

Invited paper

Unconditional compensation: reducing the costs of disagreement about compensation for research subjects

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التعويض غير المشروط: تقليص التضارب في الآراء حول تعويض من تُجرى عليهم البحوث

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الخلاصة: تُعدُّ المشاركة الطوعية في البحوث التي تُجرى على آدميين شرطاً أساسياً ومحورياً. وتتمثل وجهة نظر الباحثين في أن تضارب الآراء حول تأثير عرض تعويض مادي على مدى قابلية الناس للمشاركة الطوعية، سيستمر وسيُسفر عن تكلفة اجتماعية باهظة. وتطرح هذه الورقة البحثية أسلوباً مبتكراً يعتمد على دفع التعويض للأشخاص الذين تُحتمل مشاركتهم، سواءً شاركوا أم لم يشاركوا، وترى أن تنفيذ هذا النظام في بعض الأقاليم بما فيها إقليم شرق المتوسط قد يجد من التضارب، مما يخفف من وطأة التكلفة. كما تعرض هذه الورقة البحثية الخطوط العريضة للبرنامج البحثي لتقييم قدرة هذا الأسلوب على تقليص التكلفة.

ABSTRACT A central requirement of research involving humans is that people who participate as subjects should do so voluntarily. We argue that disagreements about the effect of offers of compensation on subjects' ability to participate voluntarily are likely to persist and to have high social costs. We propose a novel compensation practice—to pay potential subjects whether or not they participate—and argue that its implementation in some regions, including the Eastern Mediterranean Region, may reduce disagreement and thus mitigate such costs. We outline a research programme for assessing the potential of this practice to reduce costs.

Compensation inconditionnelle : réduire le coût des désaccords sur la compensation des personnes participant à une recherche biomédicale

RÉSUMÉ L'une des conditions obligatoires auxquelles doit répondre la recherche impliquant des sujets humains c'est que les sujets qui acceptent d'y participer doivent prendre cette décision « librement et volontairement ». Nous prétendons qu'il est probable que les désaccords sur l'effet d'offres de compensation financière faites aux sujets sur leur aptitude à décider *volontairement* de participer à une recherche perdurent et aient un coût social élevé. Nous proposons une nouvelle pratique en matière de compensation, à savoir payer les sujets potentiels, que ceux-ci participent ou non à la recherche, et affirmons que sa mise en œuvre dans certaines régions, notamment dans la Région de la Méditerranée orientale, peut réduire les désaccords et atténuer ainsi les coûts financiers. Nous présentons un programme de recherche visant à évaluer le potentiel d'une telle pratique pour réduire les coûts.

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Introduction

Since the Nuremberg Tribunal [1], it has been a requirement of research on human subjects that those with the mental capacity for informed consent should participate voluntarily. This requirement is upheld by the most important guidelines and regulations, which include the Declaration of Helsinki [2], the guidelines on the ethics of research published by the Council of International Organizations of the Medical Sciences [3], and the US Common Rule that governs all research on human subjects that is funded by the US government [4]. Persons who are coerced or unduly induced into making a particular decision do not make it voluntarily. Guidelines and regulations assume the common but controversial view that offers of compensation in exchange for participation can be coercive or unduly inducive, and so prohibit compensation that is such [4–6]. We will use the term *payment* instead of the term *compensation*, which is commonly used in this context, to avoid the suggestion, among others, that subjects are paid to compensate them for research-related injuries. There can be other reasons for paying subjects.

Offers of payment tend to be considered more coercive or unduly inducive the poorer the individuals are whom researchers seek to recruit, the fewer the protections, the higher the value of payment, the riskier the research and the less significant the non-monetary benefits to subjects and their communities. Nonetheless, there is widespread disagreement about which offers compromise voluntary participation. The academic community is also divided on this question. Some scholars argue that offers of payment sometimes or always compromise voluntary participation. Others who draw on sophisticated theories [7–10] argue that offers, when made in the context of legally

sanctioned research, are seldom or never coercive or unduly inducive [11–14]. The prominent bioethicist Ruth Macklin has confessed to finding the question of which values of payment compromise voluntary participation unanswerable [15].

It is not surprising that none of the national or international regulations or guidelines that prohibit involuntary participation specifies a range of acceptable values of payment. Not all institutional guidelines specify a particular range of payments as acceptable; one study suggests that fewer than 7% do so, but these guidelines have limited generality [16]. Institutional guidelines that do specify such a range are inconsistent [16]. We found that one institution's guidelines *require* payments to be higher when the subject assumes greater risk and that another institution's *prohibit* the practice of giving higher payments to subjects who bear greater risk. Payment practices vary between research projects [17].

