

Clinical Research Ethics Question of the Month: Stipends Based on Income

By Norman M. Goldfarb

You are a member of an IRB reviewing a study with an unusual feature: Because the study population will be very diverse economically, the investigator wants to vary the stipend based on each study participant's financial situation. Her reasoning is that a fixed stipend for everybody would exploit high-income people but unduly influence low-income people. For the purposes of this survey, the investigator knows everyone's income.

Question 1. Will you vote to approve this approach to stipends?

Of the 148 respondents, 7% would vote to approve the study and 93% would not.

Multiple respondents said that everyone should be treated the same as a matter of principle. A few respondents cited the principle of justice.

Multiple respondents said it would be an invasion of privacy to collect financial information.

Several respondents said it would be impractical to collect accurate financial information.

One respondent would not participate in a study that asked about income.

Several respondents were skeptical of the notion that high-income people could be exploited: "To the rich, money is not the concern."

Several respondents said that stipends are intended to cover costs and inconvenience, which are the same for everyone.

Several respondents expressed concern that differential payments would create controversy among the participants: "I would be upset if I found out that someone wealthier than I was being given more money just because of their wealth."

Several respondents disputed the notion, either explicitly or implicitly, that the time of high-income people is more valuable than the time of low-income people: "Stipends should reflect time and travel, which should be valued equally, regardless of participants' income."

Several respondents said that stipends can cover the cost of missing work, but most did not connect that concept with the fact that some people have higher salaries/wages than others.

Several respondents would want to know the purpose of the stipend. Would it be to cover costs, time and/or inconvenience, or would it just be a "thank you" to participants?

Multiple respondents suggested that differential stipends might introduce sampling or other bias into the study. On the other hand, one respondent suggested that differential stipends might produce a more representative study population.

One respondent said money should not be the motivator for trial participation in the first place. Another respondent said stipends don't make much difference in the decision to participate. Another respondent said, "Low-income people are more likely to agree if they see the study as an easy paycheck." Several respondents said, in various words, "To the rich, money is not a factor and it will not unduly cause them to enter the trial."

Several respondents suggested that travel costs and time for low-income people might be higher than for high-income people. Taking time off from work and dealing with child care is likely to have a heavier impact on low-income people.

One respondent said that differential stipends would show disrespect for low-income people in that the investigator would be treating them as less-valued individuals.

One respondent noted that income and wealth do not necessarily correlate with interest in money. For example, a poor person with a drug addiction might have a very high interest in money.

One respondent said, "Ideally, we would roughly compensate at an hourly rate equivalent to what participants would otherwise earn, to avoid coercion or undue burden." Another respondent said, "In no sense should the stipend be intended as pay for service."

One respondent suggested donating the difference to charity.

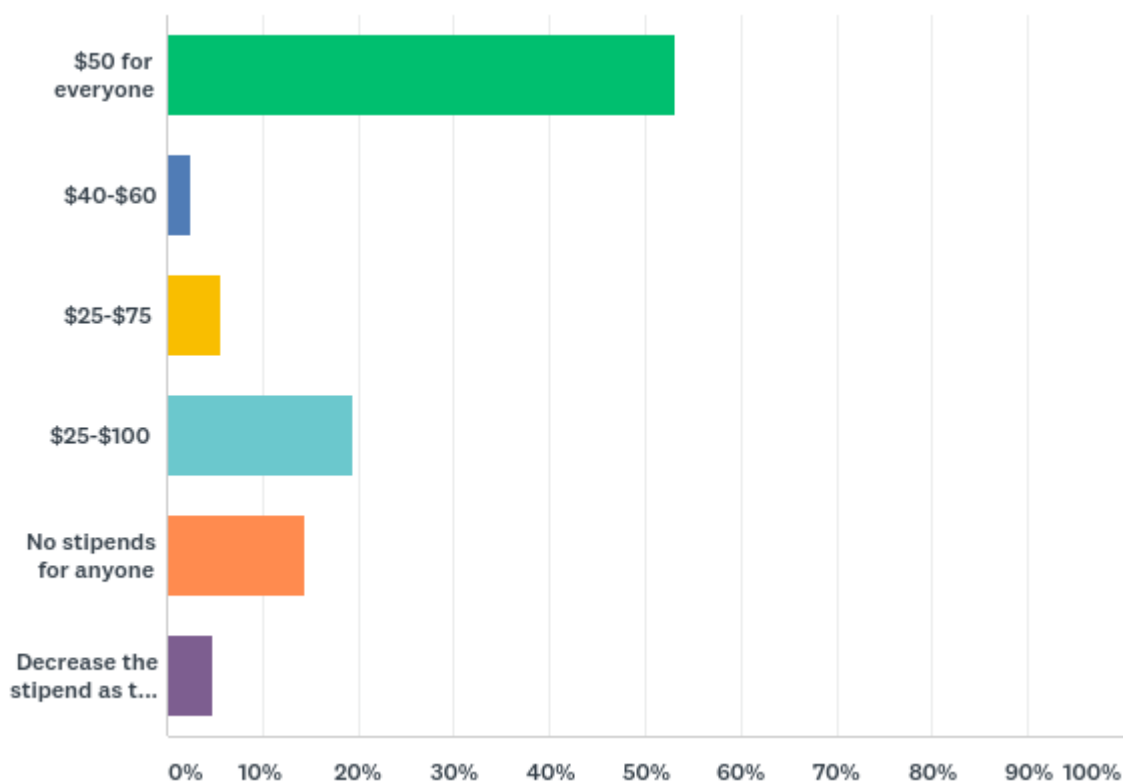
One respondent noted that EU regulations prohibit subject payment.

