Making It Harder to Say "No"

This dilemma occurred when I was completing my masters degree. I was collecting data in a very impoverished country, whose culture and language were immensely different from mine (i.e., the U.S). I signed onto the project shortly after the research proposal had been developed, funding was secured, and the protocol was vetted by both my university's IRB and the host country's. My job was to choose the site, recruit and retain subjects, and obtain baseline and endline blood samples.

We experienced recruitment problems right away. Many of our participants were illiterate, and so had to have the consent form read and explained. Also, some distrusted us and thought we were there to harm them.

At the study's end, it was necessary to collect blood samples. We had lost about 15 percent of the original sample for various reasons and therefore needed samples from all those still enrolled. I wasn't worried, though. I was confident we had assured those participants who might initially have had doubts about participating, and all the participants benefited from getting extra medical care and, often, free medicine. We also held ceremonies to honor and recognize them, and even had the study "blessed" by local religious heads.

So, it was quite a surprise when only 50 percent of the participants arrived at our make-shift clinic for their final blood draw. In something of a panic, we decided that instead of waiting for them to come to us, we would take our equipment and go to their houses. If they did not want to give us a blood sample, they could tell us at their doorsteps.

Did our strategy constitute an unacceptable level of coercion? I must say I wasn't entirely comfortable with it. Here we were, doctors and professionals in the field, arriving on their doorsteps with our lab coats on and all the equipment necessary to draw blood—wouldn't this make it harder for them to say "No"? And if we did make it harder, were we then violating their right to be left alone and refuse participation (a right guaranteed them when they initially consented to participate)?

In any event, the strategy worked. We were able to obtain enough samples to make our data credible. And after talking with other, more experienced researchers about blood sampling in other countries, I found that our strategy was not uncommon at all—that collecting enough data from certain nonwestern populations can be very difficult and that you do whatever is ethically reasonable to get the job done. In fact, we did have some participants deny our requests for a final blood draw, indicating that there was still ample opportunity for participants to withdraw. I nevertheless wonder whether our strategy crossed the ethical line of respecting our participants' right to refuse.

Expert Opinion

Let’s begin by identifying some factors in this case that might explain the dilemma contributor’s discomfort about the “home visit” blood draw strategy. First of all, most of the research participants in the study are impoverished and poorly educated. That

very fact can make it seem that they are eminently exploitable and, hence, must be protected more keenly or aggressively than a population of research subjects who are well-educated and hail from economically well-off societies. Second, the participants are provided with free medicine and health care and are invited to ceremonies where they are honored. That might make it seem that the researchers are "bribing" them for their participation or at least that the researchers are creating a "gift relationship" such that the participants will feel pressured to participate when they'd prefer not to. A third source of the dilemma contributor's feelings of moral guilt might involve the realization that the participants are vastly culturally different from the investigators. That realization might cause some of the investigators to question whether the participants could really give informed consent to the study at all, as the western notion of consent, its trappings, and western science in general might be hopelessly alien, even meaningless to them. In other words: No wonder they don't want to participate. Altogether then, this trio of concerns might explain the dilemma contributor's unease that the research team's visiting the participants' houses to collect data was morally overboard.

Zeke Emanuel and his colleagues participating in Project Phidisa (of the South African National Defense Force of Pretoria, South Africa) have recently written about undue inducement in clinical research in developing countries.[1] Their reflections and distinctions about the natures of undue inducement, coercion, exploitation, injustice, and deception are worth our attention. Saving "undue inducement" for last, let us briefly examine this list of moral turpitudes per Emanuel's analyses and ask if they apply to the dilemma contributor's scenario.

Were the participants "coerced" to participate in the final blood draw? One could make a strong argument that they weren't. Coercion should be understood as a forced choice situation wherein whatever I choose, I will be <u>worse off</u> than I was before the decision situation presented itself. The classic coercive scenario is someone's pointing a gun at you and threatening, "Your money or your life!" Either way you choose, you're worse off. But in this scenario, the research participants could, and some did, refuse the second blood draw such that their situation did not change from how it was immediately before the research team knocked on their doors. To the extent that they could return to that baseline with a simple "No," the home visit wouldn't seem to qualify as coercion, especially if the team reiterated the villager's right to refuse participation at the home visit. Nevertheless, it might be objected that the participants' refusing would make some of them feel badly or guilty, especially given the history of their relationship with the research team. Perhaps the research team's was <u>exploiting</u> a socioeconomic group such that they couldn't say no.

