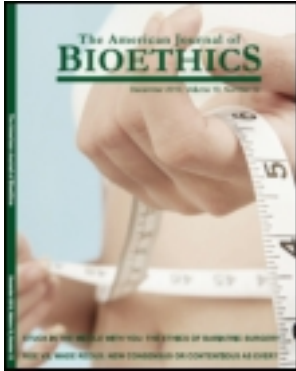


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Money for Research Participation: Does It Jeopardize Informed Consent?

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Some are concerned about the possibility that offering money for research participation can constitute coercion or undue influence capable of distorting the judgment of potential research subjects and compromising the voluntariness of their informed consent. The author recognizes that more often than not there are multiple influences leading to decisions, including decisions about research participation. The concept of undue influence is explored, as well as the question of whether or not there is something uniquely distorting about money as opposed to a chance for treatment or medical care. An amount of money that is not excessive and is calculated on the basis of time or contribution may, rather than constitute an undue inducement, be an indication of respect for the time and contribution that research subjects make.

—“EARN \$30 IN ONE HOUR” (*Washington Post* 1999b)

—“\$\$\$Skin Ulcer Research Project\$\$\$” (*Washington Post* 1999a)

Keywords

undue inducement

payment

informed consent

coercion

research participation

ethics of research

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Advertisements similar to these are increasingly common in newspapers around the United States, where, every day, people receive money for their participation in clinical research designed to test new drugs or devices or to learn more about human health and illness. Money is offered to research subjects as reimbursement for their expenses, compensation or reward for their time and effort, and/or as an incentive for studies that might otherwise have difficulty recruiting. Even though the practice of paying subjects is quite common, attitudes among investigators, members of Institutional Review Boards (IRBs) and others diverge, with some defending payment to research subjects as fair and appropriate and others condemning it as problematic and possibly even offensive or unethical.

Some of those uncomfortable with paying subjects are concerned that payment could jeopardize informed consent. Specifically, the concern is that money is potentially coercive or could cause “undue inducement.” Coercion and undue inducement are threats to the possibility of voluntary informed

consent, a tenet of ethical research as described in guidelines and codes of research ethics. The U.S. Common Rule for the Protection of Human Subjects (1991) states:

An investigator shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate *and that minimize the possibility of coercion or undue influence.* (emphasis added)

The U.S. Food and Drug Administration (FDA) requires IRBs to “review both the amount of payment and the method and timing of disbursement *to assure that neither are coercive or present undue influence*” (1998, emphasis added). In this article I will briefly explore the concepts of coercion and undue influence as they have been applied to paying research subjects. I argue that the offer of payment to research subjects is not coercive, and that although in rare circumstances money could possibly constitute an undue inducement, prohibiting the use of money for research subjects is not the solution.

An individual’s agreement to participate in research after deciding—based on information about the study—that it is compatible with his or her in-

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terests is an informed consent, widely accepted as central to the ethical conduct of clinical research. Informed consent is a process that includes several elements. In this process a potential research subject who is capable of making decisions is provided with information about a proposed study in an amount and manner sufficient to promote a thorough understanding of the purpose, risks, benefits, alternatives, and requirements of the study. Given the information, a subject then voluntarily decides whether or not he or she wants to participate. Voluntariness is understood, as suggested above, as free from coercion and undue influence. Under what circumstances or conditions might the offer of money be coercive or unduly influential and thereby limit voluntariness?

Although in common usage “coercion” is often meant to include much more, coercion is, by definition, the intentional use of a credible and severe threat of harm or force to control another or compel him or her to do something (Beauchamp and Childress 1994, 165). Coercion, although certainly possible in research, is not very probable under the current system of checks and balances. Threatening someone who refuses to participate in a research study with punishment or retaliation (for example, by a military officer, a professor, employer, warden, or even a doctor) would be coercive. Coercion may also occur if someone who refused to participate was threatened with physical or other harm (e.g., injury or loss of promotion or a job). However, since the offer of money is not a threat of punishment or harm, but rather an offer, it is hard to see how money as payment for research participation is or could be coercive (Faden and Beauchamp 1986, ch. 10; Wilkinson and Moore 1997). But what about money as undue influence?

Undue influence might be thought of as *too much* or *excessive* influence. Therefore it is worth briefly considering the nature of influence more generally. Most decisions that a person makes, including the decision whether to participate in a research study, are susceptible to multiple influences. People usually choose and act in accordance with their wants and needs, influenced by their physical, psychological, social, economic, and cultural experiences and circumstances. Ruth Faden and Tom Beauchamp in their landmark work, *A History and Theory of Informed Consent*, recognize that “influences come in many forms, and from many sources. . . . They can vary dramatically in degree of influence actually exerted” (1986, 256). Some influ-

ences are strong enough to serve as inducements, motivations, or stimuli for action.

