Data, Resource and Access Challenges for Underrepresented Researchers: How Will the All of Us Research Program Disrupt This Counter-Productive Paradigm?

THOUGHT LEADERS IN PRECISION MEDICINE
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Keith C. Ferdinand, MD, FACC, FAHA, FNLA, FASH
Professor of Medicine
Tulane University School of Medicine
Tulane Heart and Vascular Institute
All of Us Research Program: core values guiding development and implementation

• Participation is open to all.
• Participants reflect the rich diversity of the U.S.
• Participants are partners.
• Participants have access to their information.
• Data will be accessed broadly for research purposes.
• Security and privacy will be of highest importance.
• The program will be a catalyst for positive change in research.

https://allofus.nih.gov
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https://allofus.nih.gov
Figure 4. Disparity between U.S. diabetes trials participants and incidence (new cases) of diabetes. *FDA data, 1998-2001; represents 80% known diabetes trial participants. **New cases in the U.S. in 2005.
Recruiting and engaging AA men in health research

• Improving health of US black/minority ethnic men continues to be a public health priority.
• AA men - higher rates of mortality and morbidity from chronic diseases including cancer, CVD, prostate cancer, DM and HIV/AIDS.

One way to address disparities in CR: AA men

- Include AA men in CR, to elicit their perspectives on health risks and protective factors.
- These can then inform interventions aimed at reducing health disparities.
- However, challenges remain in recruiting and engaging AA men in health research.

Factors Which Impact Minority Enrollment

There are many reasons for the discrepancy in disease incidence versus clinical trial population. The factors rely on both patients and sponsors. Dr. Alanis outlined the top ten reasons why minorities do not participate in clinical trials:

1. Mistrust in healthcare system, lack of consent
2. It will delay the clinical trial
3. Retention is poor
4. Compliance is poor
5. It will add complexity
6. It will add significant cost
7. Do not have the time (childcare, lost wages, etc.)
8. Language barriers (Hispanics, Asian, others)
9. Ignorance/lack of education
10. Cultural attitudes
## NHLBI ALLHAT Baseline Characteristics

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<tr>
<th></th>
<th>Chlorthalidone</th>
<th>Amlodipine</th>
<th>Lisinopril</th>
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<td>Number</td>
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<td>9,048</td>
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<table>
<thead>
<tr>
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<th>Amlodipine</th>
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<td>Mean SBP/DBP</td>
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<td>146 / 84</td>
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<td>Mean age, y</td>
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<tr>
<td>Women, %</td>
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<td>Hx of CHD, %</td>
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<td>Type 2 DM, %</td>
<td>36</td>
<td>37</td>
<td>36</td>
</tr>
</tbody>
</table>
N=1050

Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure

Anne L. Taylor, M.D., Susan Ziesche, R.N., Clyde Yancy, M.D., Peter Carson, M.D., Ralph D'Agostino, Jr., Ph.D., Keith Ferdinand, M.D., Malcolm Taylor, M.D., Kirkwood Adams, M.D., Michael Sabolinski, M.D., Manuel Worcel, M.D., and Jay N. Cohn, M.D., for the African-American Heart Failure Trial Investigators*
Comparison of Efficacy and Safety of Rosuvastatin Versus Atorvastatin in African-American Patients in a Six-Week Trial

Keith C. Ferdinand, MD,\textsuperscript{a,*} Luther T. Clark, MD,\textsuperscript{b} Karol E. Watson, MD, PhD,\textsuperscript{c}
Ryan C. Neal, MD,\textsuperscript{d} Clinton D. Brown, MD,\textsuperscript{b} B. Waine Kong, PhD, JD,\textsuperscript{e}
Boisey O. Barnes, MD,\textsuperscript{f} William R. Cox, MD,\textsuperscript{g} Franklin J. Zieve, MD, PhD,\textsuperscript{h}
Jonathan Isaacsohn, MD,\textsuperscript{i} Joseph Yčas, PhD,\textsuperscript{j} Philip T. Sager, MD,\textsuperscript{j} and Alex Gold, MD,\textsuperscript{j}
for the ARIES Study Group\textsuperscript{f}