The costs of disagreements

Many studies have shown that disagreements and differences between institutional review boards (IRBs) on features of protocols unrelated to payments lead to high costs for investigators, IRBs and society [18–22]. Costs arise because amendments, rejections and recurring disagreements consume resources and delay the initiation of research, and thus may hinder the progress of science and improvement of public health. Such problems escalate in multisite studies that require the approval of several IRBs whose practices or decisions differ. Furthermore, biased data can result when different IRBs require idiosyncratic changes to the same protocol as a precondition to approving its implementation in their particular institution.

Studies have not been conducted on differences within or between IRBs about the acceptability of proposed payment schemes, or on resulting costs, but that there are costly differences is plausible. The law in the United States requires research projects to receive approval from an IRB but does not specify acceptable values of payment [4]. Differences in opinion among academics [13,14,23–27] and among members of the public who are considering participating in research [28] are well documented. It is unlikely that IRB members, who by law must come from various disciplines and backgrounds [4:§46.107], find payments less contentious. We have observed many such disagreements in 20 years of service on several IRBs worldwide.

If there are differences about payments, they may lead to a variety of disadvantages as outlined below.

- *Unnecessary interventions.* One study reports that 68% of the sampled IRBs claimed that they have required amendments to proposed payment schemes. The reason most commonly cited was that the schemes were coercive [16]. Amendments made to payment schemes that are morally justifiable and not coercive constitute an inefficient use of IRBs' and researchers' resources. The existing data do not enable us to classify or quantify the costs of unnecessary IRB decisions. Of course, data alone cannot settle the question of which decisions are unnecessary.
- *Unnecessary discussions.* Repeated discussions about payments are also inefficient when they do not result in schemes that better protect subjects.
- *Inconsistent intra-IRB decisions.* Because IRB membership changes and decisions about proposed payment schemes are not always explicitly justified, decisions are likely to be inconsistent unless they are recorded and consulted when reviewing similar schemes. Inconsistency prevents researchers from predicting which schemes will be approved.
- *Inconsistent inter-IRB decisions.* For reasons already mentioned, it is likely that there are costly inter-IRB differences about proposed payment schemes, just as there are about other aspects of protocols under review.

Evidently, research should be conducted on the costs of IRB disagreements about payments before implementing a payment practice designed to reduce such costs. However, we should begin to look for ways to reduce the costs of such disagreement if it is likely to persist.

We believe that disagreement will persist. It has been claimed that consensus on the permissible values of payment has not been reached because of “heavy emphasis on voluntary consent” and of insufficient discussion about the implications for subjects of commercializing research [27]. We reject the implication that discussion can resolve disagreement. Some observe that payments may have various functions, such as reward, incentive and reimbursement [29]. Multiple functions may help to explain some of the disagreements: consider a situation where investigators wish to offer high incentives to reach recruitment targets and where some IRB members consider that the only justifiable function of payment is reimbursement, while others hold that subjects must be allowed to make some financial gain in order to reward their service to society. Other disagreements may arise, even when all agree that payments function as incentives, because incentive rates may be set in various ways [29]. Yet other disagreements, we argue, are explainable if people have different concepts of voluntary

choice or coercion, or hold different views on political justice.

Voluntary choice. Suppose that a poor person participates in a research project, the risks and benefits of which he fully understands, because without payment, his family will starve. Some observers argue that he does not act voluntarily, for instance, because he has no real choice. It is implausible that a person in an affluent society, who participates for money, cannot do so freely, but this is more plausible when participants are in conditions of serious deprivation. For example, offers of a sari (clothing) to poor young women in India in exchange for their agreement to be sterilized, made in an Indian national birth control campaign in the 1970s, were widely criticized as coercive even though the women were not forced to accept the offers. A second observer might view the poor person's choice as voluntary because the offer expands the set of choices and so increases the degree of freedom; similarly, poor people who have no alternative but to do unpleasant and badly paid work nonetheless do it voluntarily. A third observer, who is moved by both sides of the argument, might point out that the offer both compromises voluntary choice and is freedom-enhancing [7 p. 109,10]. Thus, differences in opinion regarding when voluntary choice is possible may cause, and thus explain, some disagreements regarding payments.