Several respondents said that stipends could vary based on the income levels in different countries.

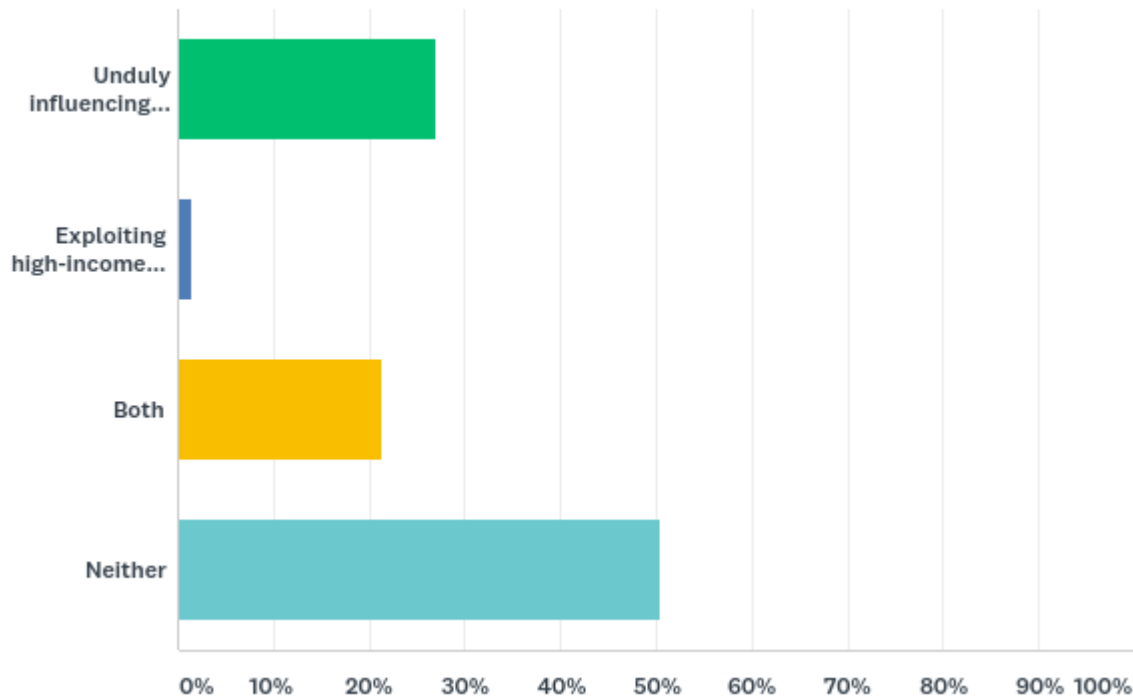
One respondent said, "Stipends killed honest research participation like video killed the radio star."

One respondent said, "I have spoken with several IRBs about stipends. They agree that patients are underpaid for their time. Average stipends have not increased a lot in the last 20 years; in fact, a lot of companies are not even giving stipends any longer and I think that is unethical."

Question 2. What range of stipends would you find acceptable?



Fifty-three percent of respondents would find it acceptable to pay all participants a stipend of \$50, 19% would pay a range of \$25 to \$100, 8% would find a narrower range acceptable, 15% would not pay a stipend, and 5% would decrease the stipend as income increases.



