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Introduction

This document aims to inform and guide research investigators and study teams involved in the design and implementation of clinical research studies about the importance of racial and ethnic diversity in clinical research. While acknowledging other populations, based on gender, age, geography and socioeconomic-status, are also underrepresented in clinical research, the focus of this paper is on the underrepresentation of racial and ethnic groups. This lack of diversity is a concern because of potential differences between races and ethnicities in response to therapies, treatment, and screening recommendations which lead to health inequities and poor health outcomes for these groups.

Background

The 2020 Census shows that while the white population is still the largest race or ethnic group, multiracial populations in the US have shown a 276% increase in the last 10 years¹ and yet non-Hispanic whites of European ancestry comprise more than 90% of the population in clinical research.²

The increasing diversity within the human population makes the new FDA guidance to increase diversity in research well-timed and of increasing importance. Research study teams are increasingly being tasked with improving racial and ethnic diversity in clinical research and are looking for methods to achieve this. This may seem as an unnecessary burden for some if their study recruitment goal is being met without regard of being inclusive to these populations, especially when overall 80% of clinical trials don't meet enrollment timelines.³ It may seem that this effort should not apply to them.

Including minority populations often takes additional effort and non-traditional methods to recruit. Participants in clinical trials should represent the patients that are most affected by a particular disease, condition or those who will most likely use the medical products. To address this lack of inclusion, research teams must be deliberate in their recruitment efforts. Investigators should consult with their research teams and community members, before submitting protocols to their Institutional Review Board (IRB) to create a study recruitment plan. Investigators should encourage diversity in the research study team. Racial and ethnic diversity are necessary to have a balanced research team. A component for community education and outreach must also be included in the study design. All of these things may help ease the stigma in minority communities about research.

Recruitment Plans Are Necessary For Success

Every clinical research study should have a recruitment plan. In fact, the study recruitment plan

In an effort to have targeted recruitment and to comply with the FDA's new guidance to enroll more participants from underrepresented racial and ethnic populations into clinical research, some questions need to be addressed early in the process while developing the recruitment plan. Is the plan addressing the prevalence rate of the disease or condition in different racial and ethnic groups? Are the selected sites located in geographical areas with high percentages of minorities? Is the main teaching hospital, where most clinical studies are located, accessible? Is there free parking available or public transportation? Or is a regional site better suited to recruit a certain population? These and many other questions should be discussed upfront.

Recruitment methods should include various communication methods. Of course, there are traditional recruitment methods such as in-person, physician referrals, phone calls, emails, brochures and fliers with pull tabs. However, it is important to include other, often non-traditional methods for recruitment and enrollment such as advertisements with QR codes, REDCap, MyChart, DocuSign and social media. The recruitment plan should also include culturally inclusive advertisement plans. Study teams that have discussions and plans before recruitment begins will be more successful in reaching their goals and will save time because they will not have to pause recruitment while items are being reviewed by their IRB. Research from Tufts Center for the Study of Drug Development highlights that 60% of protocols require one or more amendments (average 2-3) of which 20% are due to protocol design flaws and difficulties recruiting study volunteers. ⁴

Community education and outreach should also be addressed in the study design. Building trust in the community is multi-layered. Dr. Stuart Gansky conducted a study on Caries Prevention in Young Children. One study site had a primarily Latino patient population. He also had staff members who were familiar with the culture of potential participants. The study found that with Latino participants, culturally appropriate interactions included expressing interest in the participants' families and lives in ways that might seem prying to a person from another culture. These relationships were also important in retention.⁸ Diverse study team members and those that have personal knowledge of being a research participant themselves may also lead to overall trust in the system.

We must also acknowledge the fractured relationship of minority groups with medical institutions and clinical research, but look for ways to move forward to regain and maintain trust. The reasons that many African-Americans are reluctant to participate are well-documented and known. The Tuskegee Syphilis Study is often cited as one such reason. However, many decades post-Tuskegee Dr. Jackson T. Wright Jr., a well-trusted researcher in the African-American community, has conducted many multi-site studies with high African American participation. The Systolic Blood Pressure Intervention Trial (SPRINT) study reported 9,361 participants of which 30% are African American. In another study of hypertension by this same physician, the Antihypertensive and Lipid-Lowering to Prevent Heart Attack Trial (ALLHAT),

Research study teams must not take the path of least resistance, but should utilize methods and tools outside of electronic medical record searches to ensure inclusion of minority populations. It may take additional effort and non-traditional methods, but to improve health equity, it is necessary. Evidence-based is the standard for any type of research, but to reach some of these hard-to-reach populations, much of the evidence is still being gathered. Study teams will be the leaders in these efforts in creating diverse, equitable, inclusive, and accessible research recruitment methods. Getting the research messages outside of the main urban hosp

https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_January-2022-1.pdf

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