

# Incentivization and the moral problem of involuntary consent in medical research

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## Abbreviations

CIOMS, Council for International Organisations of Medical Sciences; WHO, World Health Organization.

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## Abstract

The legal and moral permissibility of clinical research entails that researchers must secure the voluntary, informed consent of prospective research participants before enrolling them in studies. In seeking the consent of potential participants, researchers are also allowed to incentivise the recruitment process because many studies would fail to meet enrollment goals without a financial incentive for participation. Some philosophers and bioethicists contend that the use of incentives to secure consent from research subjects is problematic because it constitutes undue inducement and a coercive offer. Some proponents of this view are Ruth Macklin (1981, 1989) and Joan McGregor (2005). Macklin claims that it is ethically inappropriate to pay research subjects. The payment is likely to coerce the research subject, thereby violating the ethical requirement on the voluntariness of research participation. Also, such offers can prompt subjects to lie, deceive or conceal information that, if known, would disqualify them as participants. For McGregor, incentives could be undue and coercive because they make offerees better off relative to their baseline as well as constrain them to accept the offer of incentives as the only eligible choice or option. I argue that coercive offers are distinct from undue inducement. Coercive offers are essentially morally objectionable because by making people accept an offer through threats for the sake of some interests or ends, the offeror vitiates the offeree's capacity to make informed, voluntary, and rational decisions and choices. I further claim that the quantity of an incentive does not render an inducement undue. I contend that the only condition under which incentives are regarded as an undue inducement and as such vitiates an agent's voluntary consent is if they are offered through deceptive or manipulative means.

**Keywords:** voluntariness; informed consent; incentives; coercive offers; undue inducement; human rights

## Introduction

Consent is a fundamental ethical requirement for all clinical research. The voluntary, informed consent of prospective research participants is required for clinical research to be morally permissible. The Nuremberg Code, for instance, provides that a research participant must be in a position "to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion" [1]. Also, the participant ought to have "sufficient knowledge and comprehension of the elements of the subject matter involved as to enable them to make an understanding and enlightened decision" [1].

The indispensability of the consent requirement as provided in the Nuremberg Code is reiterated in the Belmont Report. The Belmont Report states that "an agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence" [2]. The above provisions suggest that it is morally wrong to violate a participant's right to give voluntary informed consent (whether a patient or a healthy participant).

The implication of the provisions of the ethical documents cited above is that participants voluntarily consent to a study if their decision is not coerced or unduly influenced by a researcher or someone else. The Council for International Organizations of Medical Sciences (CIOMS) guidelines, for instance, state that "voluntary consent can be undermined or compromised when researchers (or a family or a person in authority) pressure eligible participants to enroll for medical research [3]. This provision suggests that an action would be deemed involuntary whenever a person is pressured. But this is not always the case. Wertheimer, for instance, notes that a person may claim that their decision to donate blood is completely voluntary because no one asked them to give blood. But it does not follow that the person's consent to donate blood is involuntary if someone is consistently persuaded or pressured to donate the blood due to a shortage [4].

Similarly, my child may consistently request that I buy chocolate for her, and I may not be willing to buy the chocolate now, but for the pressure. However, conceding to my child's pressure does not undermine my voluntariness in any way. I assume that the idea of pressure implied in the Council for International Organizations of Medical Sciences (CIOMS) guidelines concerns either coercion or undue inducement (or undue influence). The CIOMS guidelines corroborate this assumption as follows: "informed consent is voluntary if an individual's decision to participate is free from undue influence (and of course if it is not coerced)" [3].

There is no gainsaying that a patient or research subject's voluntary, informed consent can be vitiated if they are forced to enroll in studies as is the case in the infamous Nazi experiments. These experiments were grotesquely barbaric because participants were forced to enroll in the studies. For instance, during one of the experiments, the Nazi scientists forcefully infected some prisoners with typhus to test the efficacy of the typhus vaccine. In other words, the Nazi scientist exploited the prisoners by treating them as mere means or opportunities for their scientific interests and those of Hitler's Nazi government [5].

However, it is difficult to ascertain how a person's voluntary consent is vitiated in the case of undue inducement without first understanding what the concept entails. Some bioethicists contend that undue inducement is synonymous with a coercive offer. They claim that undue inducement or coercive offers occur if incentives offered to agents make them better off [6] or induce them to lie or conceal information [7]. The purpose of this paper is to examine the concepts of undue inducement and coercive offers. I will show that it is misleading to conflate both concepts because they mean different things.

