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Report on Research Compliance Volume 20, Number 6. May 25, 2023 After GAO Report, OHRP Asks SACHRP to Tackle Elusive Goal: Define, Measure IRB Effectiveness

By Theresa Defino

After releasing a report requested nearly three years ago, Sen. Elizabeth Warren said the Food and Drug Administration (FDA) and HHS "should clean up the industry to keep patients safe."[1] The industry to which the Democratic senator from Massachusetts was referring is institutional review boards (IRBs) and by patients, Warren meant participants in research studies.

The Government Accountability Office (GAO) found gaps in how FDA and the HHS Office for Human Research Protections (OHRP) oversee all types of IRBs; it also examined consolidation by two large, for-profit IRBs.[2] GAO made four recommendations, including that the agencies "examine approaches for measuring IRB effectiveness in protecting human subjects and implement the approaches as appropriate." How to assess whether IRBs are doing a good job—and first defining what that means—has bedeviled human research protection officials for years. No methods are universally accepted or widely in place today, despite numerous efforts.

Now that task has fallen to the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP), which took a first stab at it during its most recent meeting.[3] Yet, as of this month, SACHRP, whose charter calls for it to have 11 members, was expected to be down to just four due to terms expiring and a lack of new appointments.[4]

"This issue of IRB effectiveness is one that SACHRP has grappled with before, and it remains a difficult" issue, Julie Kaneshiro, acting OHRP director, said at the meeting. She added that OHRP was "really looking for your help and learning from all of you who have been doing some deep thinking about this over the many years."

As with most of its recommendations, these are being drafted by SACHRP's subcommittees and then will be presented to SACHRP for approval. In this case, David Forster, chief compliance officer for WCG, and Susan Kornetsky, director of clinical research compliance at Children's Hospital in Boston, are coauthoring them.

Forster cochairs SACHRP's Harmonization Subcommittee, while Kornetsky is a member of its Subpart A Subcommittee. Forster and Kornetsky facilitated SACHRP's discussions at the meeting.

As Forster pointed out, the assignment is twofold: defining and measuring IRB effectiveness. What SACHRP will need to decide is "what definition of IRB effectiveness is the most important to focus on and measure," Forster said, adding there may be multiple measures.[5]

GAO's specific recommendation is:

"The Secretary of Health and Human Services should ensure that OHRP and FDA convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects and implement the approaches as appropriate. These could include effectiveness measures; peer audits of IRB meetings and decisions; mock protocols; surveys of IRB members, investigators, and human research participants; or other approaches."