Question 3. What are you more concerned about?

Twenty-seven percent of respondents are more concerned about unduly influencing low-income people, 1% are more concerned about exploiting high-income people, 22% are concerned about both, and 50% are concerned about neither.

Question 4. Would you support varying stipends (not expense reimbursement) for any reason other than income?

Multiple respondents would support varying stipends based on differential burden, e.g., different procedures or assessments.

Multiple respondents would support varying stipends/reimbursement based on, for example, travel time or child care costs.

One respondent would support higher stipends for a group that is significantly harder to recruit and retain.

One respondent said, "I do not support one trial with different stipends based on any factor."

Discussion

Economics and ethics make uneasy bedfellows, so this discussion is going to be controversial...

Many respondents see the ethical question as moot because differential stipends would be impractical, require an invasion of privacy, or would be otherwise mischievous. These concerns are entirely legitimate but do not address the ethical question.

Some respondents appear to find the very idea of stipends (other than for out-of-pocket costs) abhorrent, presumably on ethical grounds. They might be correct, but it's an easy position to take when you (or your employer) is *paying* the stipends. Others might disapprove because such payments are inconsistent with the noble mission of clinical research. I fervently agree that the mission of clinical research is noble, but I do not see the inconsistency — should artists' models work for free?

Multiple respondents consider the value of a person's time to be invariant based on income. However, that position seems implausible when one considers alternative uses of that time. For example, some attorneys charge over \$1,000 per hour, so their real cost of participating in a study might be...\$1,000 per hour (leaving aside taxes, etc.) Certainly, juries in the U.S. routinely consider the earning potential of a victim when assessing damages in civil litigation.

Several participants cited the principle of justice as a reason for paying everyone the same stipend. (Many others cited the similar principle of equity.) This argument seems obvious, but there is a complication: If high-income people do not participate in clinical research because of low stipends, is the principle of justice violated because they benefit from the clinical studies populated by low-income people? Which is the more important violation of the principle of justice?

Despite all the issues raised by respondents, it is considered ethical to pay different stipends in different countries based on their national income levels, given that a stipend that would be considered nominal in a developed country might be considered extravagant in a developing country.

Researchers that conduct Phase I, healthy volunteer studies typically use a market-based approach to setting stipends: They set a price that will attract the people they need. They do not concern themselves with why participants find that price acceptable (although there are issues with subject eligibility and compliance). The fact that Phase I studies do not employ differential stipends is a strong argument against them.

From a purely economic point of view, the most efficient approach would be to auction off study participation and let the market decide the fair price for participation. In theory, once a study finds the required number of participants, they could all receive the same "market clearing" price or they could each receive the level of stipend they "bid." (Gas stations use the first strategy. Colleges and universities essentially use the second strategy with scholarships, loans, etc.)

This sounds like a ridiculous approach, but consider the gross shortage of patients that are willing and able to participate in the thousands of open oncology studies. Many of these studies will fail to enroll all the patients they need, wasting the contributions of those patients who do enroll and delaying, perhaps forever, what might be some of the best treatments. Can we really say that our current system is all that great and that a market-based approach has no role to play?

For better or worse, clinical research patient recruitment is ill-suited for a purely market-driven pricing mechanism, so we are left to set stipends (i.e., prices) that are "fair and ethical." This pricing mechanism appears to rely on the experience, attitudes and subjective

judgments of researchers, IRBs and institutions (without even asking potential study respondents what level they would consider fair).

Respondents also expressed a clear preference for simplicity and the low (or zero) stipend levels that are less likely to raise ethical issues. (No respondents raised the question of the affordability of high stipends to study sponsors.) Differential stipends are inconsistent with these preferences.

This discussion could go on much longer, but it's fair to conclude now that, whatever the ethical issues with invariant stipends, differential stipends carry their own ethical issues, along with many others.

Next Month's Question

Scientists have created entities using artificial intelligence technology. These "betas" appear to have human-like intelligence and emotions so they could, for example, serve as companions for people who are lonely. The scientists want to conduct psychological experiments on them to improve their performance and reliability. While betas are not protected by human subjects protection regulations, the scientists have asked your institutional review board to review the ethics of the experiments anyway. What limitations, if any, would you put on such experiments? Read the full question and give us *your* answer at <https://www.surveymonkey.com/r/56X3JYF>.

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