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Report on Research Compliance Volume 18, Number 6. May 20, 2021
SACHRP-Recommended Limits on Sponsor-Subject Interactions

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At its first meeting of the year, the HHS Secretary's Advisory Committee on Human Research Protections forwarded two sets of recommendations to the agency.[1] One addresses the increasingly nettlesome interactions between study sponsors and research subjects and the rise of third-party vendors, outlining a role for institutional review boards (IRBs) in establishing a framework for such interactions and for vendor activities.[2]

Noting that there are other "applicable standards and regulations," including from the Food and Drug Administration, the following are among the principles committee members said "should be respected in sponsor, investigator and site interactions with subjects:"

- "Sponsor or third-party vendor involvement in recruitment activities should not place sponsor or vendor staff in the role of final determination of trial eligibility. These personnel may share and discuss study eligibility information and answer questions from prospective subjects regarding eligibility criteria. With appropriate consents and authorization, these personnel may also collect relevant clinical information relating to prospective subjects, in order to share that information with site investigators, but should avoid acting in the role of the clinician-investigator who ultimately must make eligibility determinations based on their assessments of patients, their medical conditions and their verified medical records.

- "Sponsor or vendor interactions with subjects during the course of studies (for example, continued assistance with lodging and transportation) should respect professional and ethical boundaries, and should avoid personal involvement that could bias study results or give subjects and their families misimpressions of the sponsor's obligations. Sponsors should seek to avoid that in the course of their trial support activities, sponsor personnel (or a vendor's personnel) develop relationships with subjects and their families that exceed the sponsor support activities pre-approved by the IRB and pre-cleared with the investigator.

- "All sponsor and sponsor's vendors' interactions with subjects or prospective subjects must be planned and executed to respect applicable privacy obligations of sponsors and vendors, as well as the privacy obligations of patients' and subjects' health care providers and of research sites and investigators. As a baseline sponsor obligation in these interactions, prospective subjects should be informed of how their personal information will be used and disclosed by the sponsor and/or the sponsor's vendor performing recruitment services.

- "When, in investigator-initiated studies, the sponsor is effectively the AMC [academic medical center] or university employer of the investigator, the AMC or university should approach these issues with a respect for institutional and investigators' responsibilities and duties regarding respect for and protection of human research participants and the integrity of the research process; these responsibilities and duties may be distinct from other institutional interests. For example, it would appear to be over-reaching for an AMC or university to pressure its investigator to persuade unwilling or hesitant subjects to undergo publicity interviews, or even to expect investigators in ongoing trials to become deeply involved in crafting positive trial-specific publicity messaging meant to enhance institutional profile.

- "Sponsors planning contact and/or interactions with enrolled subjects during the course of a study must be transparent about such plans with investigators and with any cognizant IRB or ethics committees. In addition, sponsors should not contact or interact with subjects without the pre-approval of relevant activities by the site investigator and IRB/ethics committee," although there may be some exceptions.
- "Sponsors interacting with subjects during trials (as well as research institutions and investigators interacting with subjects for reasons other than regular medical care or fulfillment of trial protocol requirements) should do so in ways that are least intrusive to subjects and should be respectful of any reluctance of subjects or their families to engage in such interactions. In approaching subjects (which should be done through the site investigator initially), sponsors and investigators must be mindful of the possible perception of subjects and families that they may have little meaningful choice but to cooperate in these 'extra' requests, and should calibrate approaches accordingly.
- "Sponsor and investigator/site requests to subjects and families to engage in media and public relations activities should be confined to the period after the subject has completed his or [her] trial participation. Optimally, such requests and activities would occur after the site has completed study visits for *all* enrolled subjects," and interviews/testimonials "should accurately portray clinical studies as use of unproven, though promising, experimental agents or procedures."