But exploitation doesn't ring true either. Somewhat like coercion, exploitation also envisions the person being worse off for having accepted the offer or deal. However, although the exploited party receives some benefits from the deal, those benefits are considerably exceeded by the <u>losses</u> he or she sustains. A familiar example of exploitation would be to pay paltry wages to persons who are starving and desperate for work, such as occurs in sweatshops. The arrangement is an unjust one because it represents a lopsided distribution of benefits and burdens: Exploited parties customarily

endure immense burdens in comparison to the meager benefits they receive. Indeed, whatever substantial benefits there are go to someone else. But the exploited parties are so desperate that they will do things they would ordinarily refuse under more humane, socioeconomically respectable arrangements.

So, exploitation doesn't appear to have happened here. The burdens or discomforts of a blood draw do not seem unreasonable compared with the benefits the participants received earlier by way of free medicine and health care. And people who receive attractive, desirable benefits as part of a deal are not thought to be exploited.

But perhaps one might still object that the above doesn't get at the situation under consideration, which concerns the way the research team might have overly pressured the subjects to participate in the final blood draw by visiting them at their homes. Note, however, that one can only do justice to that issue by examining the factors leading up to the home visit, as in: Were those antecedent factors so unduly influential that the participants simply could not refuse to give blood when the researchers knocked on their doors? Did the historical factors of the research team's having provided benefits deplete the participants of their voluntariness to say "No"? Obviously, if the research team had just showed up at the participants' homes with no antecedent history and asked for their research participation, the team would almost certainly have been denied. So it seems more accurate to ask whether the history of the participants' and research team's relationship that led up to the team's physically appearing in the participant's home amounted to "undue inducement."

Emanuel and his colleagues point out that undue inducement is always a matter of a benefits/burdens calculation, usually where the risk burden is high but the benefit is even higher. Because the benefit is so attractive, the inducement is thought "undue" because it compromises the judgment of the decider, who might be inclined to dismiss the gravity of the risk. One thinks of the film *Indecent Proposal*, where a married woman tells her husband that she has been offered a million dollars to sleep with a handsome, extremely wealthy man. She and her husband accept the offer, the deed is done, and they spend the rest of the movie managing its increasingly painful repercussions.

But the present scenario does not seem to suggest an instance of undue inducement. The reason is that while it is hard to estimate the degree of benefit that accrued to the research participants—which in some instances, say, of an exceedingly ill child who was cured of his illness, could have been enormous—the actual degree of burden the participants experienced from their participation was modest. Importantly, the fact that certain participants might have reaped an immense benefit from their participation does not make the situation one of "undue" inducement because, as Emanuel points out, people are induced to do things all the time. To eradicate inducements or incentives from life would make many relationships very different from the way we have become accustomed. Relationships become ethically problematic not only when the inducement is large, but when it tempts the individual to do something excessively or unreasonably risky or unpleasant. In the extant case, that level of risk or burden appears not to have been present.

Perhaps some readers will still want to argue that the researchers' appearance at the participants houses was "coercive" by interpreting the situation this way: When the research team appeared at a home—and again we are assuming that the team members asked for the participants' permission to proceed with the blood draw—the dweller was faced with two choices: The first was to refuse participation and perhaps feel very guilty; the second was to participate and feel the unpleasantness of the needle stick. Either way, the participant is worse off than he or she was before the research team's knock on the door. Thus the situation was coercive.

Nevertheless, if the entirety of the research relationship with the participants is taken into account, especially regarding the benefits the latter received earlier by way of free medicines and health care, it is hard to indict the house call of the research team as coercive. Neither guilt induction from refusing to participate nor the prick of the needle drawing blood seems excessively nasty, while the free medicines and treatment accruing to the participants from their first blood draw seems to considerably offset, if not negate altogether, the discomfort of a second stick. One does not come away from a truly coercive offer with a striking, net benefit.

In sum, while the blood draw taken at the participants' homes might have deviated from the research protocol (and therefore must be reported as such), it does not appear to be morally tainted. Protecting the welfare of research participants appeared to have been preserved and, assuming the participants were reminded of their right to decline the second draw, respect for their right of informed consent was reasonably preserved.

We should add a postscript, however, not contemplated in the scenario. Methodologists might well question whether the data is compromised by the first set of blood draws occurring in a clinical setting, while the second occurred in the participants' homes. This was certainly a protocol deviation that merits a legitimate worry. Perhaps the best way to handle it is for the authors to disclose it in the methods section of their report or manuscript.

1. Emanuel EJ, Currie XE, Allen Herman. Undue inducement in clinical research in developing countries: is it a worry? *Lancet*, 2005;366:336-40.