

Paying research volunteers raises ethical concerns, study concludes

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(Garrison, NY) Researchers almost always offer money as an incentive for healthy volunteers to enroll in research studies, but does payment amount to coercion or undue inducement to participate in research? In the first national study to examine their views on this question, the majority of institutional review board members and other research ethics professionals expressed persistent ethical concern about the effects of offering payment to research subjects. But they differed in their views of the meaning of coercion and undue influence and how to avoid these problems in concrete research situations. The study appears in *IRB*: *Ethics & Human Research*.

The findings are important because the federal regulations for the protection of human subjects -- known as the Common Rule -- state that investigators should seek consent from potential research <u>volunteers</u> under circumstances that "minimize the possibility of coercion or undue influence." The regulations do not define these terms.

The study consisted of an online survey that asked a random sample of IRB members and others involved with upholding ethical standards in biomedical research about their views about different kinds of payments, including money, nonmonetary offers, and medical care.

Of the 610 respondents, 61 percent "reported feeling somewhat, moderately, or very concerned that payment of any amount might influence a participant's decision or behaviors regarding research participation." The higher the payment, the greater the concern. "Most



respondents expressed concern that substantial payment could compromise a participant's ability to think clearly about study risks and benefits (85%), lead individuals to enroll in a trial they otherwise would not enroll in (88%), or remain in one from which they would like to withdraw (84%)," the authors write.

Most respondents agreed that researchers could offer money to reimburse expenses, and many thought that offering money as compensation for time and inconvenience was acceptable.

But the authors conclude that the respondents' views of coercion and undue influence were "excessively expansive, or inconsistent." For example, while more than 90 percent agreed with a definition of coercion tied to threat of harm, most also agreed that research participants are coerced when an offer of payment -- not the threat of harm -- gets them to participate when they otherwise would not.

The findings pose a dilemma to those charged with ethical oversight of human subjects research. According to the authors, unless researchers can offer payment as an incentive to participate in research, people might not enroll in studies and, therefore, much valuable research "is unlikely to be conducted in a timely manner or even conducted at all." And yet IRBs should not approve protocols -- whatever their social or scientific value -- unless the possibility of coercion or undue influence has been minimized. To get around this dilemma, the authors recommend that policy and educational efforts be undertaken to clarify when payment practices actually constitute coercion and undue influence.

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