The lipid-modifying effects of statin therapy in hypercholesterolemic African-Americans have not been well characterized. This study compared the efficacy and safety of rosvastatin and atorvastatin treatment for 6 weeks in hypercholesterolemic African-American adults. In the African American Rosuvastatin Investigation of Efficacy and Safety (ARIES) trial (4522US/0002), 774 adult African-Americans with low-density lipoprotein cholesterol \( \geq 160 \) and \( \leq 300 \) mg/dl and triglycerides \(< 400 \) mg/dl were randomized to receive open-label rosvastatin 10 or 20 mg or atorvastatin 10 or 20 mg for 6 weeks. At week 6, significantly greater reductions in low-density lipoprotein cholesterol, total cholesterol, non–high-density lipoprotein cholesterol, and apolipoprotein B concentrations, as well as lipoprotein and apolipoprotein ratios, were seen with rosvastatin versus milligram-equivalent atorvastatin doses (analysis of variance with Bonferroni-adjusted critical \( p < 0.017 \) for all comparisons). Rosuvastatin 10 mg also increased high-density lipoprotein cholesterol significantly more than atorvastatin 20 mg (\( p < 0.017 \)). Although statistical comparisons were not performed, larger proportions of rosvastatin-treated patients than atorvastatin-treated patients achieved National Cholesterol Education Program Adult Treatment
Spoken and Unspoken: Mistrust of the Healthcare System
Spoken and Unspoken: Mistrust of the Healthcare System
Are Racial and Ethnic Minorities Less Willing to Participate in Health Research?

David Wendler, Raynard Kington, Jennifer Madans, Gretchen Van Wye, Heidi Christ-Schmidt, Laura A. Pratt, Otis W. Brawley, Cary P. Gross, Ezekiel Emanuel

1 Department of Clinical Bioethics, National Institutes of Health Clinical Center, National Institutes of Health, Bethesda, Maryland, United States of America, 2 Office of Behavioral and Social Sciences Research, National Institutes of Health, Bethesda, Maryland, United States of America, 3 National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, Maryland, United States of America, 4 Department of Epidemiology, Yale University School of Medicine, New Haven, Connecticut, United States of America, 5 Statistics Collaborative, Washington, D.C., United States of America, 6 Winship Cancer Institute, Emory University, Atlanta, Georgia, United States of America, 7 Section of General Internal Medicine, Yale University School of Medicine, New Haven, Connecticut, United States of America

Abstract

Background

It is widely claimed that racial and ethnic minorities, especially in the US, are less willing than non-minority individuals to participate in health research. Yet, there is a paucity of empirical data to substantiate this claim.

Methods and Findings

We performed a comprehensive literature search to identify all published health research studies that report consent rates by race or ethnicity. We found 20 health research studies that reported consent rates by race or ethnicity. These 20 studies reported the enrollment decisions of over 70,000 individuals for a broad range of research, from interviews to drug treatment to surgical trials. Eighteen of the twenty studies were single-site studies conducted exclusively in the US or multi-site studies where the majority of sites (i.e., at least 2/3) were in the US. Of the remaining two studies, the Concorde study was conducted at 74 sites in the United Kingdom, Ireland, and France, while the Delta study was conducted at 152 sites in Europe and 23 sites in Australia and New Zealand. For the three interview or non-intervention studies, African-Americans had a nonsignificantly lower overall consent rate than non-Hispanic whites (82.2% versus 83.5%; odds ratio OR = 0.92; 95% confidence interval CI 0.84–1.02). For these three studies, Hispanics had a nonsignificantly higher overall consent rate than non-Hispanic whites (86.1% versus 83.5%; OR = 1.37; 95% CI 0.94–1.98). For the ten clinical intervention
Conclusions

We found very small differences in the willingness of minorities, most of whom were African-Americans and Hispanics in the US, to participate in health research compared to non-Hispanic whites. These findings, based on the research enrollment decisions of over 70,000 individuals, the vast majority from the US, suggest that racial and ethnic minorities in the US are as willing as non-Hispanic whites to participate in health research. Hence, efforts to increase minority participation in health research should focus on ensuring access to health research for all groups, rather than changing minority attitudes.
Are Racial and Ethnic Minorities Less Willing to Participate (WTP) in Health Research?

