Manipulation in the Enrollment of Research Participants

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Researchers can design recruitment and consent processes so that potential participants are more likely to decide to enroll. These strategies work by subtly manipulating the participants. But how much manipulation is acceptable?

Dr. Khan is trying to enroll patients at his hospital into a clinical trial of a new hypertension medication, but recruitment is slow. A colleague advises him: "Stop having the staff ask people if they want to be in the study. You need to use the 'white coat effect.' Have the nurse show the patients into your office. Make them wait, like it's a privilege to see you. Put on your coat and stethoscope and sit behind your desk. These people don't like to say no to doctors—they'll agree if you ask them."

Recruitment is a challenge for many biomedical research studies with human participants. Recruiting sufficient eligible participants for a study is essential if the study is to be adequately powered to yield socially valuable information, but recruitment can also be a time-consuming and expensive process. Strategies to increase the speed and ease of recruitment are therefore valuable.[1]

Various factors can influence whether someone enrolls in a research study. She may be hoping for a cure for her illness, trying to help other people, or simply in it for the money.[2] More subtly, the chances of her agreeing to participate may be increased by her respect for the authority of the recruiting physician, trust in the research institution, or peer pressure. When researchers are aware of the factors that affect their potential participants' decisions, they may be able to design recruitment strategies that make use of them in order to encourage people to enroll. In the case above, for example, Dr. Khan's colleague suggests that he leverage patients' respect for the medical profession in order to motivate them to take part in his study. Most discussions of

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inappropriate ways in which people could be influenced to give consent to research participation have focused on coercion or undue inducement.[3] But Dr. Khan would be engaged in neither. Instead, if his recruitment strategy is problematic, it is because it would be manipulative.

In this paper we analyze the noncoercive ways in which researchers can use knowledge about the decision-making tendencies of potential participants in order to motivate them to consent to research enrollment. We identify which modes of influence preserve respect for participants' autonomy and which disrespect autonomy, applying the umbrella term "manipulation" to the latter. We then apply our analysis to a series of cases adapted from the experiences of clinical researchers in order to develop a framework for thinking through the ethics of manipulating people into research participation. All manipulation disrespects autonomy and is therefore pro tanto wrong. However, only deceptive manipulation invalidates the consent that results from it. Use of the other forms of manipulation can be permissible, but only if the outcome of using manipulation is sufficiently good, *and* the research cannot be carried out using ethically preferable means to obtain consent.

We begin by parsing out the ways in which one agent can influence another in order to motivate a specific action that the second agent has an autonomy right to decide whether to perform. (An autonomy right is a right whose possession depends on the bearer possessing the capacity for autonomous action such that she can exercise it.) Although we are ultimately interested in the action of giving consent to research participation, our analysis uses examples of actions that are from outside the domain of research and over which competent adults also have autonomy rights. In each case, we determine whether one agent's influence of another respects or disrespects his autonomy.

Altering Perceptions

Some forms of influence involve changing a person's beliefs or preferences—and, therefore, his perception of the options available to him—in order to motivate him toward a specific action.

Persuasion. Elizabeth wants Miguel to join her on a ten-mile run. To motivate him to do so, she points out that the marathon he signed up for is only a month away, and that going with her on a long run would be great training. Elizabeth presents facts about the ten-mile run and makes a logical link between Miguel's existing interest in running a marathon and the benefits of the ten-mile run. In doing so, Elizabeth persuades Miguel to go running with her.

One agent persuades another to pursue a specific action when she motivates him by showing rational links between his existing set of reasons to act and that action. She can do this by showing logical connections between his existing reasons and the act she wants him to perform, or by honestly presenting facts that are relevant to his reasons to act. Because she does not illegitimately interfere with his decision-making process, this persuasion is respectful of autonomy.[4]

Deceptive manipulation. Bill wants Anne to buy his bike. She asks him if it is in good repair. Although he knows the bike is in poor condition, Bill tells Anne that it is in perfect shape. Anne pays Bill one hundred dollars for the bike. When she first rides it, the brakes don't work and the cogset falls off. Bill has deceived Anne into buying a broken bike.

When one agent deceives another about facts that are relevant to his reasons for or against pursuing a specific action, thereby changing his perception of the options available to him in a way that disposes him to perform that action, she uses deceptive manipulation.[5] Deceiving him is an illegitimate way to interfere with his decision-making. It therefore disrespects his autonomy.

Persuasion and deceptive manipulation both involve changing a person's perception of the options available to him. Although persuasion, as we have defined it, respects a person's autonomy and deceptive manipulation does not, both involve some reliance on that person's rationality. There is a third form of motivation that also changes a person's perception of the options available to him but does not appeal to his rational faculties.

Identifying manipulation as a pro tanto wrong is not enough to tell us how to evaluate its use to encourage people to enroll in research. We are interested in finding out if the use of manipulation to increase participation in socially valuable research is ever ethically permissible.

Motivational manipulation. A Hare Krishna member cheerfully hands a flower to a passerby and tells her it is a gift for her on this beautiful day. When she accepts the flower he asks if she will give a donation to the Hare Krishna Society. With the flower already in her hand, the woman feels bad about just walking on. Despite having no interest in supporting the Hare Krishna Society, she reaches into her wallet and hands him some cash.[6]

The woman's considered preference would be not to donate, but the Hare Krishna has manipulated her motivations so that her immediate desire to reciprocate his gift is stronger than her desire to avoid giving money to the Hare Krishna Society. The Hare Krishna takes advantage of

Table 1. Forms of Influence

	Respects Autonomy		*Disrespects Autonomy*			
Motivational Method	altering perceptions	altering options	altering perceptions		altering options	
Form of Influence	persuasion	offers	deceptive manipulation	motivational manipulation	circumstantial manipulation	coercion

the woman's predictable susceptibility to social norms of reciprocity so that she makes her decision about whether to donate on the basis of this immediate desire instead of on the basis of the values and preferences she would otherwise deem most relevant.

