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Panel Offers Strategies to Ensure Privacy in Research Recruitment

By Theresa Defino

As academic medical centers (AMCs), hospitals and other sponsors of clinical trials increasingly turn to third-party vendors to find patients and other individuals to enroll in research, they need to take extra steps to safeguard privacy, including signing detailed business associate agreements (BAAs). This may also mean empowering institutional review boards (IRBs) to push back against activities that go too far.

The Secretary's Advisory Committee on Human Research Protections (SACHRP), the highest federal advisory panel concerned with research oversight, recently weighed in on this topic, submitting recommendations to HHS that address often problematic interactions between study sponsors and research subjects.[1]

"The increased frequency and intensity of sponsor and vendor involvement in recruiting subjects and assisting subjects during the course of a trial (for example, with travel arrangements) has made more pressing the need for all parties to understand, respect and plan for honoring their various privacy obligations," SACHRP said.

The past several years have seen "an increasing relationship in both intensity and frequency between sponsors of research on the one hand and the research subjects and research subject families and disease advocacy groups on the other," according to Mark Barnes, partner with Ropes & Gray LLP and co-chair of the SACHRP subcommittee that formulated the recommendations.[2]

This "has led to a number of questions about…what is the appropriate role of a sponsor, either an industry sponsor or academic medical sponsor, in the course of interventional clinical research with living, breathing subjects," he said during the meeting at which the recommendations were approved.

At the same time, industry sponsors are frequently "securing the services of third-party vendors who in turn provide recruitment services," said Barnes. Such organizations may either have their own databases of unknown origin or may "comb" pharmacy or other medical records for potential enrollees. These individuals "would be either approached by their treating physicians, the investigator, and in some plans, the third-party vendor might approach these individuals themselves under the waiver of authorization" or if permitted by a BAA, Barnes said.