After providing a succinct distinction between a coercive offer and undue inducement, I will argue that coercive offers are essentially morally objectionable because by making people accept an offer through threats for the sake of some interests or ends, the offeror

vitiate the offeree's capacity to make informed, voluntary, and rational decisions and choices. Finally, I will show that the quantity of an incentive does not render an inducement undue. The only condition under which incentives are regarded as an undue inducement and as such vitiates an agent's voluntary consent is if they are offered through deceptive or manipulative means. To start this discussion, let us first explore the concept of undue inducement and its interrelatedness with the concept of coercive offer based on the views of Ruth Macklin and Joan McGregor. I will use textual analysis and some relevant case studies to defend my arguments.

## The problem of coercive offer and undue inducement: Macklin and McGregor

The use of incentives in clinical trials is common in medical research. The success of any clinical study depends on the availability of research participants. Some bioethicists and policymakers believe that incentives are essential for medical research because they motivate volunteers to enroll and remain in clinical studies [3, 8, 9].

Some bioethicists, however, claim that the use of incentives like money or the promise of medical care is morally problematic and exploitative because it coerces potential participants to enroll in medical research that they would not consent to if they were economically advantaged. One of the proponents of this view is Ruth Macklin. She contends that it is ethically inappropriate to pay research subjects. The payment is likely to coerce the research subject, thereby violating the ethical requirement on the voluntariness of research participation [10]. Elsewhere, Macklin argues that some financial incentives are undue inducement and as such morally inappropriate if they are so much that they "prompt subjects to lie, deceive, or conceal information that, if known, would disqualify them as participants" [7].

Like Macklin, Joan McGregor conflates undue inducement with a coercive offer. Note that Macklin thinks that undue inducement is coercive because it forces the offeree, who is in a desperate situation, to agree to offers they would not consent to if they were well off. McGregor, on the other hand, thinks that undue inducement plays two fundamental roles, namely: (i) it makes an offeree better off relative to their baseline, and (ii) it constrains the offeree to accept the offer or proposal as the only eligible choice or option [6].

McGregor's description of undue inducement as a coercive offer is in response to Ezekiel Emanuel's claim that undue inducement involves four essential elements, which are that "a good is offered in order to do something; 2) the offered good is excessive so that it is irresistible; 3) this leads to poor judgment on the part of the offeree; 4) that poor judgment leads to a high probability of a serious risk of harm" [11]. McGregor used an example of a lecherous millionaire to explain why the above elements of undue inducement outlined by Emanuel are inadequate to explain the concept of undue inducement.

For instance, she says we should assume that "a Millionaire proposes to an impecunious mother that he will pay for the medical treatment that her child needs if she will become his mistress." Accessing the conditions of undue inducement outlined by Emanuel shows that the lecherous millionaire example does not meet most of them. For example, although the offer was made to persuade the woman to fulfill a demand of being a mistress, it is difficult to ascertain whether the offer was excessive. The point is that it is difficult to quantify being a mistress with paying for the woman's child's hospital bills. And as McGregor claims, making an offer to pay for the impecunious woman's child's treatment may be irresistible because of her desperation to see that her child receives urgent medical care, however, it does not seem that the offer is 'excessive' since the notion of excessive is extremely context-dependent [6].

McGregor also notes that the decision of the woman is rational and well thought out because it will be misleading to assume that it is poor judgement for a woman to accept an offer of being a mistress in exchange for money to treat her child. Even though such a decision is made in a desperate situation, it still shows that the woman considered her failure to refuse the offer and may have reached the conclusion that the consequences of refusing the offer are worse than

accepting it. And as McGregor rightly points out, "From the perspective of her child's welfare, it is in her interest to accept the offer" [6]. And finally, there is no indication that the example suggests that the millionaire exposed the woman to a serious risk of harm. While the woman would have preferred financial assistance without any extra demand like being the millionaire's mistress, on the hand, she will be extremely happy that at least, her child will be able to receive medical treatment for her ailment.

So, McGregor argues that what is wrong with the lecherous millionaire case is not that the woman is exposed to any serious risk of harm or that the offer is excessive that she can make a poor judgment. The problem is that "the lecherous millionaire used her vulnerability to "force" the woman to do what he wanted" [6]. She believes the presence of force in the offer renders it coercive. But even though the offer entails force, it still makes the woman better off because the offer of money relieves her from the trauma of seeing her child dying due to a lack of funds for treatment. So, the implication of the lecherous millionaire example, according to McGregor, is that "people who are in desperate situations can be made "better off" by offers that would be unacceptable to people whose normal course of events are not desperate or deprived in some way" [6].

