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## Increasing the amount of payment to research subjects

DB Resnick

### Abstract

This article discusses some ethical issues that can arise when researchers decide to increase the amount of payment offered to research subjects to boost enrollment. Would increasing the amount of payment be unfair to subjects who have already consented to participate in the study? This article considers how five different models of payment—the free market model, the wage payment model, the reimbursement model, the appreciation model, and the fair benefits model—would approach this issue. The article also considers several practical problems related to changing the amount of payment, including determining whether there is enough money in the budget to offer additional payments to subjects who have already enrolled, ascertaining how difficult it will be to re-contact subjects, and developing a plan of action for responding to subjects who find out they are receiving less money and demand an explanation.

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Consider the following scenario. Some investigators are conducting a prospective, case control study of environmental and genetic factors in Parkinson disease. The population in the study will be drawn from a group of farm workers, who participated in an agricultural health study and gave permission to be contacted about future studies. The subjects will be asked to provide a sputum sample for DNA analysis, to complete health surveys, and to give the researchers access to their medical records. The study will last 15 years. The investigators have been contacting potential participants by mail and phone, but recruitment has gone poorly. The investigators have recruited 210 subjects during the past year, but they had planned to recruit 670 subjects. Their goal is recruit 1000 subjects in two years. To improve their recruitment rate, investigators would like to change the compensation for participating in the study from \$25 to \$50. They submit the proposed change as an amendment to the Institutional Review Board (IRB) as an amendment to the protocol. How should the IRB respond? Should the investigators be required to pay the 210 people who have already been recruited an extra \$25?

This scenario represents a situation that probably happens from time to time in research involving human subjects but is not covered by any existing regulations, policies, or guidance. In the US, the federal research regulations describe requirements for informed consent and subject selection but do not address the issue of financial compensation for research subjects.<sup>1</sup> The Food and Drug Administration's guidance document on payments to research subjects states that payments to subjects are recruitment incentives (not benefits), that payments should not be coercive or constitute undue influence, and that payments should not be contingent upon completion of the entire study. The document does not discuss the issue of changes in payments.<sup>2</sup> The Office of Human Subjects Research, which oversees the intramural programme at the National Institutes of Health (NIH), has detailed guidelines concerning remuneration to research subjects, but none of these address the topic of changes in remuneration.<sup>3</sup> The World Medical Association's Declaration of Helsinki

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Correspondence to: Dr D B Resnick, National Institutes of Health/NIEHS, Box 12233, NH06, Research Triangle Park, NC 27709, USA; resnikd@niehs.nih.gov.

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discusses informed consent but does not say anything about financial compensation.<sup>4</sup> The Council for the Organization of Medical Sciences Guidelines states the subjects may be paid for their time and inconvenience but that payments should not be so large that they induce subjects to participate in research against their better judgment.<sup>5</sup>

## PAYMENTS AND JUSTICE

Since there are no regulations or guidelines that specifically address the topic of increasing the amount of payment offered to subjects, committees that oversee research with human subjects, such as IRBs, must rely on their moral and practical judgment to decide how to handle these situations. One of the ethical dilemmas related to increasing the amount of payment concerns justice (or fairness): is it fair to the subjects who have already consented for less money to offer other subjects money? Although there are many reasons why investigators offer subjects money other than to treat them fairly, it is appropriate to view payment policies from the point of view of justice, because justice is a well recognised principle of research ethics, which addresses questions concerning the distribution of benefits and burdens in research.<sup>6</sup> While some regulatory agencies do not consider payments to be research benefits, ordinary people consider money to be a benefit. If a research subject discovers that he is receiving less money than someone else in a study even though he has performed the same tasks, he may become angry because he believes that he has been treated unfairly.

