority investigators in the peer review process. In September 2014, the NIH announced winners of two competitions on increasing the fairness and impartiality of the scientific review process and for novel methods of identifying bias. A program assessing the complete anonymization of grant applications is also being piloted. These efforts are part of a larger campaign to identify and root out unconscious bias in peer review. The NIH must act on these data to ensure a just and fair voice for all stakeholders.

NIH proposals passing scientific peer review are forwarded to a second level of review, conducted by Institute and Center (IC) National Advisory Councils or Boards (henceforth referred to as "Councils"). NIH Councils make funding decisions based on the priority score and the priorities of the IC, which have varying levels of discretionary funds. A reasonable way to fund meritorious applications that reflect the diversity priorities of the ICs is to use the discretion of the Councils. Other NIH efforts to increase support for the diversity pipeline (e.g., NIH's Building Infrastructure Leading to Diversity (BUILD) Initiative) and for diversity-related scientific initiatives are commendable, but in the absence of strong changes throughout the review process, research will continue to suffer.

**Inclusive Research Needs the Support of the Entire Country**

Efforts by the NIH and other agencies to address disparities in research priorities will have limited impact unless broader themes of political and economic inequality are addressed. The most important changes in our approach to science will only come when we consider inclusion and diversity important by default—not just in biomedical science, but in all aspects of society. Homogeneity in study populations will cease when racial/ethnic and socioeconomic diversity are considered socially desirable and social norms, be it in study populations, academic faculty, NIH study sections, or boardrooms and classrooms.

We have suggested a number of measures for the NIH to build upon the Revitalization Act. Despite the Act's stipulation that cost not be used as justification for failure to enroll diverse populations, no discussion of new mandates for NIH-funded research can take place without addressing the crisis of declining inflation-adjusted NIH budgets. Society and patients will benefit when the NIH exercises the full scope of power provided under the 1993 Act: a call for the inclusion of historically under-represented communities in clinical research. The NIH alone will not be able to correct the disparities or inequities of the health care system, but it can send a powerful message that may promote changes in our health care and health science systems. There must be a collective will to prioritize diversifying our study populations, rallied by

outreach to the lay community to educate voters who can exercise their franchise to their own best health care interests.

Fulfilling the promise of the Revitalization Act does not pit a future of precision medicine and the advancement of science against the realization of social justice for under-represented communities. Rather, the choice to study diverse populations is itself a promising path toward sound science. By reprioritizing our approach to clinical research and recruitment, we may accomplish an even greater goal: to usher in a new era of scientific discovery and health prosperity for all citizens of the world.

# Appendix D

***Lack Of Diversity In Clinical Trials Presents Possible Health Consequences – National Public Radio Transcript featuring host Ari Shapiro, Rae Ellen Bichell and Sam Oh***

Despite striking ethnic disparities in the incidence and mortality of diseases like cancer and respiratory disease, minorities are not well represented in clinical trials. A paper out in the journal *PLOS Medicine* says two main barriers to achieving diverse clinical trials are the expense of recruiting minority subjects, and fears of exploitation in medical research.

ARI SHAPIRO, HOST:

About 40 percent of Americans belong to a racial or ethnic minority. But the people who participate in clinical trials are much more homogeneous. These trials are the studies that test whether drugs work and inform doctors' decisions about how to treat their patients. As NPR's Rae Ellen Bichell reports, that mismatch can have big health consequences.

RAE ELLEN BICHELL, BYLINE: Here's the gist of an article this week in the journal PLOS Medicine - clinical trials in biomedical research are too white.

SAM OH: Yeesh (laughter) it's a little jarring to hear it that way.

BICHELL: But that's the reality. Sam Oh is an epidemiologist at UC San Francisco. He was one of a group of 14 researchers who found that diversity in biomedical research does not reflect the American population.

OH: Only 2 percent of cancer studies and less than 5 percent of pulmonary studies have studied enough minorities to provide useful information.

BICHELL: When subjects in clinical trials don't look like the patients who could end up taking the medications, that can be problematic.

OH: And we've known for years that certain drugs don't work on parts of our population.

BICHELL: The blood thinner clopidogrel, or Plavix, doesn't work in most Pacific Islanders. Their bodies don't produce the enzymes required to activate the drug, so taking the medication is like taking a placebo. People with epilepsy who are of Asian descent have to get genetic testing before being prescribed the seizure medication carbamazepine because the drug can severely damage the skin and internal organs of patients with a certain gene variant.

OH: African-Americans and Puerto Ricans don't respond as well to some of the most common asthma controller medications. And that's really a tragedy since these two groups are also the most affected by asthma in the United States.

BICHELL: Coming across disparities like the asthma example, Oh says...

OH: You begin to wonder, well, why is this the case? And part of that reason might be because our studies in the past have not recruited as heavily in those populations.

