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Chatting Online May Help, Hurt Participants; SACHRP Highlights Planning, IRB Involvement

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People are naturally inquisitive, and those who enroll in clinical and other trials might be more so than most. But what happens if that curiosity prompts them to turn to the internet for information or answers? Particularly for those in blinded studies, learning too much—such as the research arm they might be in—could threaten the integrity of the trial.

On the other hand, after comparing notes with fellow research participants, individuals might discover a nettlesome pain or rash is really an adverse reaction they need to report.

Recognizing more of the potential perils than positives from participants' use of social media, the HHS Office for Human Research Protections (OHRP) asked its advisory committee to look into the issue, including whether it might be appropriate to ban participants from talking about their study on social media.

Such a prohibition could be imposed, but only rarely, and should be addressed in consent forms, according to new recommendations approved by the Secretary's Advisory Committee on Human Research Protections (SACHRP) at its recent meeting.[1]

The recommendations accompany SACHRP's answers to seven questions OHRP posed about research participants and social media. They were drafted by a SACHRP subcommittee co-chaired by David Forster, chief compliance officer for WIRB-Copernicus Group, who led members through the document prior to adoption on Oct. 19.

In the introduction, SACHRP notes that research participants "finding one another and communicating about their experiences" isn't new; this occurred with AIDS activists in the 1980s, for example. But now there is "increasing attention as a result of the steady growth of the use of social media platforms."

Forster credited Janet Freeman-Daily, a lung cancer patient advocate whose term on SACHRP ended in June, with "changing this from just concentrating on the possible negative effects to also including the possible benefits of subjects communicating on social media about research studies they're participating in."

Overall, the document addresses three themes regarding the impact of social media: how it may affect participants' safety, concerns related to scientific validity and potential positive outcomes when used by research subjects.

Social media may be an issue for a variety of trial types, from biomedical to social and behavioral, SACHRP said.

"Most of the concern with scientific validity is going to have to do with multi-arm blinded studies where potentially either the research subjects or the research staff, through the social media discussions, can realize which arm they're on [or staff could] identify which arm various subjects are on," Forster explained. "Maybe it's discussion of what the placebo looks like or the taste, or a side effect of the drug, something like that."