However, inducements—many of which are nonmonetary—do not necessarily invalidate or preclude voluntary choice. We welcome and respond to inducements all of the time in many areas of life, including selecting employment, making purchases, and other choices. For example, even if we are attracted to a job by a higher salary, we still generally choose a job based on a number of other factors, including what we feel qualified for, what would be satisfying, as well as where, with whom, and what hours we would work. Since human motivation is complex and almost always involves multiple considerations, there is rarely a single reason for doing something. In the same way, being attracted to the money offered for research participation does not necessarily negate the possibility of other influential motivations and considerations. Subjects participate in research for multiple reasons. For some subjects money may be one reason among others. If inducements can be compatible with voluntary choice, then money, as an inducement, does not inherently obviate or compromise voluntariness.

Payment for research participation has been objected to, however, not simply because it is an inducement, but because it can be an *undue* inducement or influence. In Faden and Beauchamp’s analysis, influences exist along a continuum from controlling to noncontrolling. Control beyond a certain point is not compatible with voluntary autonomous decision making and action. The control of influences found “irresistible” by an individual might compel unwelcome choices and in this sense compromise voluntariness (Faden and Beauchamp 1986, 256). These influences might be regarded as “undue” or excessively influential. On this analysis individuals who find participation in a particular research study unwelcome yet are unable to refuse because of the influence or inducement of money could be “unduly induced.” Presumably, most subjects attracted to research by money, or subjects who choose to participate in research partly because of the money, do have the freedom to refuse. Prospective subjects are reminded of their right to exercise this freedom in the process of obtaining informed consent. They are advised that participation is their choice and they have the right to refuse or withdraw at any time without penalty. In addition, many people who are attracted to research because of the money (including students,

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people looking for a little extra income, or even the “professional guinea pig”) generally do have additional options for obtaining money, usually from other full or part-time unskilled jobs. Perhaps they select research participation because it has more flexible hours, is time limited, or seems more interesting or easier. In addition, research volunteers can and do exercise their freedom to refuse when they decide participating in the particular study is not in their interests. Perhaps the potential for undue inducement—in the sense that money literally makes research an offer that one cannot refuse—is a worry when a person is economically destitute and truly has no other options for acquiring comparable amounts of money. Even then, do we protect such people by allowing them to participate in (the same kind of) research without receiving money or by not allowing them to participate at all? In fact, denying the possibility of financial payment to a research subject may serve only to eliminate an option—the option of obtaining money through research participation. Careful attention, in the process of obtaining informed consent, to a subject’s reasons for participating, his or her understanding and expectations of research, and his or her sense of freedom to choose to participate or not seems more appropriate and may be more effective than eliminating the opportunity to receive money. The offer of money for research participation may actually expand options for some people, while not restricting their options to do anything else they could otherwise have done (Wilkinson and Moore 1999).

If a principal concern with respect to undue influence is a limited freedom to refuse research participation because of the lack of other available money-making options, we ought to be at least as or more concerned about other influences on research subjects with other types of need and limited options. These influences include: the promise of treatment, albeit investigational, for the desperately ill who have exhausted other treatment options; access to care or medications or other treatment for those who cannot afford these on their own or have no or inadequate healthcare coverage; the advice from a trusted physician or healthcare provider that the study is the best or only hope; or course credit for student participants. People in these situations may find research participation extremely difficult to resist or refuse. However, as Wilkinson and Moore (1997) argue, there may be a distinction between autonomy—understood as the ability to decide what to do for oneself—and freedom—the presence of more than one acceptable

option. According to their analysis, even people who are unfree, in that they have no other good options, may still be capable of autonomous consent. A nonresearch example of this is our acceptance of individuals’ right to refuse life-sustaining therapy, based on respect for their autonomy, knowing that, in many cases, their options are limited to either accepting the therapy or death. There are few data on the extent to which research participants feel free to refuse or withdraw from research within the context of their often limited options, and the extent to which some actually do agree to participate in research that compromises their values or interests. Of note is data collected in the Subject Interview Survey by the Advisory Committee on Human Radiation Experiments. They report that 31% of responding patients felt they had no choice but to participate because of their few medical alternatives (1996, 469). Nevertheless, greater than 98% felt that “the decision to participate had been theirs to make and that they had not felt pressured into that decision” (472). Further empirical research would help us to better understand these issues.