## MODELS OF PAYMENTS TO RESEARCH SUBJECTS

The focus of our inquiry in this paper boils down to this specific question concerning justice in research: do researchers have an obligation to offer subjects who have already consented additional money if they decide to increase payments to new subjects to enhance recruitment? The answer to this question depends, in part, on how one conceives of payments to research subjects. What is the purpose of making payments to research subjects? There are at least five distinct models of payments to research subjects: (1) the free market model; (2) wage payment model; (3) the reimbursement model; (4) the appreciation model; and (5) the fair share model.<sup>7-9</sup>

The first two models characterise research participation as a form of paid labour. According to the free market model, subjects are paid for providing services (such as completing surveys and undergoing tests and procedures) and goods (such as blood, tissue or other biological samples). Payments can be based on not only the amount of goods and services that subjects provide, but also on the amount of risk and inconvenience associated with the study. For example, subjects should be paid more money for a risky and painful procedure, such as a lumbar puncture, than for a relatively safe and painless procedure, such as a venipuncture. One implication of the free market model is that there should be no upper limits on wages, since workers should be paid according to what the market will bear. When labour is in short supply, wages may need to rise to attract labourers.<sup>10</sup>

One of the main criticisms of the free market model is that high wages allowed under this approach could constitute undue inducement. Many research subjects, especially poorer ones, would act against their better judgment when deciding whether to participate in research.<sup>11</sup> The lure of money may encourage subjects to enrol in dangerous research studies without carefully weighing the risks and benefits. Some commentators have attempted to debunk these concerns about undue inducement, arguing that investigators and research oversight committees, such as IRBs, will protect subjects from harm. Subjects will not be able to enrol in dangerous studies because oversight committees will not approve studies that expose subjects to unreasonable risks or do not minimise risks.<sup>12</sup> Others have conducted

empirical studies which show that payments to subjects may increase their willingness to participate in research but are not likely to blind them to the risks of research.<sup>13</sup>

Though these arguments dispel some of the concerns related to undue inducement, they do not remove all of them. First, the lure of money may entice some subjects to undercut the efforts to protect them from harm: subjects may lie about their medical history in order to qualify for the study, or fail to report adverse effects in order to stay in the study.<sup>13</sup> Second, excessive risk-taking is not the only problem related to paying subjects too much money: exorbitant payments can also compromise the autonomy of research subjects by causing them to make ill-considered or careless choices. Subjects might agree to be in studies without giving careful thought to the research procedures, benefits and risks, and so on.

To deal with these and other objections to the free market approach, some commentators have developed a regulated market model of research known as the wage payment model.<sup>7,14</sup> Like the free market approach, the wage payment model characterises research participation as a form of labour, but the model places restrictions on the wages that participants may earn to avoid the potential for undue inducement. To prevent research subjects from taking significant risks against their better judgment, participants should earn a wage equivalent to that of a typical unskilled labourer.<sup>7</sup> Although the wage payment model has many defenders, it also has its share of critics. Some commentators have objected to the model on the grounds that the model may exploit research subjects by keeping payments artificially low. By placing restrictions on the free market, the model prevents research subjects from earning money they might earn under a free market system, which may allow research sponsors, such as pharmaceutical companies to save money on labour costs.<sup>15</sup>

The reimbursement model, unlike the free market model and the wage payment model, holds that research participation is not paid labour but a type of public service (or altruism). Subjects participate in research to make a voluntary contribution to science, not to earn a wage. They may be compensated for their own costs of participating in research, such as their travel, lost wages, baby sitting expenses, but they should not be paid for the labour per se. The appreciation model, like the reimbursement model, also views research participation as public service, not as paid labour. Under the approach, subjects are not compensated for the costs of participation, but they may receive money as a sign of the investigators' appreciation for their participation in the study. Small gifts, such as t-shirts, mugs, gift certificates or money, may be offered to subjects in recognition of their public service.

Although the reimbursement model and the appreciation model are interesting alternatives to the free market and wage payment models, they also have some shortcomings. The main problem with both of these approaches is that they do not accurately describe the motivations of human subjects. Many research subjects enrol in studies to earn money or obtain free medical care, not just to make a contribution to science.<sup>16</sup> Few people would enrol in a Phase I dosing study of a new medication without a financial incentive. Since the models do not accurately reflect the motivations of research subjects, they could lead to difficulties with recruitment.<sup>7</sup>

