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SACHRP: Sharing of Info Doesn't Require Full 'Re-Consent' Process

By Theresa Defino

The term "re-consent" doesn't appear anywhere in federal regulations governing human subjects research, but both investigators and institutional review boards (IRBs) may spend a fair amount of time fretting over the concept, which generally refers to assuring that a research participant wants to remain in a study or has the chance to quit—following the disclosure of relevant new information.

The HHS Office for Human Research Protections asked its advisory panel to study the issue and provide feedback for possible guidance by OHRP. With little discussion because versions had been shared at previous meetings, the Secretary's Advisory Committee on Human Research Protections (SACHRP) last month adopted a series of recommendations that address "circumstances in which participants already enrolled in a study should be provided with relevant new information and have the opportunity to either withdraw from the research or to affirm and document their willingness to continue in the research."

Because much research has to be scaled back or paused because of COVID-19, SACHRP's recommendations may prove especially timely in offering options for both communicating with subjects and IRBs on protocol changes. (For other COVID-19 information, see related stories).

As the recommendations explain, neither the Common Rule nor Food and Drug Administration (FDA) regulations refer to re-consent. But 45 C.F.R. § 46.116(c)(5) states that significant new findings developed during the course of the research "that may relate to the subject's willingness to continue participation will be provided to the subject," SACHRP said.

Yet, "providing new findings is not the same as asking an individual to explicitly review their consent to participate in research and confirm their willingness to continue participation," the committee explained. "The intent of this document is to identify mechanisms for providing new information to participants in a manner that is both consistent with the principle of respect for persons and compliant with the requirements" of the Common Rule, as revised in 2018.