

## Report on Research Compliance Volume 17, Number 11. October 22, 2020

# Engaging the Community, Looking Inward: Meeting the Imperative of Diversity in Trials

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As the pandemic continues to grip the United States, bringing more illness and death to minorities in particular, and the nation reflects on a summer of unrest over racial injustice, the linked issues of lack of diversity among clinical trial participants and growing health disparities have come to the fore perhaps like no period in recent history.

For institutions and researchers alike, achieving diversity is no longer just a goal: especially for studies aimed at either treatment or vaccines for COVID-19, it has become an imperative. Fortunately for researchers and institutions, there are strategies, tools and ideas to assist with this challenge.

Among common themes: diversity begins at home. Experts say institutions should reflect on the number of their investigators who are members of the minority groups being studied and recommend all trial staff undergo cultural sensitivity training. Another key component of success is ensuring recruitment strategies aren't an afterthought; they must be built into every aspect of a trial, even before a protocol is designed. In addition real—and sustained—community engagement is essential.

In recent weeks, the Food and Drug Administration (FDA) has sought to bring attention to the issue, as has an institutional review board (IRB) firm. The Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard has also made resources available to increase the diversity of trial participants.

MRCT's new report, "Achieving Diversity, Inclusion, and Equity In Clinical Research," was the subject of a Sept. 22 webinar sponsored by the FDA Office of Minority Health and Health Equity.<sup>[1]</sup> FDA representatives were among the members of a work group that helped draft MRCT's 341-page "guidance document," issued in August along with a 129-page "toolkit."<sup>[2]</sup> Other resources are available on a dedicated website, <https://mrctcenter.org/diversity-in-clinical-trials>.

FDA's office of minority health "is committed to reducing health disparities and improving health equity," said Richardae Araujo, FDA associate commissioner for minority health and the office director. She added that "a key priority for our office is working to advance the participation of racial and ethnic minority groups in clinical trials." The webinar was organized to "convene thought leaders and experts to educate and dialogue about the pressing issues that our communities face."

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