BICHELL: There are a lot of reasons why minorities are underrepresented in biomedical research, from limited access to the specialty care centers where patients are often recruited to trials to fears of exploitation in medical research based on trials in the past like Tuskegee where researchers crossed serious ethical lines with minority subjects. Dr. Michael Lauer oversees grant applications at the National Institutes of Health.

MICHAEL LAUER: There have been some bad experiences, some very bad experiences which have appropriately led people from minority communities to have less trust in the research environment than they otherwise might have.

BICHELL: But Lauer says the importance of increasing diversity among study subjects has been on NIH radar for almost 30 years. And things are starting to look up.

LAUER: For example, between 2010 and 2014, the proportion of participants in clinical trials who are black has increased from 10 percent to 23 percent.

BICHELL: The review boards that decide which studies will get funding, however, remain mostly white. The community of researchers applying for grants also skews white. That's one of the things Oh and his colleagues say needs to change because people are more likely to sign up for a clinical trial if the recruiter looks like them or at least speaks their language.

OH: So it's really important when you want to do science in diverse communities you have a scientific team and a scientific staff that is also diverse.

BICHELL: As the U.S. becomes more diverse, Oh says, these gaps are more important to fill, and filling them might help make a dent in the estimated $300 billion lost each year to health disparities. Rae Ellen Bichell, NPR News.

# Appendix E

***The Disturbing History of African-Americans and Medical Research Goes Beyond Henrietta Lacks – By Lily Rothman***

Ask a given person what they know about the history of the use of African-Americans as unwilling research subjects and they are likely to mention one infamous incident: Tuskegee. “Such a failure seems almost beyond belief, or human compassion,” TIME wrote when the study made headlines in 1972, as the world learned that for four decades the U.S. Public Health Service had been conducting an experiment in which proven remedies were kept from syphilis patients in Alabama, all of whom were black men. But there's a lot more to that history.

"Tuskegee shouldn’t be the first thing people think of," Harriet A. Washington, the author of Medical Apartheid, tells TIME. "It's the example that the government has admitted to and acknowledged. It's so famous that people think it was the worst, but it was relatively mild compared to other stuff."

With the premiere on Saturday of the HBO film The Immortal Life of Henrietta Lacks, based on Rebecca Skloot's best-selling book of the same name, another piece of the puzzle may get a little closer to the first-to-mind fame of Tuskegee. Lacks was, as TIME explained in its initial review of Skloot's book, a black woman treated unsuccessfully for cervical cancer in 1951, from whose tumor doctors kept a sample of tissue. Her cells provided a breakthrough would prove invaluable to medical research, but her family was kept in the dark even as they themselves became the subjects of scientific interest.

Washington, who has interviewed the Lacks family, says that one problem with the national narrative about Tuskegee is the risk that those unaware of the larger history that surrounds both that study and the story of Henrietta Lacks might think that African-Americans are "overreacting to a single study" if they express distrust of the medical establishment. Rather, as Skloot also notes in her book, distrust like that expressed by the Lacks family is related to what's summed up by the subtitle of Washington's book as The Dark History of Medical Experimentation on Black Americans From Colonial Times to the Present.

"We're talking about something that began in the 17th century," Washington says.

Though the line between therapeutic medicine and research was blurrier at the time, she says it's clear that doctors in the colonial American context would often try out new ideas on white patients when they hoped that the experiment would help the person in question; they would use African slaves and Native Americans as subjects when the point of the research was to benefit others. Perhaps the most infamous example of antebellum medical research being performed on slaves is that of J. Marion Sims, whose innovation of a revolutionary gynecological procedure was made possible by multiple practice runs on enslaved women. Washington also found that slaves' bodies were used for experiments after they died, despite widespread belief that maintaining the body's integrity after death was religiously necessary.

"Historically, one of the larger connections is that, if you're talking about the appropriation of African-American bodies when enslavement was part of the law of the land, that represented an extension of slavery into eternity," she explains.

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When it comes to the 20th century, though slavery was no longer the law, Washington says that there was a widespread belief that people who did not pay for their medical care would "owe their bodies" to the medical community in return. As a result, patients from marginalized communities, like the poor and immigrants, did not receive the same ethical consideration that others did. Though that idea would have applied to poor patients of all races, segregation at the time meant that black patients were confined in many places to "black wards," and they were disproportionately affected.

Washington says that one big misconception she often hears is that in 1951, when Lacks was treated, what happened to Lacks would have been just the common practice at the time. In reality, she has found that — while it is true that the laws and regulations that govern such experimentation have changed between then and now — basic ethical concepts such as informed consent were already very much in play. In fact, she says, especially in the wake of the world learning of Nazi medical experimentation, some organizations kept consent rules that were even more stringent than those in play today. "These conventions tended to be rigorously adhered to when it came to white people," Washington notes.