### ***Rethinking the concepts of undue inducement and coercive offer***

Macklin and McGregor's claim that incentives are coercive if they make the offeree better off or induce offerees to lie or conceal information is wrongheaded. There is nothing coercive about financial incentives or any other kind of incentives if they do not involve threats or if the offeror did not contribute to the vulnerable situation of the victim before making the offer. Financial incentives may indeed be morally problematic. Wertheimer and Miller contend that the wrongness of financial incentives could be explained within the context of undue inducement but not as a coercive offer. Wertheimer and Miller, for instance, note that "if a physician (A) has an obligation to provide a patient (B) with medical services free of charge, say, because the national health service employs A, then A actually does coerce B into paying a fee if A proposes not to provide such services unless B pays" [12]. This is coercive because the doctor's unilateral decision to *deny* the patient free medical service violates the patient's right to free medical care.

The view of coercion proposed by Wertheimer and Miller is interesting because it helps to explain when an offer is coercive and when an offer is not. Every coercive proposal is backed up by threats, no matter their degree of severity. This point does not mean that all forms of threats are coercive. Some threats are manipulative, as in the Synflorix medical research case, in which the researchers claimed that the parents would expose their children to the risk of death if they withdrew them from the study. However, a paradigm case of coercion is the vicious robber case. We say that the vicious robber case is coercive because the robber's threat to kill the house owner if they refuse to disclose the code of the safe violates the house owner's rights and because the house owner does not have any other reasonable alternative but to comply [4, 12].

But when is an offer coercive? An offer is coercive when backed up by a threat to violate the victim's rights. For example, a doctor promises financial incentives to her patient if the patient enrolls in a study. Still, she threatens to withhold the patient's treatment if she refuses to enroll. This is a case of a coercive offer. It is an offer because it proposes to make the patient better off relative to their baseline. However, it is coercive because it violates the patient's right to receive treatments from the doctor.

A coercive offer is clearly distinguished from undue inducement. A coercive offer is an offer made using threats of physical harm or other forms of harm like withholding services or promotion with the intent of violating the victim's rights to secure compliance. I have also noted that where threats are not present, an offer could also be coercive if the offeror contributes to the vulnerable situation of the victim and then cashes in on the vulnerable situation to make the offer. On the other hand, Undue inducement refers to offers intended to predictably

stimulate a person to enter an exchange or perform an action they would not ordinarily consent to if they were well off or in an advantaged position.

The concept of undue inducement is often used to describe the wrongfulness of using financial and non-financial incentives to predictably stimulate prospective research subjects to enrol in a study against their better judgment, thereby vitiating the research subject's capacity to make voluntary, informed decisions about the study [3, 12-14]. Some bioethicists who view undue inducement in terms of a motivation that impairs or distorts an offeree's rational judgment also think that the reason for this impairment stems from the size of the offer made. Macklin, for instance, notes that the larger the financial incentives, "the more potential subjects are unduly influenced to participate in studies that are not in their best interests" [10]. The CIOMS guidelines also corroborate Macklin's intuition about undue inducement. The guidelines state that "compensation must not be so large as to induce potential participants to consent to participate in the research against their better judgment" [3]. In other words, the larger the compensation, the higher the risk of beclouding prospective participants' sense of better judgment and vitiating their capacity to make voluntary, informed decisions about enrolling in a study. In other words, for very needy people, "incentives" satisfy basic needs, and as such, those persons are barely able to refuse.

Nevertheless, it is important to note that the issue of describing undue inducement based on the size of a compensation is controversial. It is controversial in the sense that the amount of compensation that would attract A to perform a task could be different from what would attract B to perform the same task. This suggests that what constitutes large or little compensation depends on individual needs. Someone could quickly consent to a study merely with an offer of condoms and pills as in the case of the poor sex and illiterate sex worker in the Tenofovir clinical trial [15, 16]. A person of the middle class who has a job but urgently needs £5000 to meet some pressing needs like taking one's child for surgery would ignore the offers of condoms and pills because they would not serve their needs. So, the amount of financial incentives that would constitute undue inducement is relative.