According to the Belmont Report, an influence may be *undue* not only when it is *excessive*, but also when it is *inappropriate* or improper (National Commission for the Protection of Human Subjects of Biomedical Behavioral Research 1979). Some may believe that money, unlike the need for treatment or care, is an *inappropriate* influence in decisions about research participation. It is sometimes argued that since research participants volunteer with altruistic motives of contributing to science and society, money has no place in this arrangement. The ethical concern, then, is not simply that some might find the offer of money irresistible, but also that money is simply an inappropriate motivating factor for research participation. Money certainly has a reputation for getting people to do things they otherwise would not do, and, in some cases, for getting people to do something they know is wrong. Hence, we see daily newspaper accounts of scandals, bribes, and extortion. Money is also believed capable of inappropriately distorting people’s judgments and motivations. The U.S. Office of Protection from Research Risks (OPRR, replaced in 2000 by the Office of Human Research Protections (OHRP)) says that money as a possible undue inducement for research is problematic because it can impair an individual’s judgment regarding what is at stake in the research or blind him or her to the potential risks of research partici-

pation (1993, 3–44). OPRR further notes that offers of money could cause potential participants to misrepresent something about themselves in order to gain or maintain enrollment in a study and receive the money. Misrepresentation may not only jeopardize the participant's informed consent, but possibly also his or her well-being as well as the integrity of the study. An individual's susceptibility to distorted judgment because of money is relative to his or her particular circumstances, but importantly also to his or her values, as some people even in very desperate straits cannot be "bought." Presumably, however, the larger the sum of money involved, the greater the potential for distorting judgment or prompting potential participants to lie or ignore risks. Commentators and common wisdom have argued that limiting the amount of payment offered for research participation minimizes the possibility that money will distort judgment and push people towards deception (Levine 1986; Macklin 1981). Payment as recognition of the research participant's contribution and calculated according to some regularly applied and locally acceptable standard (per day, visit, or procedure) is likely to be more modest and less likely to distort judgment than amounts designed solely to attract subjects and outperform the competition in terms of recruitment (Dickert and Grady 1999). Arbitrary or large amounts of money designed simply to entice, to outbid other studies, or to make up for risk should not be allowed. Modest payment thought of as remuneration for the participant's contribution minimizes the possibility of undue inducement, because the offer of money is neither excessive nor inappropriate.

On the other hand, it is not clear that money is uniquely capable of distorting judgment about the risks and benefits of research. Again, a person with few or no other treatment options might also be prompted to conceal something about past medical history or current behaviors that would otherwise disqualify him or her from the option he or she perceives as the best "treatment" or only hope. In the process of obtaining informed consent, particular care should be taken with people who might be feeling desperate. In order to assess comprehension and ensure an adequate voluntary informed consent, reasons for participating should be carefully assessed, as well as participants' understanding of the research risks and benefits and the alternatives available to them. Information about the potential for therapeutic benefit or lack thereof in any particular study should be presented clearly and accu-

rately. In addition, the threshold of understanding should be higher for those who are invited to participate in risky, uncomfortable, or even inconvenient research without the prospect of direct benefit to them, whether they be healthy students looking for a little extra cash or chronically ill and vulnerable patients dependent on us for their treatment and care.

Some may object that careful evaluation of a research participant's motivations for participating and his or her understanding of risks, benefits, and alternatives puts too much additional burden on the process of obtaining informed consent—a process which is already less than ideal. In my view, by focusing less on the details and words in written documents and focusing more time and attention assuring that research subjects understand and feel confident that the choice about participation is theirs, we could improve the reality of informed consent.

Summary

A decision about whether or not to participate in research is subject to many influences, of various forms and degrees and from different sources. Money may be one of these influences, although it is often just one among several other factors that an individual will consider in making a decision. In asking prospective research participants to give informed consent for research participation, it is incumbent upon us not only to provide clear and honest information about the study and assess how well they understand the information provided, but also to assess their reasons for participating and whether they feel free to refuse. Particular attention should be given to the informed consent of individuals who perceive they have no other choice because they need the money or the "treatment" or something else available to them only through the research. In these cases extra effort to assure that they understand the nature, risks, benefits, alternatives, and requirements of the study is warranted. In addition, the amount of money offered through research participation should be standardized and calculated so that it is more or less comparable to that available through other similar unskilled moneymaking opportunities in the relevant community. In these ways the potential that money will unduly influence an individual to participate in a research study against his or her interests, or with a distorted view of what is at stake, is minimized.

Research participants volunteer and sacrifice

their time and effort to generate knowledge that is helpful to others and society, often with little or uncertain benefit for themselves. Rather than an undue inducement, money to reimburse research participants for their expenses and compensate them in some way for their time and effort may be a demonstration of respect and appreciation for these generous individuals. ■

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