And, though medical research can be complicated, she believes the basic idea — then and now — is simple: "Subjects who have normal adult intelligence are capable of understanding whether their permission has been asked."

But, if those ethical standards have generally endured, other things have changed. Washington points to 1980 as a turning point, thanks to changes like the law that changed the medical-research economy and a Supreme Court decision that has been interpreted to mean that living things are subject to patents. The need for tissue on which to experiment continues, but now it can be a lot more financially valuable if things work out. Washington believes that economic pressures have led to an erosion in the application of informed consent in the years since.

That's part of the reason why Washington is glad that Henrietta Lacks' name is becoming more famous. "People tend to underestimate the extent and breadth of this," Washington says. "There's no sphere of American medicine that was not touched by the use in research of African-Americans."

# Appendix F

***How the US Government used Black people as guinea pigs – By Leslie Goffe***

*There is a reason why African-Americans do not like to go to their doctors or even to hospital. Many fear that they will be probed, prodded, and experimented upon without their consent, and return home sicker than when they left – or may not return home at all. It is because throughout their long history in the USA, African-Americans have been secretly used as guinea pigs for medical experimentation by various American governments. - Leslie Goffe, Washington DC.*

The fear that the us government and medical authorities had been engaged in what has been called a "dark history" of medical experimentation on African-Americans is supported by the release over the past several years of once-secret US government documents showing how, from slavery until today, African-Americans have been America's favourite guinea pig.

During slavery days, when they were recognised in law as only three-fifths of a man, African-Americans were thrown into burning hot pits by white physicians seeking a cure for sunstroke and had boiling water poured on them by white doctors determined to develop a cure for typhoid and pneumonia.

Free to use and abuse African-Americans as they pleased, white surgeons cracked open and probed the brains of black children and operated on the genitals of enslaved black women, all without anaesthetics. One white physician even pressed hot pokers onto the legs and arms of enslaved African-Americans to discover "how deep black skin was."

Reluctant to inflict such horrors on their fellow whites, white physicians and medical researchers found in enslaved African-Americans the perfect substitute. "It was said that blacks didn't experience pain, that they were immune to diseases like malaria and heat sickness that made it impossible for whites to work in the field," says Harriet Washington, an African-American, and author of Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present.

Slavery, Washington writes, probably "couldn't have persisted without the physicians who said blacks were inferior and made by the creator to be the workhorses of the white man." The exploitation of African-Americans for medical research did not end with slavery. It continued long afterwards.

### Ebb Cade's horrific ordeal

In 1945, African-American Ebb Cade was secretly injected with plutonium, the substance used to make nuclear bombs. Cade, a 53-year-old truck driver, was taken to a hospital in Oak Ridge, Tennessee, after breaking several of his bones in a car accident. He became an unwitting guinea pig in a deadly government experiment, and did not realise the doctors caring for him were also employed by the US Atomic Energy Commission. The doctors had been ordered to find out what exposure to plutonium did to the human body.

Injured and helpless in a hospital bed, Ebb Cade was injected with 0.29 microcuries of plutonium-239, more than 40 times the amount a person might expect to be exposed to in an entire lifetime.

A researcher who worked at the hospital in the 1940s described it as “a whopping dose” years later. In their efforts to see the effects of plutonium, the researchers pulled out 15 of Cade’s teeth to measure plutonium levels in his system. They also collected chips of his bones for study. Held in the hospital for more than six months, Cade rightly suspected that it did not take this long for his broken bones to heal and that he was, in fact, being kept in hospital to be used as a guinea pig.

So, his broken limbs healed, Cade fled the hospital when doctors and nurses were not looking. But he could not escape what the secret nuclear experiments had done to him. Described by doctors when he arrived at the hospital in Oak Ridge as a “well developed and well-nourished coloured male in good health”, Cade died a few years later of heart failure, aged 61.

Undaunted by what it had done to Cade in 1945, the US government targeted other African-Americans for experimentation in the 1950s. Early in that decade, the CIA and the US military released close to half a million mosquitoes infected with yellow fever and dengue fever into several black neighbourhoods in Florida.

The mosquitoes were dropped from planes in special paper bags designed to burst open when they hit the ground, sending the infected insects off to bite as many African-Americans as they could. The military wanted to find out whether the mosquitoes could prove to be an effective weapon of war that could be used to infect, incapacitate, and kill America’s enemies.

Dozens of African-Americans in the mostly black city of Avon Park, in South Florida, became ill and at least eight residents died from the invasion of the mosquitoes. “Nobody knew about what had gone on here for years,” said a long-time resident of Avon Park. “But in looking back, it explained why a bunch of healthy people got sick and died at the time of those experiments.”

