

## **Clinical Research Ethics Question of the Month: Overnight Caregivers in a Pediatric Study**

**By Norman M. Goldfarb**

You are the member of an institutional review board that has approved a pediatric study. The protocol requires that study participants, accompanied by a responsible adult, stay overnight in a Phase I facility. The investigator is having trouble meeting the study's diversity goals because economically advantaged parents (predominantly Caucasian) are unwilling to spend the night in the facility. However, they would be willing to pay a caregiver to stay with their children, provided the study reimbursing them for the cost. If you approve amending the protocol to include this payment, the other parents (predominately minority) will want the same payment, even if they stay with their children themselves, as is their strong preference. However, that payment could be considered unduly influential. You have no other information to make your decision and no clever way to dodge it.

### **Results**

The 228 respondents answered the following questions:

#### **1. Would you approve payments to caregivers for the overnight stay?**

- 56.2% of respondents would cover the cost or equivalent of any caregiver, including parents.
- 12.0% of respondents would cover the cost of any caregiver other than a parent.
- 31.9% of respondents would not approve payments.

#### **2. If the study covers the cost of a caregiver, should there be a means test?**

- 31.5% of respondents say there should be a means test.
- 68.5% of respondents say there should not be a means test.

#### **3. If the study covers the cost of a caregiver, should it be a set amount?**

- 92.7% of respondents say yes, it should be a set amount.
- 7.3% of respondents say no, it should be the amount charged by the caregiver, within reason.

#### **4. Should the study cover the costs whether or not the parents want it?**

- 45.4% of respondents say the payment should be a condition of participation, whether or not the parents want the payment.
- 20.4% of respondents say the payment should be made unless the parents refuse it.
- 19.9% of respondents say the payment should be made if the parents request it (per the consent form).
- 14.4% of respondents have a different answer. Some respondents do not accept the premise that the study should cover the costs. Others say that, if a payment is not made, that amount should be donated to a charity instead.

#### **5. If the study makes payments to caregivers, who should make them?**

- 65.6% of respondents say the research site should pay the caregivers.

- 20.5% of respondents say the research site should reimburse the parents for making the payments.
- 14.0% of respondents say payments should be made in the most convenient manner.

### **6. What other conditions or rules, if any, should the IRB place on payments to caregivers?**

32% of respondents answered this question. Some respondents would require the caregiver to be qualified, licensed and/or have had a pre-existing relationship with the child. Some respondents would want the site to review and approve non-parental caregivers. Some respondents would want signed documentation that parents have given permission to non-parental caregivers, and that the non-parental caregivers understand their responsibilities and will not to interfere in the conduct of the study.

### **7. Are caregiver payments unduly influential?**

- 13.3% of respondents say "Yes."
- 20.2% say "Yes, if to the parents, no if to some other person."
- 48.7% say "No."
- 17.9% have a different answer, principally that more than a reasonable payment would be unduly influential.

## **Discussion**

Clinical research gets complicated when children or money are involved. In this case, both are central to the question.

Clinical studies often make extra efforts to enroll participants from minority groups who cannot participate for economic or other reasons. This study faces the opposite problem: attracting participants from the majority (Caucasian) population, who are economically advantaged but find participation inconvenient for lifestyle reasons. Whatever the parents' reasons, the FDA requires diversity in study populations.

Over two-thirds of respondents say the study should cover the cost of a caregiver, but perhaps not if the caregiver is a parent (leaving aside out-of-pocket expenses like transportation). It might not be the best policy to incentivize parents to hire caregivers rather than accompany their children.

Most respondents would probably agree that payments should be fair and reasonable, although there is a wide range of opinion on the definitions of "fair" and "reasonable." Only 7% would require a means test, which is helpful, since it is the economically advantaged parents who are insisting on caregiver compensation.

Almost half of the respondents would insist that parents accept payment for caregivers, and additional respondents would donate unaccepted payments to a charity. The basis for these positions might be that all participants should be treated equally whether they like it or not.

The question of "fair and equal" treatment in this case, as it is with participant stipends, does not have an easy answer. One argument is that everyone should receive the same amount, but that can be trivial for the wealthy and unduly influential for the poor. Another argument is that payments should be based on need, but why should the wealthy be penalized for their hard work and/or good fortune? A third argument is that payments should be calibrated to have the same economic impact on everyone, but that would create a wide range from the poor to the wealthy. In this case, economically advantaged parents might pay much more for childcare than economically disadvantaged parents. Setting a low flat rate might not be acceptable to economically advantaged parents, the very people the

payments are intended to satisfy. Setting a high flat rate might be unduly influential for economically disadvantaged parents. Perhaps a number in the middle would work for most parents. One approach might be to establish a range based on the actual amount charged by the caregivers, but what would prevent the parents and caregivers from saying that *their* payment needs to be at the top end of the range?

This situation thus leaves the IRB with a judgment call, potentially after a long and ultimately unsatisfying discussion.

### **Next Month's Question:**

As a member of an institutional review board, you are reviewing a study in a geriatric population. The investigator wants to enroll patients in a nursing home. Certain residents of the nursing home meet the study's eligibility criteria in all respects. The only catch is that some of them have intermittent cognitive capacities. In other words, at some times, they are competent to give informed consent but, at other times, they are not...

Read the full question and give us *your* answer at:  
<https://www.surveymonkey.com/r/GVWBM3S>.

***Please send your ethical conundrums to [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).***

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