Coercion. Different concepts of coercion may explain other disagreements about the permissibility of offers. Empirical accounts of coercion hold that whether or not coercion takes place depends on empirical facts about the context or the recipient's motivations, emotions or cognition, such as that the recipient of the offer i) has no real choice but to participate, or ii) feels compelled to participate, or iii) finds the offer so enticing that he is unable to reason about

whether or not participation is in his best interests in the long term. Empirical concepts of coercion are frequently expressed in the theoretical and empirical literature on payments [for example 24,30] and also, in our experience, in IRB and lay discussions. Other accounts of coercion explain it in terms of moral concepts such as those of obligation or right. A classic moral account of coercion holds that A coerces B to do X only if A proposes to make B worse off than he ought to be unless B does X [7 p. 109,8]. This account implies that a researcher's offer of payment to a person in exchange for participation is coercive only if the person is entitled to receive the money with "no strings attached". In this case, the researcher's proposal to withhold the money unless the person participates is in fact a threat that makes him worse off than he ought to be. Thus, when people disagree about whether or not an offer is coercive, this might be because their concepts of coercion differ.

Political justice. Other disagreements may arise when people have the same concept of coercion but different views about the entitlements of the poor. Consider again the poor person who participates in a research project because, without payment, his family will starve. Those whose concept of coercion is a moral one may agree that if the potential participant is entitled to receive the money without having to participate then the offer is coercive, because it makes him worse off than he ought to be. However, not everyone considers the very poor to be entitled to cash with "no strings attached" and so may disagree on whether or not the offer is coercive. If we cannot agree about the coerciveness of offers unless we first agree on the even more contentious issue of political justice, we should expect disagreements about payments to persist.

There is no systematic study of the reasons and causes of disagreements about

payments. However, if people consider the ethics of payments in terms of voluntary choice or coercion or political justice, and if their concepts of these differ, we should expect there to be such disagreements. Moreover, payments are widely considered to be *incentives*, such as when it is argued that subjects should *not* receive payment that enables them to gain financially, because subjects may otherwise be lured into exposing themselves to risk; or when researchers wish to offer larger payments to accelerate recruitment. Institutions that require higher payment for higher risk participation may consider payment to be a *reward*. Admittedly, they may simply think that higher incentives may be needed to recruit individuals for riskier research projects, but it is hard to see why institutions would consider this a reason for *requiring* higher payments when risks are greater. Certainly, some academics consider that subjects are rewarded insufficiently [26]. It is also clear that there is disagreement about the entitlements of the poor, particularly when they are nationals of other countries.

One might claim that, even if our explanations are correct, disagreement can be reduced in various ways. These include:

- To prompt IRB members to question the theoretical basis of their views on payments by exposing them to theoretical literature [11,12] that criticizes common concepts of coercion and undue inducement, and criticizes arguments for the claim that payments compromise voluntary participation.
- To expose IRB members to preliminary data that suggest that the conditions for empirical coercion are not, in fact, satisfied [30]. Further research should be conducted on whether or not such conditions are met in practice.
- To reduce the chance that such conditions are satisfied by implementing

measures which improve the reasoning of potential subjects such as: i) to require several days to elapse between describing the research to potential recruits and accepting their consent to participate; and ii) to enable potential recruits, in the interim, to discuss the costs and benefits with disinterested experts. Protocols under IRB review should describe the measures that will be or are being taken.

Assuming such actions are taken, we believe that disagreement will persist. It is unlikely that overtaxed IRB members will read the literature even if included with the protocols that it is their task to review. Even if the 3 measures are implemented and reduce disagreement, some will still disagree about whether or not offers are coercive because they disagree on the entitlements of the poor. Also, there are other possible versions of the argument for the claim that high payments compromise voluntary participation—versions that have not been conclusively refuted—and yet other arguments that reject payments for reasons unrelated to voluntary choice [31]. Even scholars of the ethics of research are fundamentally divided on many aspects of the ethics of payments [14,23–25]. This suggests that some disagreement is reasonable and so is likely to persist. This should come as no surprise as prominent philosophers have argued that it is essential to complex moral questions that they have multiple conflicting but individually reasonable answers [32].