**Even in the prisons**

Elsewhere in the USA in the 1950s, African-Americans were being experimented on in prisons. Inmates at a prison in Philadelphia, Pennsylvania, were used as guinea pigs to test toothpaste, skin cream, hair dye, and soap for several pharmaceutical companies. They were also used to test radioactive, toxic, and mind-altering drugs for the US military.

The head of the study, Dr Albert Kligman, told a newspaper in the 1960s how thrilled he was to have such a large, and captive group, to experiment on. “All I saw before me were acres of skin. It was like a farmer seeing a field for the first time.”

There have been hundreds of horrific experiments conducted on African-Americans without their knowledge or consent. But what happened to 600 African-American men in Tuskegee, Alabama, in the American South, between 1932 and 1972 has been described as “arguably the most infamous biomedical research study in US history”.

What happened at Tuskegee was a secret US government study of the effects of syphilis on the human body. It made President Bill Clinton so angry and ashamed that, in 1997, he felt compelled to issue an official apology on behalf of the US government.

“What was done cannot be undone,” Clinton said in a speech in front of the handful of African-American survivors of the Tuskegee syphilis experiment. “But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the US government did was shameful, and I am sorry … To our African-American citizens, I am sorry that your federal government orchestrated a study so clearly racist.”

There have been songs about what happened at Tuskegee – Tuskegee 626 by Gil Scott-Heron. There have been plays about what happened at Tuskegee – the award- winning Broadway play, Mrs Evers’ Boys.

**The wicked study**

In 1932, the US Public Health Service (PHS) launched a study to find out what untreated syphilis did to the human body and chose the town of Tuskegee, in Alabama, to conduct its experiments. It selected 600 poor, African-American sharecroppers living in the Tuskegee area as its guinea pigs. Four hundred of them had contracted syphilis before the study began, but they did not realise they had the disease. The other 200, used as a study control, were free of the disease. All were told they had “bad blood”, which many took to mean they had anemia or some other non-lethal malady.

As an enticement to participate in the study, which became known as “The Tuskegee Experiment”, the men were offered free medical care, and free meals on the days they were examined at the PHS clinic. They were also offered a free funeral. Poor and uneducated, the men gladly accepted, unaware they were guinea pigs in a study that would leave dozens of them dead and their wives and children infected with syphilis.

Shockingly, when penicillin, which cured syphilis, became widely available in the 1940s, the medical researchers elected not to inform the men and even prevented some who suspected they had the disease and wanted to sign up for a syphilis treatment programme, from doing so. “The men’s status did not warrant ethical debate,” Dr John Heller, a director of the syphilis experiment, is reported to have said when the Tuskegee Experiment became public. “They were subjects, not patients; clinical material, not sick people.”

Shocking as this is, perhaps the most shocking thing about what happened in Tuskegee is the role played by African-American health workers, like Eunice Rivers, who helped convince the 600 sharecroppers to participate in the experiments and helped keep them ignorant of what was going on for 40 years. “So far, we are keeping the known positive patients from getting treatment,” Nurse Rivers boasted to her bosses.

Other African-Americans, too, were complicit. The president of the black college, the Tuskegee Institute, allowed his institution to be used by the PHS to conduct its research. Several black physicians aided white researchers in their syphilis experiments.

The Tuskegee Syphilis Study lasted 40 years, until the whistle was blown to the media in 1972 by Peter Buxton, a PHS employee. Before he went to the media, Buxton tried to have the PHS shut down the study, but he was told by the study's directors that it would be continued until all the men had died, been autopsied, and the findings logged.

The New York Times headline of 26 July 1972 that broke the story 40 years ago was emphatic: "Syphilis Victims in US Study Went Untreated for 40 Years; Syphilis Victims Got No Therapy", it said. In all, 28 of the men died of syphilis, and 100 died of complications related to the disease. There were other casualties, too. Of the men's wives, 40 became ill and 19 of their children were born with congenital syphilis.

