

# Expert offers suggestions for standardizing subject payments

*Wage-payment model might work well*

Ethicists and others continue to find it troubling that payments to research participants are part of the recruitment process.

"I think a lot of the talk about undue inducement is about compromising someone's judgment," says **Neal Dickert**, PhD, MD, a resident at Johns Hopkins Hospital in Baltimore, MD. Dickert has been studying research participant payments for more than a decade.

"It's not that people are making involuntary decisions," Dickert adds. "But when we think about the role of the human subjects research enterprise, it's disturbing that we would allow unrestricted amounts of money that would encourage people to override certain values that they hold."

For instance, the role of an excessive payment changes according to the study's type and risk.

"Imagine a study where you're doing a finger-stick blood glucose test, which diabetics do all the time," Dickert says. "If you want to pay people \$5 million to take the glucose test, it's hard for me to say something other than 'That's a terrible use of resources.'"

But if the same payment is being made to subjects who are participating in a study that involves significant risk in a product that never before has been tested in humans and where there is a very real concern about toxicity, then that's where IRBs and ethicists will worry a little bit more about the potential impact of money, Dickert explains.

A possible solution to the ethical dilemma of undue inducement for study participation is to standardize how research subjects are paid.

Dickert has studied several models for how payments to participants could be made, and his research has described three types.

## **Market model**

According to this model, participants would be paid according to the potential for benefit and the degree of risk in a study. So if the chance for a benefit is nonexistent and the potential risk is great, then they would receive a greater pay-

ment. Alternately, if they might be motivated to participate because they could be receiving a new drug for their disease, and the risk is proportional to not receiving the treatment, then they might be expected to participate as an unpaid volunteer.<sup>1</sup>

This model could lead to charges of undue inducement, and this model also could provide enough incentive for some people to become professional research participants.

"There are no data that this is happening, but some people have a gut level reaction that people might become professional research subjects," Dickert says.

Even if this were to happen, it might not be ethically misguided unless participants are lying about conditions to meet eligibility or are ignoring adverse events after enrolling so that they might stay in a study, he notes.

"We don't have good evidence to suggest that either of those kinds of things are happening," Dickert says. "This would be a separate kind of issue, if that's the case, where people are distorting their medical history to continue to receive payments."

Another problem with the market model is that it could drive up fees for participants and encourage recruitment for the wrong reasons, he notes.

"By that I mean the studies that happen to have a lot of money to pay subjects will have the best ability to recruit," Dickert says. "It would be unfortunate to have studies compete based on payment."

## **Wage-payment model**

This model suggests that research participation does not require skills, but does require time, endurance, and effort. It has an egalitarian viewpoint that all subjects performing similar functions should be paid similarly.<sup>1</sup>

This would lead to a standardized, low hourly wage with some additional payments to augment the more uncomfortable or burdensome procedures and a completion bonus that is not disproportionately large.<sup>1</sup>

"The amount is calibrated to the typical amount of payment for relatively unskilled labor in the market where the project is being conducted," Dickert says. "I think this is the best way to think through this issue."

Although the amount subjects are paid would be increased for any inconvenience they

experience, it would not be tied to the study's potential risk, he adds.

"You would pay people in a way that appropriately recognizes the kind of job or service that research participants are providing," Dickert says.

"I like the idea of this type of standardization because it prevents competition between studies based on how well they pay subjects," he notes.

One criticism that might be made of this model is that if a site offers relatively low amounts of money for participation then the only people who will find those offers attractive are poor people, Dickert says.

"My counter to that is that we think research is a good thing and people are providing a valuable service," he says.

As long as the compensation is fair, then no single group should be preferentially induced to participate, he adds.

### **Reimbursement model**

This model has research sites paying participants only enough to cover their expenses. It's based on the viewpoint that research participation should be revenue-neutral for participants, and it does not provide financial compensation for participants' effort or discomfort.<sup>1</sup>

The chief drawback would be that the model might make it even more difficult to enroll people in clinical trials.

Dickert favors the wage-payment model because he believes it is the most ethical approach to paying research subjects.

Some more recent research has drawn on his wage-payment model and found it appropriate even for younger children who are recruited to participate in studies involving their specific diseases.<sup>2,3</sup>

IRBs might keep these different types of models in mind. But considering a study's incentive pay should be a separate issue from reviewing the protocol, Dickert says.

"I think IRB members should evaluate a study first and later evaluate the payment that's offered," he says. "If a study is unapprovable, it doesn't matter how much subjects are paid."

Also, investigators, sponsors, and participants would benefit from more explicit and better guidelines regarding payments to participants, Dickert says. ■

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### **References**

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