Unconditional payment: a possible means to reduce the costs of disagreements

It may be possible to reduce disagreements and so their costs by changing how payments are used to recruit subjects. *Unconditional*

payment (UP) in the context of research is payment that is given to prospective participants irrespective of whether or not they participate. (A prospective participant is someone who has been told that there is research in which he may wish to participate and who has agreed to learn more about it. He may or may not, at that time, be interested in participating.) After prospective participants have been informed about the research and their understanding has been assessed, but before they are asked if they would like to participate, they are told that they will be paid whatever their decision. They are also free to decline the payment. Furthermore, if they decide not to participate, they will not lose benefits to which they are otherwise entitled. In contrast, subjects who are given *conditional payment* (CP) are paid only if—and typically only after—they actually participate. To our knowledge, all past and current payments to subjects are conditional, although some research projects give the same payment to subjects who have commenced participation irrespective of whether or not they *complete* it. When payment is unconditional, potential subjects are given the same payment whether or not they *commence* participation.

Research has been conducted on the use of UP as an incentive to fill out postal surveys on health status, but not on its use to recruit subjects for research [33,34]. UP enclosed with such surveys has been shown to raise the rate of response compared to when no payment is enclosed, and also compared to when payment is promised on return of the completed survey [33,34]. However, we still need to conduct research on the benefits and costs of UP to recruit subjects: it is often more time-consuming and risky to be a human subject than to complete a postal survey. Furthermore, the postal surveys were US-based whereas, as we will argue,

UP would be used to recruit subjects in less developed countries. UP may have different effects on members of other societies.

It is worthwhile to use UP in recruitment only if it is practical, fair to subjects and more acceptable to IRB members than CP. We will argue here that the use of UP could avoid costly disagreements, assuming that they do exist, and that its use is ethical. We will also outline some research that needs to be done.

UP is less contentious than CP

We predict that IRB members would find UP more acceptable than CP because the common objections to payments—which presuppose that all payments are conditional—do not apply to UPs.

If one understands coercion in any of the moral or empirical senses explained before, one should agree that UP is not coercive. Unconditional offers of payment are not morally coercive because they do not make the individual worse off than he ought to be; even if he is worse off than he ought to be prior to the offer, the receipt of UP *improves* his situation, at least when he chooses not to participate. (That the receipt of UP improves his situation assumes, of course, that the offer is not accompanied by a threat that harm will ensue unless the person participate.) Such offers are probably not *empirically* coercive: subjects presumably will not *reason badly or feel compelled to participate*, however much they need the money, because they know that they can receive it with “no strings attached”. One might object that UP may have negative effects on members of some cultures, perhaps those in which strangers do not give away gifts. Research should therefore be conducted on the psychological impact of UP in the intended contexts of use (to conduct such research, the concept of internal coercion will need to be given a

plausible operational definition). Furthermore, even if a person is coerced when *all his choices are bad*, UP is not coercive: it gives recipients at least one choice that is not bad, namely, to accept payment without participating. However, empirical research should be conducted on IRB members' perceptions of UP and CP. Members may feel that UP compromises voluntary choice even if their objections to CP do not apply to UP. Moreover, there are many objections to payments that do not focus on their alleged effect on voluntary choice.

UP is practical

UP is impractical if so many individuals accept payment without participating that the increased cost of recruiting outweighs potential gains to investigators, even if its use benefits IRBs and society. Not only participants but also non-participants must be paid, including "free riders" who have learned about the payment scheme and who approach the trial with the prior intention of taking the money and leaving. If the recruitment rate is lower with UP, the labour costs of recruitment will be higher and recruitment may be lengthier.

We propose to test UP for use in resource-poor countries, including some that are in the Eastern Mediterranean region, where the extra cost of paying non-participants is very low by global standards. The extra cost of skilled labour varies, but may also be low, particularly when locals are employed, even when investigators from the sponsor's country and from the host country receive salaries with equal purchasing power. Nonetheless, if recruitment is lengthier, this may outweigh the benefits of a speedier approval process. However, we cannot know *a priori* how potential participants will react to offers of UP and the extent to which free riding will be a problem. Although the recruitment rate may be lower, it may be higher if UP induces a

desire to reciprocate, as unsolicited gifts sometimes do. An initial study should compare the recruitment rates with CP and UP.

Even if the recruitment rate is lower with UP, it may still be in the interests of investigators to use it if this speeds up the approval process, or if this increases subjects' trust in investigators and hence compliance. Further research should seek to compare the total net benefit/cost to investigators of CP with that of UP.

UP is ethical

To treat people ethically, it is not sufficient (or necessary) to avoid treating them in ways that are commonly considered to be unethical. One must give them any benefits to which they are entitled and treat them fairly. If the value of the UP is sufficiently high, the payment will satisfy the subject's entitlement to an adequate reward for participation. We will not consider here how the value of a reward should vary with the features of the research project. Admittedly, there may be some disagreement on this issue. Still, it is plausible to suppose that there will be much less disagreement about whether or not payments are sufficiently rewarding than about whether or not they compromise voluntary choice. The latter appears to be IRB's central concern [16].