**Africa, the current guinea pig**

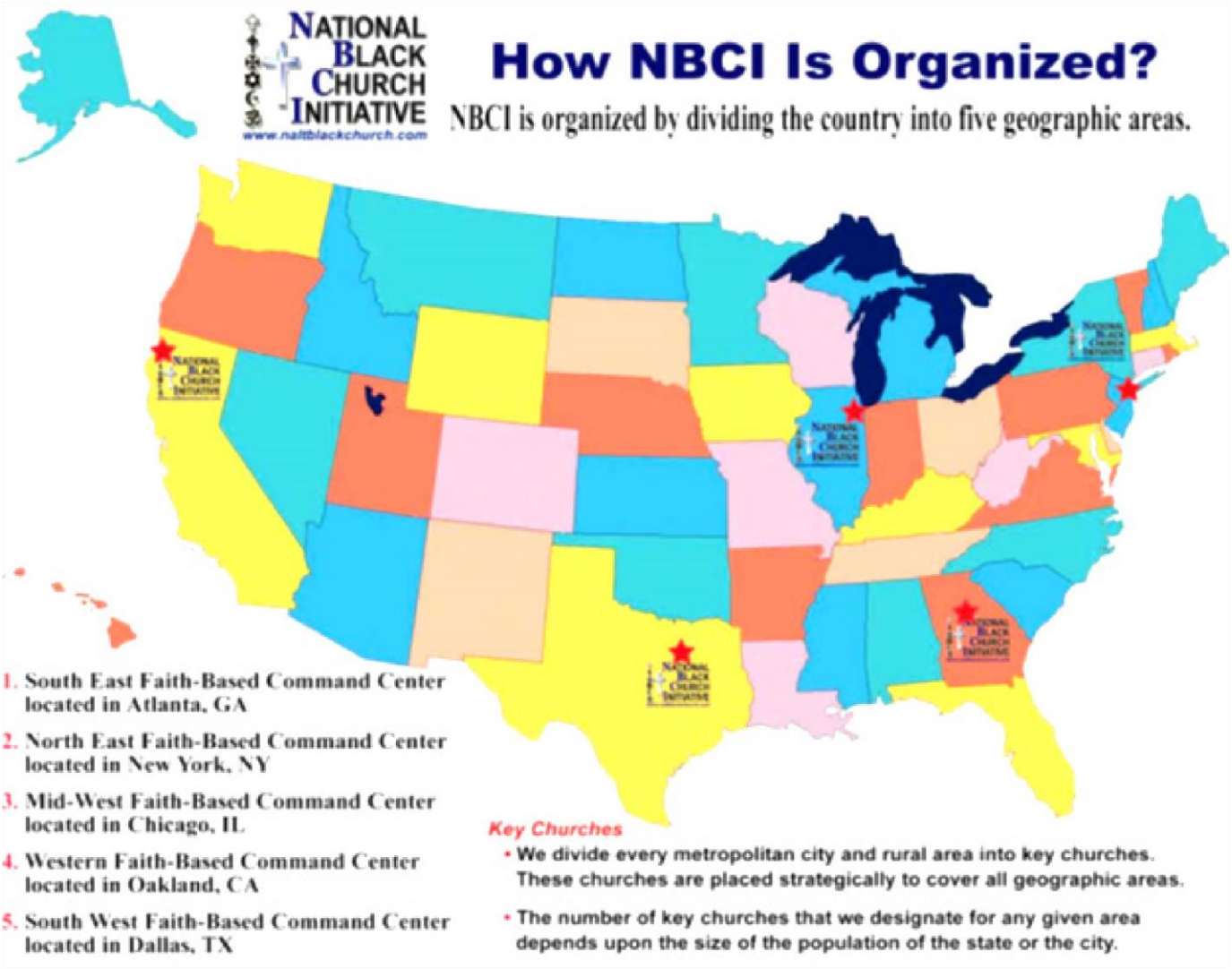
In the wake of the Tuskegee Experiment, the US Congress passed, in 1974, the National Research Act. The laws regulated experimentation on humans and ensured that anyone participating in an experiment be properly informed, beforehand. But despite new restrictions and regulations, experimental abuses continued.

In the 1990s, medical researchers gave a banned diet drug, fenfluramine, to dozens of African-American and Hispanic boys, aged 6 to 10, to see, bizarrely, whether or not the drug could help predict if the boys were likely to become criminals as adults. The boy's families were given $125 for their children's participation in the study.

Harriet Washington, the author of Medical Apartheid, worries that after years of progress, regulations governing medical experimentation are being diluted by pressure from drug companies and medical researchers. She is upset, for example, at recent changes allowing researchers to experiment, without consent, on anyone who seeks care in a hospital emergency room. "I'm very concerned about the erosion of informed consent in this country," says Washington. "I say we have to stop this."

Washington is also concerned about experimentation without consent in Africa, which she says has been a chief target in the past and will be a chief target of foreign researchers in the future. "A lot of the abuse on African-Americans has dissipated," she says, "but that kind of research is being conducted in Africa. They don't have rights. They don't have access to medical care otherwise, and Africa is being treated as a laboratory for the West by Western researchers. It is troublesome."