The final approach to be considered in this commentary is the fair share model.<sup>9</sup> Under this approach, subjects are neither paid labourers nor unpaid volunteers, but partners in research. As partners, research subjects should share in the benefits of research, including the economic ones. Payments may be offered to subjects as a way of providing them with a fair share. The fair share approach, like the other approaches, has some weaknesses. The first one is that it does not accurately reflect the realities of the research enterprise. A true partner in a research project would play a key role in study design or implementation, recruitment, consent, data collection and analysis or publication. But subjects rarely have any significant

input into any of these activities. The second problem is that the most research regulations and guidelines treat money as a recruitment incentive, not as a benefit.<sup>37</sup> Although most people regard money as a benefit, the regulations and guidelines do not treat it as such to avoid using an offer of money to justify risky research. If money is factored into the benefits of a research study, then a benefit/risk ratio that would be unjustifiable without money would become justifiable with it.

## APPLICATIONS

While it is instructive to think about the strengths and weaknesses of these different models, the aim of this commentary is not to defend any particular approach to paying research subjects but to explore what these different models would have to say about how one should treat research subjects who have already consented when a decision has been made to increase the amount of payment in order to boost recruitment. Let's consider the free market and wage payment models first. Both of these approaches hold that paying research subjects for their participation is like paying for labour. Paying for labour is like any other business transaction where money is exchanged. "Fairness" in this context can be equated with "fair dealing", that is, bargaining in good faith, keeping one's promises and being honest. If a deal is fair to begin with, then subsequent changes in market conditions may be ignored. For example, suppose that a farmer is hiring fruit pickers at the rate of \$8 per hour during the month of June. Since he is having difficulty recruiting labourers, he decides to increase the rate of pay to \$9 per hour in July. As long as he reached a fair deal with the labourers who worked in June, he has no obligation to revisit his contracts with them: he does not owe them any additional payment for the work they have already completed. However, if they are still working for him during the month of July, he should increase their compensation to \$9 per hour, so that they will receive the same rate of pay as the new workers.

If we carry this analogy to the research setting, it implies that when the amount of payment offered increases during the study, researchers and sponsors have no obligation to pay subjects who have completed all of the study requirements (ie, procedures, etc) any additional pay, provided that the original consent was valid. A deal is a deal and there is no need to revisit it. However, if the subjects have not completed all of the requirements, then they should receive the new rate of payment when it increases. For example, suppose that a study only requires subjects to provide a blood sample for DNA analysis and that it pays \$20. If the rate of pay increases to \$30, researchers do not need to give an additional \$10 to subjects who have provided their blood sample already. Suppose that a different study requires subjects to provide a blood sample every year for five years and that it pays \$20 per sample. Investigators increase that rate of pay per sample to \$30 after the second year of the study. Subjects who are already in the study and have provided two payments for \$20 each should now be offered \$30 per samples.

The reimbursement model would not require investigators to offer subjects who have already consented additional money when the payment increases, if we assume that the reason for giving subjects more money is to increase recruitment. If the amount of reimbursement was fair to begin with, and investigators want to change the payment for the purposes of boosting recruitment, then they would not need to offer people who have consented any additional money, because this money would be paying for something besides their expenses, such as labour. However, if the subjects have consented but not completed all of the study requirements, then investigators may need to offer them additional money, so that all the subjects will receive the same amount of reimbursement. For example, if a study requires parents to bring a child to a clinic for four visits, and the parents were initially offered \$10 per visit to pay for travel expenses, and investigators decide to increase that

amount to \$15 per visit, parents who have not yet completed the study should receive \$15 for each visit they need to complete.

The appreciation model would not require investigators to offer subjects who have already consented to participate in a study additional money when the payment increases, if the reason for offering more money is to boost recruitment. Subjects who have already consented have presumably already received a token of appreciation for their participation and there is no need to offer them anything more. However, once again, if the subjects have not completed all the study requirements, then it may be appropriate to adjust their payment accordingly.

Finally, the fair benefits model would require investigators to offer to pay subjects who have already consented to participate in a study additional money when they increase the rate of payment to boost recruitment, since all subjects deserve a fair share of the benefits of research. The situation would be analogous to slicing a pie. If each person is supposed to receive a fair share of the pie, but the person slicing the pie cuts larger pieces as he finishes slicing the pie, then the person should cut portions off some of the larger pieces and distribute pie to people who did not get as much. The same point would apply regardless of whether the subjects have completed the study requirements or have already been paid in full. If the purpose of payment is to distribute benefits fairly, then subjects should all receive the same amount of money.

