

## Report on Research Compliance Volume 20, Number 4. March 23, 2023 In This Month's E-News: April 2023

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◆ During its first meeting of the year, scheduled for March 22–23, the Secretary's Advisory Committee on Human Research Protections (SACHRP) will review a Government Accountability Office (GAO) report that faulted both the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) for spotty oversight of institutional review boards (IRBs). The 11-member committee, which currently has three vacancies, will hear from a "panel of expert speakers addressing the topic of defining stakeholders and evaluating" the quality and effectiveness of human research protection programs and IRBs, according to the agenda described in a March 2 *Federal Register* notice.

SACHRP will also discuss draft FDA guidance, "Ethical Considerations for Clinical Investigations of Medical Products Involving Children Guidance for Industry, Sponsors, and IRBs." The meeting will be held via webcast. Links to watch the webcast will be posted on SACHRP's meeting webpage. (3/16/23)

◆ Researchers who study genomics and genetics should "tailor their use of population descriptors based on the type and purpose of their study, and explain why and how those descriptors were selected in their work," concludes a report by the National Academies of Sciences, Engineering, and Medicine (NASEM), *Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field*.

"If appropriate, researchers should consider using multiple descriptors for each study participant to improve clarity," according to a March 14 news release about the report. "The report offers a decision tree to help researchers choose whether race, ethnicity or indigeneity, geography, genetic ancestry, or genetic similarity are most appropriate for their work. Genetic similarity will be the preferred population descriptor in most cases, though in some instances, other population descriptors may be considered appropriate. In the case of studies investigating the effects of racism on health, for example, racial labels may be appropriate." NIH Acting Director Larry Tabak and two other NIH officials offered praise for the report, saying it "will inform NIH's ongoing efforts to safeguard scientific integrity in genomics and promote the responsible design of research studies so that all populations benefit from scientific advances." (3/16/23)

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