# Map of NBCI Churches



# NBCI Faith Communities Demographics and Statistical Composition

**NBCI has created a statistical analysis of its churches, locations and demographics**

| | |
|---|---|
| The South-East Faith Command | 16,830 Churches |
| The West Faith Command | 8,502 Churches |
| The Mid-West Faith Command | 3,047 Churches |
| The South West Faith Command | 3,265 Churches |
| The Western Faith Command | 2,356 Churches |

# THE NATIONAL BLACK CHURCH INITIATIVE
# DEMOGRAPHIC AND STATISTICAL COMPOSITION

| Faith Command | No. of Churches | Age Range | Gender % | | Race % | |
|---|---|---|---|---|---|---|
| | | | Male | Female | Black | Hispanic |
| **SOUTHEAST FAITH A COMMAND** *Atlanta, GA* | | | | | | |
| **Florida** | | | | | | |
| Tallahassee | 268 | 30-75 | 36 | 64 | 100 | |
| Miami | 280 | 42-80 34-80 | 35 | 65 | 100 | |
| West Palm Beach | 12 | | 39 | 61 | 100 | |
| Fort Lauderdale | 58 | 45-80 | 35 | 65 | 100 | |
| **Georgia** | | | | | | |
| [B] Atlanta Savannah | 2,560<br>99 | 28-85<br>39-85 | 45<br>34 | 55<br>66 | 100<br>100 | |
| **Louisiana** | | | | | | |
| Baton Rouge | 600 | 45-85 | 34 | 66 | 100 | |
| New Orleans | 356 | 46-85 | 35 | 65 | 100 | |
| **Alabama** | | | | | | |
| [C] Birmingham Montgomery | 780<br>656 | 28-85<br>32-85 | 45<br>45 | 55<br>55 | 100<br>100 | |
| **Arkansas** | | | | | | |
| Little Rock | 86 | 35-85 | 40 | 60 | 100 | |
| **Tennessee** | | | | | | |
| Memphis | 860 | 28-85 | 45 | 55 | 100 | |
| [D] Nashville | 906 | 28-85 | 45 | 55 | 100 | |
| Chattanooga | 458 | 28-85 | 45 | 55 | 100 | |
| **Kentucky** | | | | | | |
| Louisville | 362 | 33-85 | 38 | 62 | 100 | |
| Lexington | 198 | 35-85 | 38 | 62 | 100 | |
| **Mississippi** | | | | | | |
| Jackson | 1,807 | 24-85 | 41 | 59 | 100 | |

| Faith Command | No. of Churches | Age Range | Gender % | | Race % | |
|---|---|---|---|---|---|---|
| | | | Male | Female | Black | Hispanic |
| **E** | | | | | | |
| **North Carolina** | | | | | | |
| Charlotte | 450 | 25-85 | 45 | 55 | 100 | |
| Winston Salem | 346 | 25-85 | 45 | 55 | 100 | |
| Raleigh | 462 | 25-85 | 45 | 55 | 100 | |
| Durham | 241 | 25-85 | 45 | 55 | 100 | |
| Greensbroro | 250 | 25-85 | 45 | 55 | 100 | |
| **South Carolina** | | | | | | |
| **F** Columbia | 838 | 29-85 | 45 | 55 | 100 | |
| Charleston | 99 | 39-85 | 34 | 66 | 100 | |
| **Washington, DC** | | | | | | |
| Washington, DC | 1609 | 45-85 | 40 | 60 | 100 | |
| **Virginia** | | | | | | |
| Richmond | 780 | 28-85 | 45 | 55 | 100 | |
| Northern-Virginia | 656 | 32-85 | 45 | 55 | 100 | |
| **NORTHERN FAITH COMMAND** | | | | | | |
| **A** New | | | | | | |
| **New York** | | | | | | |
| New York City | 2,680 | 47-85 | 32 | 68 | 99 | 1 |
| Albany | 156 | 38-85 | 50 | 50 | 100 | |
| **New Jersey** | | | | | | |
| **B** Newark | 680 | 45-85 | 31 | 69 | 100 | |
| Trenton | 692 | 45-85 | 31 | 69 | 100 | |
| **Pennsylvania** | | | | | | |
| **C** Phildelphia | 1,001 | 38-85 | 35 | 65 | 100 | |
| Pittsburgh | 500 | 43-85 | 35 | 65 | 100 | |

**16,830**

| Faith Command | No. of Churches | Age Range | Gender % | | Race % | |
|---|---|---|---|---|---|---|
| | | | Male | Female | Black | Hispanic |
| **Maryland** | | | | | | |
| [D] Baltimore Prince Georges | 1,008 | 28-85 | 45 | 55 | 100 | |
| County | 985 | 28-85 | 45 | 55 | 100 | |
| **Massachusetts** | | | | | | |
| Boston | 400 | 47-85 | 32 | 68 | 100 | |
| **Connecticut** | | | | | | |
| Hartford | 200 | 38-85 | 38 | 62 | 100 | |
| New Haven | 200 | 39-85 | 38 | 62 | 100 | |
| **MIDWEST FAITH COMM** | **ND** | | | | | |
| A Chicago | | | | | | |
| Ohio | | | | | | |
| Columbus | 162 | 47-85 | 32 | 68 | 100 | |
| [B] Cleveland Dayton | 289 | 47-85 | 32 | 68 | 100 | |
| | 316 | 47-85 | 32 | 68 | 100 | |
| Cincinnati | 186 | 47-85 | 32 | 68 | 100 | |
| **Illinois** | | | | | | |
| C Chicago | 800 | 27-85 | 40 | 60 | 100 | |
| **Kansas** | | | | | | |
| Kansas City | 89 | 38-85 | 38 | 62 | 100 | |
| Topeka | 69 | 38-85 | 38 | 62 | 100 | |
| **Wisconsin** | | | | | | |
| D Milwaukee | 58 | 38-85 | 38 | 62 | 100 | |
| **Michigan** | | | | | | |
| E Detroit | 969 | 38-85 | 38 | 62 | 100 | |