For all the models, informed consent procedures would need to be modified to take into account any changes in payment. If the investigators increase the rate of payment during the study, they should update the consent document to reflect this change. If subjects who have already enrolled will receive additional payments, the investigators should inform them of this change in procedure and they should provide the subjects with an updated consent document.

## PRACTICAL CONSIDERATIONS

First, are there any financial limitations to offering subjects who have already consented additional money? If the budget for the study is very tight, there may not be enough money to pay subjects who have already completed the study additional money. Budgetary considerations become more important as the number of subjects who will be offered additional money increases. While paying 10 subjects an additional \$25 may be feasible, paying 1000 subjects an additional \$25 may not be. If researchers do not have sufficient funds to pay subjects who have already completed the study additional money, they may need to decide whether it would be better to (a) change the rate of payment but not offer to pay these subjects additional money, or (b) keep the rate of payment the same. There is no obvious answer to this dilemma, as it involves a fundamental conflict between cost (or utility) and fairness. Being as fair as possible can be a good idea in theory but difficult to implement in practice.

Second, how difficult will it be to re-contact subjects to offer them more money? Re-contacting subjects can be very difficult or even impossible, depending on how long the study has been running and how the data have been identified. Re-contacting subjects may be difficult if the investigators do not have updated information on how to locate subjects who have completed the study requirements, such address, phone number or email. Re-contacting subjects will not be possible when the data are anonymous, since the investigators would have no way of identifying the subjects. Re-contacting is another practical problem that could undermine the researchers' ability to implement moral ideals concerning fairness.

Third, is it likely that subjects who have enrolled earlier in the study will find out that subjects who have enrolled later will receive more money? If subjects find out that they are receiving less money, they may become angry and demand an explanation. Researchers should be prepared to discuss payment issues with discontented subjects, and offer to pay them the difference, if necessary, even if they had not planned to pay in the first place. The reason that researchers should pay careful attention to subjects who find out that they are receiving less money is to foster trust, which is essential to research with human subjects.<sup>17</sup> People who do not trust researchers will be less likely to enrol in studies, remain in studies (if enrolled) or adhere to study requirements. Subjects may become distrustful if they believe that they are being harmed, exploited or treated unfairly. While researchers should always strive to promote trust, they should be especially mindful of how their conduct may affect trust when they are following the same group of subjects for a long time or are planning to contact them again for future studies.

## CONCLUSION

Ethical dilemmas can arise when investigators working with human subjects decide to increase the amount of payment to boost recruitment. The main ethical dilemma is whether increasing the amount of payment would be fair to subjects who have already enrolled in the study. To determine whether a change would be fair, it is important to understand why subjects are being paid. If the payments are being paid to compensate them for their labour, then researchers do not need to offer any additional payments to subject who have already completed the study, provided that the original consent was valid. If some subjects are already enrolled but have not completed all the requirements of the study, then those subjects should receive the new rate for completing those requirements. If the payments are to reimburse subjects for their costs, then researchers do not need to offer additional payments to subjects who have already enrolled and have completed the study requirements, if one assumes that the amount of reimbursement was fair to begin with. If subjects have not completed all of the requirements, then they should be reimbursed according to the new payment plan for their remaining participation in the study. If the payments are offered as a token of appreciation, then researchers would not need to offer additional payments to subjects who have already enrolled and completed the study requirements. As in the other models, subjects who have not completed all the requirements should receive the new rate of pay for their remaining participation. Finally, if payment is being offered to give subjects a fair share of the benefits of research, then researchers should offer to pay subjects who have already enrolled in the study additional payments, regardless of whether they have completed all of the requirements.

There are several practical problems related to increasing the amount of payment, including determining whether there is enough money in the budget to offer additional payments to subjects who have already enrolled, ascertaining how difficult it will be to re-contact subjects, and developing a plan of action for responding to subjects who find out they are receiving less money and demand an explanation. Researchers must deal with these practical problems, as well as the ethical dilemmas, when deciding whether to increase the amount of payment.

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