One might object that UP is unfair because fairness requires participants to receive a greater reward than non-participants—at least when participation is burdensome or risky—whereas participants and non-participants would, on our proposal, receive the same payment. We reply that there is little unfairness, because participants can choose whichever option they prefer: to receive payment, or to receive payment *and* to participate. However, we concede that it seems fairer to give participants a bonus, and this suggests that equal payment is somewhat unfair to participants. Unfortunately, even

if bonuses are not mentioned during recruitment, a practice of bonuses for participants may become common knowledge in the long run, and so some benefits of UP may disappear. We need to decide, after gathering the relevant facts, if it is more important to avoid this slight unfairness and to reap UP's benefits, or to continue to use CP and to live with costly disagreements.

Contrast between our proposal and others

Our proposal to reduce the costs of IRB differences—to switch to less controversial recruitment tactics—contrasts with other possible reforms. These include: i) to adopt uniform guidelines that specify the range of acceptable payments, ii) to require multisite protocols to be reviewed by only one IRB [22], or iii) to shift the burden of overseeing research onto investigators who have received special training [35]; this would leave to IRBs the task of monitoring research in progress. We believe that ours—to recruit subjects with offers of UP instead of CP—is more promising.

In the first proposal, disagreements about the ethics of payments are likely to stall the choice of national guidelines that specify a range of payments as acceptable, and to compromise compliance with the guidelines if implemented. With the second proposal, appointment of a single IRB will avoid the costs of inter-IRB but not of intra-IRB disagreements, if its members are unable to agree on guidelines that are sufficiently detailed. If the single IRB does not have guidelines on payments, it is likely that there will be unnecessary interventions and discussions, and inconsistent decisions, leading to further inefficiencies. Shifting the burden of overseeing research onto investigators—the third proposal—will greatly

reduce disagreement, although some may still arise in collaborations. However, the conflict of interest and the extreme vulnerability of some subjects strongly suggest that compliance must be imposed externally; history has shown that some investigators cannot be entrusted to police themselves.

We cannot review here all the proposals for reforming the IRB system. However, those that appear viable are not designed to reduce disagreements about the ethics of payments and are, for this reason, unlikely to reduce its costs. We believe that our approach is more likely to succeed because it removes the bone of contention: the use of CP in recruitment of subjects.

Extending our proposal

Unconditional payment has a wider potential use than has been considered here. Non-monetary benefits may be offered unconditionally, not only monetary benefits. Furthermore, UP may be used in resource-rich countries, as well as in resource-poor ones. We have focused on the use of unconditional, monetary payment in resource-poor countries because there is more disagreement about the ethics of conditional payment when the payment is monetary or the research is conducted in resource-poor countries. A further, pragmatic reason for focusing on monetary benefits is that this allows us to write more simply. Some non-monetary benefits can only be given conditionally, such as medical benefit resulting from the experimental treatment: only participants can receive such benefit. A proposal to give non-monetary benefits unconditionally must therefore be qualified so as to exclude some benefits. Also, objections to conditional offers of benefits often refer to their *value*: it is argued that only *high* offers of payment are coercive. The

values of non-monetary benefits, such as medical benefits, are not always obvious, so claims about value may be confusing. Last, the net benefits of UP may differ for non-monetary and monetary benefits: it may be more expensive to offer medical care unconditionally than cash.

Conclusion

It is widely believed that offers of payments to individuals can compromise their ability to give voluntary consent; a reason that is commonly cited for reducing payments, or eliminating them altogether, is that offers compromise this ability. We have argued that disagreements about the impact of offers of payment on subjects' ability to participate voluntarily are likely to have high costs to investigators, IRBs and society. The reason is that the law requires research projects to receive approval from an IRB but does not specify acceptable values of payment; furthermore, IRB members and IRBs differ about the values that are accept-

able. We have predicted that differences will persist because commonly held views on payments, voluntary choice and political justice support incompatible views on the values of payment that are appropriate. We have proposed a novel practice that has the potential to reduce costs and does not involve institutional reform: a practice of recruiting individuals as subjects for research by offering them unconditional payment. Last, we have outlined the research that should be conducted in order to discover if UP, when used to recruit subjects in some contexts, is a practical solution to an important problem.

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Author note

Some citations were omitted because of the journal's limit on references. We are happy to provide full citations on request.

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