Improving Representation in Clinical Trials and Research

Building Research Equity for Women and Underrepresented Groups

The National Academies of Sciences, Engineering, and Medicine undertook the most comprehensive examination to date of the representation of women and underrepresented populations in clinical trials in research. This included a review of the health and economic impact this lack of inclusion has on the United States, a review of factors that prevent full inclusion, and facilitators to broaden representation in clinical trials and research in the United States.

The study committee found that while progress has been made with representation of white women in clinical trials and clinical research, there has been little progress in the last three decades to increase participation of racial and ethnic minority population groups. This underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.

The report emphasizes the urgency needed to address this issue, as failure to do so will only prove more costly over time and will prevent meaningful reductions in disparities in chronic conditions. However, improving representation in clinical trials and research requires an investment of time, money, and effort. Building trust with local communities requires a sustained commitment and presence and investing in systems and technologies to reduce barriers to participation takes resources. This investment is the responsibility of everyone involved in the clinical research landscape, which is complex and involves multiple stakeholders. However, we must *all* make this a priority to drive change on a systems level.

As the largest federal sponsor of clinical trials in the United States, NIH has a large role to play in diversifying the clinical trial enterprise. They have the ability to be an accountability check for individual investigators, as well as provide guidance to Institutional Review Boards (IRBs) on equitable compensation for research participants.

NIH has been working on this issue since 1985 and has made progress in a number of areas, including the representation of women in clinical trials and research, largely thanks to the creation of the Office of Research on Women's Health in 1990. However, key gaps remain.

An analysis commissioned for the report shows that representation of racial and ethnic minority populations in NIH-sponsored trials has largely stalled. Although representation varies widely by institute, it is clear that action is needed to improve representation of racial and ethnic minority populations in clinical trials and research.

In addition to having responsibility as the major federal funder of clinical trials in the Unites States, NIH also runs *ClinicalTrials.gov*, which tracks clinical trial participation in this country. However, major gaps in the collection of data within *ClinicalTrials.gov* means we do not have a full grasp on who is participating in trials in this country. FDA provides an analysis of participants in approved drugs and we were able to analyze data from NIH-sponsored trials, but these leaves many clinical trials unaccounted for.

RECOMMENDATION 1

The Department of Health and Human Services (HHS) should establish an intradepartmental task force on research equity charged with coordinating data collection and developing better accrual tracking systems across federal agencies, including FDA, NIH, CDC, AHRQ, HRSA, IHS, and CMS.

RECOMMENDATION 3

The NIH should standardize the submission of demographic characteristics for trials to *clinicaltrials.gov* beyond existing guidelines so that trial characteristics are labeled uniformly across the database and can be easily disaggregated, exported, and analyzed by the public.

RECOMMENDATION 4

In grant proposal review, the NIH should formally incorporate considerations of participant representativeness in the score-driving criteria that assess the scientific integrity and overall impact of a grant proposal.

RECOMMENDATION 12

Federal regulatory agencies, including OHRP, NIH, and FDA, should develop explicit guidance to direct local IRBs on equitable compensation to research participants and their caregivers.

RECOMMENDATION 13

All sponsors of clinical trials and clinical research (e.g., federal, foundation, private and/or industry) should ensure that trials provide adequate compensation for research participants.

RECOMMENDATION 14

All entities involved in the conduct of clinical trials and clinical research should ensure a diverse and inclusive workforce, especially in leadership positions.

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For additional information regarding the consensus study, visit http://www.nationalacademies.org/cwsem.

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