Figure 2. Comparison of African-American versus non-Hispanic White Consent Rates

Willingness of Minorities to Participate in Biomedical Studies: Confirmatory Findings from a Follow-Up Study Using the Tuskegee Legacy Project Questionnaire

Ralph V. Katz, DMD, MPH, PhD; B. Lee Green, PhD; Nancy R. Kressin, PhD; Cristina Claudio, PhD; Min Qi Wang, PhD; and Stefanie L. Russell, DDS, MPH, PhD

Financial support: The three-city research subject study was supported by NIDCR/NIH grant U54 DE 14257, the NYU Oral Cancer Research on Adolescent and Adult Health Promotion, an Oral Health Disparities Research Center.

Objectives: The purposes of this analysis were to compare the self-reported willingness of blacks, Puerto-Rican Hispanics and whites to participate in research projects in biomed.
WTP Minorities in Biomedical Research

The findings from the current three-city study, ...reinforce the conclusion that blacks and Hispanics self-report that, despite having a higher fear of participation, they are just as likely as whites to participate in biomedical research.

Racial Differences in Factors that Influence the Willingness to Participate in Medical Research Studies

VICKIE L. SHAVERS, PHD, CHARLES F. LYNCH, MD, PHD, AND LEON F. BURMEISTER, PHD

PURPOSE: The relative absence of racial/ethnic minorities among medical research subjects is receiving considerable attention because of recent government mandates for their inclusion in all human subject research. We examined racial differences in the prevalence of sociocultural barriers as a possible explanation for the underrepresentation of African Americans in medical research studies.

METHODS: During 1998–1999, a total of 198 residents of the Detroit Primary Metropolitan Statistical Area (PMSA) participated in a survey that examined impediments to participation in medical research studies. Chi square tests and logistic regression analyses were used to examine the association between race, issues related to trust of medical researchers, and the willingness to participate in medical research studies.

RESULTS: Study results indicate that African Americans and whites differ in their willingness to participate in medical research. Racial differences in the willingness to participate in a medical research are primarily due to the lower level of trust of medical research among African Americans. African American respondents were also somewhat less willing to participate if they attribute high importance to the race of the doctor when seeking routine medical care, believed that minorities bear most of the risks of medical research, and if their knowledge of the Tuskegee Study resulted in less trust in medical researchers.

CONCLUSION: These data reiterate the need for medical researchers to build trusting relationships with minority communities. Researchers can begin by acknowledging the previous medical abuse of minority research participants, discussing their specific plans to assure the protection of study participants, and explaining the need for the participation of racial/ethnic minorities including studies that specifically target or that are likely to result in disproportionate representation of racial/ethnic minorities among study participants.

Ann Epidemiol 2002;12:248–256. © 2002 Elsevier Science Inc. All rights reserved.
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<table>
<thead>
<tr>
<th>Belief</th>
<th>African Americans (%)</th>
<th>Whites (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks are equally shared by all racial/ethnic groups</td>
<td>34.6</td>
<td>40.5</td>
</tr>
<tr>
<td>Risks are not equally shared by all racial/ethnic groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Minorities bear most of the risk</strong></td>
<td>25.2</td>
<td>5.2</td>
</tr>
<tr>
<td><strong>Other racial/ethnic groups bear most of the risk</strong></td>
<td>8.2</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Group bearing most of the risk not specified</strong></td>
<td>32.0</td>
<td>49.3</td>
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<td>Risks are equally shared by the rich and the poor</td>
<td>22.8</td>
<td>57.8</td>
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<tr>
<td>Risks are not equally shared by the rich and the poor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The poor bear most of the risks</td>
<td>65.9</td>
<td>42.2</td>
</tr>
<tr>
<td>The rich bear most of the risks</td>
<td>11.3</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^a\)Weighted proportion.
Need for Diversity in Clinical Researchers

https://www.uab.edu/medicine/diversity/initiatives/minorities/history
Need for Diversity in Research and Care

• Minority providers more likely than their Whites to practice in underserved minority communities.

