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Report on Research Compliance Volume 16, Number 12. November 20, 2019
SACHRP: Payment for Food, Income, Don't Compromise Research Consent

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Individuals who participate in research trials make some sacrifice to do so, there can be little argument, even if they expect to benefit personally—and many do not. So shouldn't they be compensated in some way, with payments or gifts that recognize their contributions?

But investigators, institutional review boards (IRBs) and institutions have struggled with how to offer payments and tokens without providing "undue influence," as this is not permitted under regulations enforced by the Food and Drug Administration (FDA) or the HHS Office for Human Research Protections (OHRP).

As requested by FDA and OHRP, a federal advisory committee has now weighed in.[1] The Secretary's Advisory Committee on Human Research Protections (SACHRP) recently submitted detailed recommendations on the topic to HHS.

As the committee explains, "SACHRP has been asked to consider whether there is a need for additional updates to guidance related to payments that go beyond reimbursement of participant expense." In particular, "recommendations are sought as to whether and when payments to study participants may constitute an undue influence" as included in FDA regulations 21 C.F.R. § 50.20 and HHS regulations 45 C.F.R. § 46.116.

In 2018, FDA added some nuance to its regulations,[2] noting that an "information sheet" provides "explicit recognition that reimbursement payments do not raise concerns about undue influence."

SACHRP's view is that this document "does not go far enough," and that both FDA and OHRP should issue new guidance that both addresses the fact that "compensation and token appreciation payments [also] do not raise concerns about undue influence."

IRBs Need 'Tools'

The committee "further recommends that FDA and OHRP issue guidance that recognizes the concerns about unduly influential incentive payments can be managed without necessarily lowering or eliminating the payments." SACHRP members believe "such guidance could support IRB decision-making regarding participant payments and encourage appropriate use of payments to facilitate the conduct and completion of research."

IRBs, SACHRP said in its recommendations, "are granted considerable discretion, but few tools, to help them determine when payment (or other benefits) may unduly influence an individual's decision-making about whether to enroll or remain in a research study."

SACHRP lamented that given "the directive from regulators to 'be vigilant,' some IRBs may take a 'better safe than sorry' approach that prioritizes avoiding undue influence but fails to give adequate consideration to other important goals." As the committee notes, "SACHRP believes that this approach is problematic."

As noted, SACHRP recommends guidance that addresses three types of payments: reimbursement of reasonable costs incurred as a result of participation, fair compensation for participants' time and effort, and token payments of appreciation.

SACHRP's letter to HHS provides many details for each that, in the absence of HHS recommendations, are likely to be of significant benefit to researchers and IRBs. The research compliance community has come to rely on SACHRP's documents because OHRP has rarely followed up on the committee's recommendations by issuing formal guidance, a situation that has disappointed SACHRP chairs and members in the recent past.

Under development for several years, SACHRP formally submitted its recommendations to HHS Secretary Alex Azar on Sept. 30.