**8,502**

| Faith Command | No. of Churches | Age Range | Gender % | | Race % | |
|---|---|---|---|---|---|---|
| | | | Male | Female | Black | Hispanic |
| **Indiana** | | | | | | |
| Indiannapolis | 109 | 38-85 | 38 | 62 | 100 | |
| **SOUTHWEST FAITH COMMAND** | | | | | | |
| **A** Dalla | | | | | | |
| **Texas** | | | | | | |
| Dallas | 956 | 26-85 | 48 | 52 | 96 | 4 |
| **B** Houston | 1,206 | 26-85 | 48 | 52 | 96 | 4 |
| Forth Worth | 603 | 26-85 | 48 | 52 | 98 | 2 |
| San Antonio | 500 | 26-85 | 48 | 52 | 95 | 5 |
| **WEST FAITH COMMAND** | | | | | | |
| **A** Oaklan | | | | | | |
| **California** | | | | | | |
| Oakland | 1,356 | 41-85 | 33 | 67 | 100 | |
| Los Angeles | 700 | 41-85 | 33 | 67 | 100 | |
| San Francisco | 300 | 48-85 | 32 | 68 | 100 | |

**34,000**

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*"Bringing people together to serve humanity"*

February 4, 2017

Honorable Dr. Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins,

We are writing you to congratulate you and the National Institute of Health on the progress you have made regarding the *NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research*. We know that this is a difficult task for NIH however we also want to express our deep concerns that since 2001 we have not seen nor heard the type of substantial progress that needs to be made in this area. We are concerned because of the impact of the rate of disease in critical areas that affect African American mortality and morbidity. We largely know that is due to the fact that there has been insufficient participation from racial minority groups. The crisis we have is that we do not see nor do we hear any alarms about these concerns in our community.

The National Black Church Initiative (NBCI) is a coalition of 34,000 African American and Latino churches comprised of 15 denominations and 15.7 million African Americans, working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to provide critical wellness information to all of its members, congregants, churches and the public. Our methodology is utilizing faith and sound health science.

We have developed an incredible answer to these concerns and we would like to engage NIH on what we have discovered. Our concerns come from the fact that neither the pharmaceuticals nor the government agencies are knocking down our doors to engage us even though we possess the largest targeted population of African Americans and women in the African American community.

We have developed a brand new and we believe, effective approach through the ***National Black Church Initiative Clinical Trial Education Awareness and Participation Program (CTEAPP)***. We have been engaged with the pharmaceutical community over the past 20 years but neither the government nor the big pharma seem to be terribly concerned about this participation. We have heard from one or two pharmaceuticals over the years but their approach has always been limited and narrow at best.

Instead of them offering us resources to engage us, their approach is to have us prove that the method we have noted above works with our limited resources and it cannot properly work without the necessary resources. This is a government commitment to its citizens. Organizations such as us with the reach that we have should be offered the resources necessary to get the job done and done well with the expert guidance of our own National Institute of Health.

Consider the African American church as a major key stakeholder who has assisted into engaging in clinical trials and providing critical information around drug therapy and compliance. Let us share with you some of the bold actions we have taken in the recent years to be considered a major player in this space:

> We have engaged our membership concerning the value of clinical trials. This is the reason why we have created a clinical trial handbook, the ***Clinical Trial Education Awareness and Participation Program*** which you will find enclosed and our material working with the Leukemia and Lymphoma Society.
>
> We have created a lecture series which we will begin several months from now on the values of clinical trials in the African American community. We are very happy and proud to share with you that Dr. Doris Brown who is President of the National Medical Association will be our first speaker.
>
> We have engaged the Partnership for Prescription Assistance to help our low income members with assistance on their drugs.
>
> We are creating the first of its kind website called the Black Church and Clinical Trials to make it easier for our members to participate in clinical trials. In other words we are trying to create a one stop easily engaged assistant for 150,000 Black Churches in this country.
>
> We are engaged into assisting the National Institute of Health with best practices regarding how to implement and make a reality the 30% participation of African Americans and other racial minorities into clinical trials.