• As such, diversity is an important element of a patient-centered health care and research

www.ahrq.gov
Primary drivers of low minority representation are poor "clinical research literacy" and
Access to centers involved in clinical trials.
Difference in distrust of physicians or PIs less a factor today vs. previous decades,
but lack of trust lies in the entire public, not just minorities
Physician’s race and gender may influence the race and gender of study volunteers.
The Project IMPACT Experience to Date: Increasing Minority Participation and Awareness of Clinical Trials

James H. Powell, MD; Yolanda Fleming, BA; Cheryl Lynn Walker-McGill, MD, MBA; and Michael Lenoir, MD

Objective: This study evaluated activities of Project IMPACT (Increase Minority Participation and Awareness of Clinical Trials), a National Medical Association (NMA) project chartered to identify ways to increase minority physician and patient involvement in clinical trials. Project IMPACT included physician education and training workshops, establishment of a physician-investigator database and other activities to facilitate minority-physician clinical trial participation.

Methods: A descriptive survey was used. The survey was distributed to 542 African-American physicians. Physicians were queried about prior involvement in clinical research, barriers and facilitators to clinical trial participation by patients and physicians, and perceptions regarding Project IMPACT.

Results: Two-hundred physicians responded to the survey. Common practice characteristics were self-employment (51%), solo practice (39%) and office based (58%). Prior involvement in clinical trials was generally low. Barriers to participation included lack of awareness of clinical trial opportunities and lack of resources to conduct clinical trials. However, most respondents had referred patients to clinical trials.

severity of disease than whites for most if not all of the leading causes of morbidity and mortality in the United States. These include heart disease, cancer, stroke, diabetes and unintentional injuries. If issues of health disparities are to be addressed appropriately, it is important that observations from clinical trial populations that are sufficiently diverse with respect to the race and ethnicity of the participants and the investigators be incorporated into evidence-based medical practice. Indeed, well-designed, adequately controlled clinical trials are the basis for modern clinical decision-making in the prevention, diagnosis and treatment of disease, and in the development of policies that guide medical interventions. Therefore, racial and ethnic minority groups must be active in all aspects of biomedical research if disparities in health are to be overcome.

Innovative discovery and development of pharmaceutical and biotechnology products have had a tremendous impact on the quality and quantity of life the American population has come to enjoy over the past century. Diseases such as cancer, diabetes, asthma, depression,
Conclusions: Minority physicians are interested in participating in clinical trials. However, multiple barriers, including lack of awareness and lack of access to clinical research coordinators, continue to exist and must be addressed. Clinical trials training programs alone are not enough.
Race, Medical Researcher Distrust, Perceived Harm, and Willingness to Participate in Cardiovascular Prevention Trials

Joel B. Braunstein, MD, MBA, Noëlle S. Sherber, MD, Steven P. Schulman, MD, Eric L. Ding, ScD, and Neil R. Powe, MD, MPH, MBA

Abstract: Minority underrepresentation exists in medical research including cardiovascular clinical trials, but the hypothesis that this relates to distrust in medical researchers is unproven. Therefore, we examined whether African American persons differ from white persons in perceptions of the risks/benefits of trial participation and distrust toward medical researchers, and whether these factors influence willingness to participate (WTP) in a clinical drug trial.

