

Diverse, Equitable, Inclusive, and Accessible Clinical Research Recruitment

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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 is required for NIH submissions. It is primarily written by the PI. The recruitment plan is the roadmap for study recruitment. It should answer more than just where the participants will be recruited. Although it's one of the most important parts of the protocol, most studies have recruitment plans that contain only a few sentences that address how the overall recruitment goal will be attained, such as the clinic of a certain department.

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

Representation in Study Teams Makes a Difference

At an institutional level, diversity in the research study teams is crucial for recruitment and retention. Representation builds trust in minority participants. Investigators should recruit and retain research teams that are diverse in many facets, but more specifically race and ethnicity. When there is diversity on the study team, staff members can easily assist and give feedback when creating culturally inclusive advertisements and messaging. In a study of bias and stereotyping among research and clinical professionals, two findings that emerged for why minorities were not being asked to participate are: 1) recruitment interactions with minority participants were perceived to be challenging, making them not ideal study candidates; and 2) respondents withheld trial opportunities from minorities based on their perceptions.⁵ Creating diversity at the team level, is a strong method to overcome biases that may be present when there is no experience dealing with minority groups. Diversity in the demographics of the team makes the team more relatable and can help minority participants feel more comfortable which can help increase the diversity of the research participant population. This phenomenon is similar to what we see when there is racial concordance between physician and patient resulting in improved healthcare use and lower healthcare expenditures among minority populations.⁶

A study examining HBV knowledge in Seattle's Vietnamese community revealed that while cultural practices contribute to their lack of utilization of health services, they are related to the lack of language appropriate health education, interpreter services, translated material and community health fairs. Culturally tailored education programs that increase liver cancer awareness can be effective in increasing HBV screening among underserved Vietnamese populations.⁷ Having representative staff on the research team, consents in different languages, and training staff on the importance of inclusive recruitment materials are all important facets that help diversify recruitment and build trust with the medical community while advancing health equity.

Building Relationships in the Community Fosters Trust

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), more than 15,000 African Americans participants were enrolled in a study group of 42,000.⁹

As researchers we must not let historical perceptions block us from asking people from underrepresented minority groups to participate in clinical research. People don't participate in things that they are not aware about. Researchers need to develop networks to inform diverse communities about research opportunities. This builds trust and understanding of the clinical research process. There may be groups within your institutions that have community outreach efforts that you may be able to partner with. Community organizations, often sponsor events such as health fairs or community discussions. Leverage those existing opportunities and networks to start building your own connections. Social organizations, such as fraternities, sororities, book clubs, neighborhood clubs, and masonic organizations also provide opportunities for outreach that haven't historically been overburdened with requests.

Conclusion

The resources invested in clinical research demonstrates the importance of successful recruitment and diversifying the participant population in order to achieve the desired study results. In the United States medical and health research spending has reached \$245 billion.¹⁰ The NIH invests approximately \$43 billion of its \$ 45 billion dollar budget on research.¹¹ When 80% of clinical research trials fails to meet enrollment timelines more work must be done. Historically, research studies have relied almost exclusively on White male study participants. Non-Hispanic whites of European ancestry comprise more than 90% of the population in clinical research leaving all minority group participation at a mere 10%.¹² This severe lack of minority representation in clinical research only exacerbates already prevalent health disparities, which is a reason for serious concern. This shortcoming has created gaps in our understanding of diseases and conditions, preventive factors, and treatment effectiveness across populations. These gaps in knowledge can impede the quality of health care decision making, ability to counsel people on ways to reduce their risk, and even the development of more effective medications or interventions.

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 hospital location and to the communities who are underrepresented in clinical research is imperative.

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