Now you have seen over the past several years what we have accomplished with very little resources, we would like to report to you that when we have asked for assistance from PhRMA and your organization and also other pharmaceutical companies they have not necessarily shown the same enthusiasm that we have shown towards the biopharmaceutical industry.

We understand that this is a learning process, but we have been in this process way too long to still be in the learning phase of it. We appeal to you on behalf of the African American Church to work with us over the next years as we help to implement CTEAPP. We have already spoken to the Trump Administration during the transition and members of the White House on policies towards the pharmaceutical industry and they have told us to keep them abreast of our progress with you.

We would appreciate an opportunity to sit down with you and relevant individuals in your organization to discuss how we can partner together at this incredible juncture in our nation's history regarding research and development issues.

We hope our letter gives you warm feelings of the possibilities of the future that is to come. Our point person is Dr. Owen Garrick at Bridge Clinical who has assisted us in this endeavor. We are very excited.

Sincerely,

The Right Most Rev. Anthony Evans
President
**CC:**

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*"Bringing people together to serve humanity"*

February 4, 2017

Stephen J. Ubl
President and CEO
Pharmaceutical Research and Manufacturers of America®
950 F Street, NW Suite 300,
Washington, DC 20004

**Through:**

Church of God in Christ
African Methodist Episcopal Church
African Methodist Episcopal Zion Church
Christian Methodist Episcopal Church
Full Gospel Baptist Church Fellowship International
National Baptist Convention, USA, Inc.
National Baptist Convention of America, Inc.
Progressive National Baptist Convention, Inc.
Pentecostal Assemblies of the World, Inc.
The Union of Black Episcopalians
National Council of Churches
International Council of Community Churches
Unity Fellowship Church Movement
Mount Calvary Holy Churches of America
Greater Mount Calvary Holy Church
American Baptist Churches
Berean Missionary Baptist Church
The Potter's House

Dear Mr. Ubl,

We are writing you to express our support for PhRMA's new initiative GOBOLDLY to highlight the men and women who are the unsung heroes, doing the heavy lifting in bringing us critical new drugs and innovative therapies. We believe that this is one of the only ways to close the health disparity gap and this is why we are supportive of this and other initiatives that will move us closer to parity.

The National Black Church Initiative (NBCI) is a coalition of 34,000 African American and Latino churches comprised of 15 denominations and 15.7 million African Americans, working to eradicate racial disparities in healthcare, technology, education, housing, and the environment. NBCI's mission is to

provide critical wellness information to all of its members, congregants, churches and the public. Our methodology is utilizing faith and sound health science.

We have been engaged with the pharmaceutical community over the past 20 years and this is the reason why we are excited about what you are doing and the reason why we wrote President Trump about the concerns surrounding research and development when he highlighted the biopharmaceutical industry's pricing issues.

We would like to engage PhRMA once again to make sure that whatever initiative you launch in the future that you consider the African American church as a major key stakeholder who has assisted into engaging in clinical trials and providing critical information around drug therapy and compliance. Let us share with you some of the bold actions we have taken in the recent years to be considered a major player in this space:

> We have engaged our membership concerning the value of clinical trials. This is the reason why we have created a clinical trial handbook, the ***Clinical Trial Education Awareness and Participation Program*** which you will find enclosed and our material working with the Leukemia and Lymphoma Society.
>
> We have created a lecture series which we will begin several months from now on the values of clinical trials in the African American community. We are very happy and proud to share with you that Dr. Doris Brown who is President of the National Medical Association will be our first speaker.
>
> We have engaged the Partnership for Prescription Assistance to help our low income members with assistance on their drugs.
>
> We are creating the first of its kind website called the Black Church and Clinical Trials to make it easier for our members to participate in clinical trials. In other words we are trying to create a one stop easily engaged assistant for 150,000 Black Churches in this country.
>
> We are engaged into assisting the National Institute of Health with best practices regarding how to implement and make a reality the 30% participation of African Americans and other racial minorities into clinical trials.

Now you have seen over the past several years what we have accomplished, we would like to report to you that when we have asked for assistance from PhRMA, your organization and also other pharmaceutical companies they have not necessarily shown the same enthusiasm that we have shown towards the biopharmaceutical industry. We understand that this is a learning process, but we have been in this process way too long to still be in the learning phase of it. We appeal to you on behalf of the African American Church to work with us over the next months as we help to implement these critical phases in development which are listed above and engage the Trump Administration on policies towards the pharmaceutical industry.

We would appreciate an opportunity to sit down with you and relevant individuals in your organization to discuss how we can partner together at this incredible juncture in our nation's history regarding research and development issues, pricing and other affinity issues.

Sincerely,

The Right Most Rev. Anthony Evans
President

**CC:**

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