self-administered a survey willingness to participate (WTP) N=1440 randomly 13 Maryland outpatient cardiology and general medicine clinics
<table>
<thead>
<tr>
<th>Question</th>
<th>White Participants (n = 460)</th>
<th>African American Participants (n = 257)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>If your doctor wanted you to participate in research, you trust that he/she would fully explain it to you. (% disagree/DK)</td>
<td>12</td>
<td>23</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Do you believe that you can freely ask your doctors any questions that you want? (% no/DK)</td>
<td>2</td>
<td>8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Your doctor would not ask you to participate in medical research if he/she thought it would harm you. (% disagree/DK)</td>
<td>15</td>
<td>25</td>
<td>0.002</td>
</tr>
<tr>
<td>Do you believe that doctors have ever given you treatment as part of an experiment without your permission? (% yes/DK)</td>
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<td>34</td>
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<tr>
<td>How likely is it that you, or people like you, might be used as guinea pigs without your consent? (% very likely/somewhat likely/DK)</td>
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<td>73</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>How often, if ever, do you think doctors prescribe medication as a way of experimenting on people without their knowledge or consent? (% very often/fairly often/DK)</td>
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<td>58</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>In deciding what treatments you will get, do you feel that your doctors always try to protect you from unnecessary risk, or do you feel that they sometimes expose you to unnecessary risk? (% expose to unnecessary risk/DK)</td>
<td>22</td>
<td>28</td>
<td>0.05</td>
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## Racial Differences in Response Types to Questions in the Medical Researcher Distrust Index

<table>
<thead>
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DK = don’t know  
Braunstein et al Medicine Volume 87, Number 1, January 2008
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DK = don’t know

Braunstein et al. Medicine Volume 87, Number 1, January 2008
Racial Disparities Among Clinical Research Investigators

Survey 1376 physicians

Kenneth Getz, MBA* and Laura Faden, BA

Evidence shows that minority patients are underrepresented in clinical trials. The development of new drugs and treatments, however, requires that clinical research studies include representative participants, particularly in light of evidence indicating that minority populations sometimes respond differently to prescription medications. Racial disparities among clinical investigators are often cited as a major reason why minority patients are underrepresented in clinical trials. However, there is little to no empirical data to support or refute the prevalence of disparities among clinical investigators. The Tufts Center conducted two online surveys of 1376 physicians. The first survey (N = 859 respondents; 31% response rate) assessed the overall incidence of minority physician involvement in clinical research. The second survey (N = 768 respondents; 20% response rate) assessed the demographics, experience, and infrastructure of minority physicians who have participated in clinical research as a principal investigator or subinvestigator. The results of this study indicate that significant racial disparities exist among clinical investigators. The results also support assertions that physician race influences race of the clinical trial volunteer. The incidence of participation in clinical research among minority physicians is well below that observed among white physicians, more so with regard to U.S. Food & Drug Administration–regulated clinical trials funded by industry. Minority investigators tend to conduct and initiate fewer clinical trials annually. Yet minority and white physician interest in participating in clinical research is similarly high. Minority investigators tend to be younger, with more limited clinical research infrastructure and support than their white counterparts. New strategies, policies, incentives, and reforms are needed to...
Racial Disparities Clinical Research (CR) Investigators: Tufts Center 2 online surveys  N=1376 physicians

• Minority patients underrepresented in clinical trials.
• Racial disparities among clinical investigators often cited as major reason why minorities underrepresented in CR.
• However, there is little to no empirical data to support or refute the prevalence of disparities among clinical investigators.

Racial Disparities Among CR Investigators

- Significant racial disparities exist among clinical investigators.
- Physician race may influence race of the clinical trial volunteer.
- CR participation by minority physicians well below whites, more so with industry trials.
- Minority investigators tend to conduct/initiate fewer clinical trials annually.
- Yet minority and white physician interest in CR is similarly high.
- Minority investigators: younger, more limited CR infrastructure and support.
Racial Disparities Among CR Investigators

• Minority physicians often practice in areas that serve minority communities.

• Physicians properly trained to conduct CR in compliance with federal guidelines- an important source of minorities for trials.