Moreover, Ethics committees often struggle with defining an appropriate financial benchmark that researchers could meet that would not constitute undue inducement. So, I think that the size of a compensation is not necessary to explain the notion of undue inducement. Moreover, some research participants also enrol in research not for the sake of money but to secure adequate but free medical care. As Lee observes, the issue of undue inducement is not limited to money. People could also be unduly induced to enroll in study based on some promise to offer them free medical care [17, 18].

Undue inducement is morally objectionable and exposes an offeree to exploitation because the offeror uses it to secure compliance [13, 19, 20]. However, in all cases, undue inducement impairs a victim's better judgment or vitiates their capacity to make voluntary, informed decisions. In the case of the Lilly clinical experiment on homeless alcoholics, the financial incentives offered to the homeless alcoholics to make them enrol in the study constitute undue inducement. The reason the incentive is undue inducement is not that the amount of the incentive is so large. The amount offered by Lilly is modest compared to other pharmaceutical companies. Cohen, for instance, observes that for most companies to woo prospective participants to enrol in studies, they "advertise heavily and shell out \$125 or so a day, occasionally as much as \$250. SmithKline Beecham PLC even pays referral bonuses. By contrast, Lilly advertises less frequently and, at \$85 a day, pays what competitors believe is the lowest per diem in the business" [19].

Also, the moral issue of undue inducement in the case of the Lilly clinical trial is not because it impaired their better judgment. There is nothing irrational about agreeing to participate in a study to meet one's economic needs, just as it is not irrational for the woman to become the millionaire's mistress in exchange for money for her child's surgery. It is also not the case that the offer made the homeless alcoholics lose their capacity to make voluntary, informed decisions. Jansen rightly observes that due to therapeutic misconception, some

participants could be irrationally optimistic about the benefits they will derive from participating in a study even when they have been informed about the benefits and risks of enrolling in the study. However, “enrolling persons in a study when they are under a therapeutic misconception or some other kind of irrationality may not violate the requirement of informed consent. But it plausibly constitutes exploitation if exploitation occurs when one person uses another for her ends by “playing on some weakness or vulnerability in that person” [21].

Moreover, some participants voluntarily consent to studies even though they are unsure if it is in their best interest. For instance, the homeless alcoholics agreed to enroll in the Lilly trial, not because of any therapeutic misconception. The study involved only healthy participants, so there was no need to expect direct therapeutic benefits from the study. They enrolled because of the financial incentives they were to receive.

So, just as people voluntarily enroll in studies they know are not in their best medical interest, others enroll in studies for the sake of financial incentives irrespective of the risks involved in the study. For instance, in the Tenofovir clinical trial, the poor and illiterate sex workers agreed to enroll in the study because they received condoms and some pills. They believe that these incentives were enough to boost their opportunities to make more money. So, it would be absurd to suggest that the decisions of the sex workers were involuntary and uninformed even though the researchers notified them of the purpose of the study. However, what is fundamental about the offer made by the researchers in the above cases is that they constitute exploitation. The offers, strictly speaking, were intended to make the participants submit to the demands they would usually reject if they were in an advantaged situation.

The condition that would make undue inducement to vitiate or inhibit a participant's capacity to make voluntary informed decisions about a study is if the researcher uses deception or manipulative means to make the offer. For instance, in the Pfizer case, the parents of the meningitis children enrolled their children in the Pfizer clinical trial because the researchers informed them that the children were receiving adequate medical care [15, 22]. This case is an example of undue inducement because their parents ignorantly agreed to enroll them in the trial. Their ignorance does not in any way suggest that the parents acted irrationally. However, it vitiated their capacity to make voluntary, informed decisions. If the parents had known that Pfizer was administering a trial drug that was not meant to be taken by sick children, possibly they would not allow their children to take it, especially when Doctors without Borders were also administering the sick children with Chloramphenicol, safe and effective antibiotics that World Health Organization (WHO) approved.

## Conclusion

I note that a coercive offer is different from undue inducement. The coercive offer involves threat while undue inducement does not. Financial or other forms of incentives (promise of therapeutic benefits) may constitute undue inducement when offered to induce the recipient to act in a way that furthers the offeror's interests. Also, the size of an offer does not count because what can unduly induce A may not induce B. Undue inducement does not essentially impair an offeree's capacity to make voluntary, informed decisions. Undue inducement triggers involuntariness on the part of the offeree only when the offeror incorporates deception like lying to cover up facts about the exchange or manipulation like withholding some information that would have assisted the offeree in making an informed decision.

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