• Along with strategies to raise awareness, educate, and motivate minority physician participation, research sponsors can also assist

Clinical Research (CR) Participation:

• Primary drivers of low minority representation are poor “clinical research literacy” and
• Access to centers involved in clinical trials.
• Difference in distrust of physicians or PIs less a factor today vs. previous decades,
• but lack of trust lies in the entire public, not just minorities
• Physician’s race and gender may influence the race and gender of study volunteers.
Racial Disparities Among CR Investigators

• New strategies, policies, incentives, and reforms needed to address racial disparities among clinical investigators.

• In addition, disparities among both volunteers and investigators need to be tracked more closely and methodically

Kenneth Getz, MBA* and Laura Faden, BA
American Journal of Therapeutics
15, 3–11 (2008)
Pipeline Concerns

• Paucity of black and Hispanic CR investigators
• Racial/ethnic investigators younger, limited research infrastructure and less likely to initiate or be involved in CR
• Lack of representation of black/Hispanic populations important given CVD disparities and overall health
• Continued efforts to enhance recruitment of underrepresented racial/ethnic populations in CR remain a priority
A PERSPECTIVE ON PROMOTING DIVERSITY IN THE BIOMEDICAL RESEARCH WORKFORCE: THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE’S PRIDE PROGRAM

Josephine E.A. Boyington, PhD, MPH, CNS; Nita J. Maithle, PhD; Treva K. Rice, PhD; Juan E. Gonzalez, PhD; Caryl A. Hess, PhD; Levi H. Makala, DVM, MBA, PhD; Donna B. Jeffe, PhD; Gbenga Ogedegbe, MD, MS, MPH; Dabeeru C. Rao, PhD; Victor G. Dávila-Román, MD; Betty S. Pace, MD; Girardin Jean-Louis, PhD; Mohamed Boutjdir, PhD

Aspiring junior investigators from groups underrepresented in the biomedical sciences face various challenges as they pursue research independence. However, the biomedical research enterprise needs their participation to effectively address critical research issues such as health disparities and health inequities. In this article, we share a research education and mentoring initiative that seeks to address this challenge: Programs to Increase Diversity among Individuals Engaged in Health Related Research (PRIDE), funded by the National Heart, Lung, and Blood Institute (NHLBI). This longitudinal research-education and mentoring program occurs through summer institute programs located at US-based academic institutions. Recruited participants are exposed to didactic and lab-based research-skill enhancement experiences, with year-round mentoring over the course of two years. Mentor-mentee matching is based on shared research interests to promote congruence and to enhance skill acquisition.

Program descriptions and sample narratives of participants’ perceptions of PRIDE’s impact

INTRODUCTION

The Journal of Medical Biography recently published an extraordinary story about a man named Vivien Theodore Thomas, an African American who overcame substantial odds to make medical history. He lived in a time of complex social dynamics and encountered significant personal and professional challenges, which led to a career as a laboratory technician, instead of the doctor he had dreamed of becoming. That notwithstanding, he became a notable innovator in the field of cardiac surgery, and an effective mentor to many future leaders. Similar to Mr. Thomas, today’s aspiring investigators from racial and ethnic backgrounds underrepresented in the biomedical sciences, face daunting challenges in their pursuit of biomedical research careers. The lack of “cumulative advantage” gained across the span of the educational experience from kindergarten through graduate school, and “variability in access to mentoring and other resources” are two possible contributory factors.

Since 2006, the National Heart, Lung, and Blood Institute (NHLBI), in recognition of these challenges, has funded a unique, early-career, faculty-targeted, research-skill enhancement,
Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE)

• All-expense-paid Summer Institute, research education and mentoring initiative by NHLBI.

• Expand ethnic/racial representation of individuals who pursue research in NHLBI mission-relevant, scientific areas.

• To 2016, more than 275 early career investigators have benefited
Traditional investigator-driven model for clinical trial patient recruitment vs. an innovative community-driven model.
Conclusion: Crucial Steps to Inclusion

• Set clear goals to ensure a diverse research cohort, targeting underrepresented populations
• Identify minority physician investigators with experience in clinical trials
• Encourage minority physician investigators and their institutions to ultimately enhance underrepresented racial/ethnic population recruitment in clinical trials.
Thank you!