When one agent causes another to act on desires that, upon reflection, he would reject as reasons to pursue a specific action, she uses motivational manipulation.[7] She can do this by stimulating a novel desire in her victim or by amplifying an existing desire. Either way, her interference in her victim's decision-making causes him to act based on immediate desires instead of the values and preferences he would, absent her influence, choose to involve in his decision-making. By interfering with his process of weighing his considered preferences and values, she makes his decision-making process less rational (without his consent). She thereby disrespects his autonomy.

Altering Options

The forms of motivation discussed so far involve changing a person's perception of his options. It is also possible to motivate someone by changing the options themselves.

Coercion. A robber holds a gun to Rebecca's head and says, "Your money or your life!" Faced with the robber's credible threat, and with no reasonable alternative but to comply with his demand, Rebecca hands the robber her wallet.

When one agent proposes to make another agent worse off if he does not comply with her demands, she coerces him.[8] In a coercive situation, the coerced person's action may be completely rational. Nonetheless, if the coercer does not have the right to control that person's decision by changing his options in this way (limiting the available options and presenting new risks of harms to him), then the coercion disrespects his autonomy.[9]

Offers. Mudit offers Frank twenty dollars to wash his car. Frank wouldn't have washed Mudit's car prior to the offer, but the financial incentive gives him a reason to do so.

While coercion involves a proposal to make a person worse off if he does not pursue a particular action, an offer is a proposal to make a person *better* off if he pursues that action. Unlike threats, offers do not constrain a person's options or present new risks of harms to him. Making an offer is a way that you can change someone's options in order to motivate him toward a particular action while still respecting his autonomy.[10]

Circumstantial manipulation. Peter calls his friend John and asks if he wants to go out to dinner. They meet at an upscale restaurant. When the time comes to pay the bill, Peter tells John that he "forgot" his wallet and that he lives too far away from the restaurant to return home for it. As Peter knows, John places a high value on standing by his friends. Unlike Peter, John would not countenance leaving a restaurant bill unpaid. Not wanting to make a fuss or appear rude, John pays for dinner. If John had known that Peter would pull such a stunt, he would not have agreed to go to dinner with him in the first place.

By deceiving John about his intentions to leave his wallet at home, Peter has caused John to go out to a dinner at which the option of paying for the whole meal ends up becoming the most reasonable option for him. Without Peter's influence over his circumstances, John would not have chosen to put himself in such a situation.

When one agent motivates another using circumstantial manipulation, she illegitimately changes the options open to him in order to cause him to pursue a specific action. Because she uses illegitimate means, her control over him is illegitimate and therefore disrespects his autonomy.

In the case of Peter's dinner, Peter's interference is illegitimate because he deceives John. His deception puts John into a situation in which the most reasonable thing for him to do is to act as Peter wants him to. Note that this is quite different from deceptive manipulation. In deceptive manipulation, the person manipulated is deceived about facts relevant to the decision about whether to pursue a specific action. In circumstantial manipulation, however, the deception is used only to get the person into a situation where he has to choose whether to pursue a specific action—in John's case, paying for dinner. Once there, John may have a clear understanding of the facts that are relevant to his decision about whether to pay for dinner, and the decision to pay may be perfectly reasonable; the problem is just that he would not have put himself into such a situation were it not for Peter's earlier wrongdoing.

There are several ways in which someone may control another's circumstances in order to influence his decision; not all of these constitute circumstantial manipulation. For example, suppose I want Sebastian to donate to my favorite charity. I know he has no interest in donating, so there is no point in asking him privately in his office. However, if I

ask him in the break room, where his colleagues are present, he will donate something because he wants to preserve his reputation for generosity.

Being perceived as generous is something that, upon reflection, Sebastian values. He would therefore consider it reasonable to take it into account in his decision-making process (so my influence of him does not constitute motivational manipulation). However, Sebastian would still rather not be put in a position where he donates. Is my asking him to donate in front of his colleagues in the break room manipulative? Not if I simply make sure to ask him there when he is there anyway, since there is nothing wrongful in the way that I control the situation in which he chooses. On the other hand, it would be manipulative to lure him there under the false pretext that there was free cake and then ask him. I would then wrong him through deception and thereby disrespect his autonomy by illegitimately controlling his decision. These fine distinctions are ones that a normative theory of manipulation can help us make.

The Wrong of Manipulation

As our analysis indicates, the forms of motivation that may be described as manipulation are diverse.[11] Even so, our definition is not intended to capture all everyday uses of the term. Instead, it is a moralized definition that captures a set of forms of motivation with common normative features. There are two reasons for preferring such a stipulative definition. First, we are skeptical that the term "manipulation," as used in everyday English, refers to a single unified concept that could be analyzed in order to draw normative conclusions about people's behavior. Second, we are interested primarily in the ethics of different research enrollment strategies rather than in the concept of manipulation per se. A definition that allows us to capture all the noncoercive but autonomy-disrespecting ways to motivate people is therefore most helpful for our purposes.

The most well-known definition of manipulation in the bioethics literature can be found in Ruth Faden and Tom Beauchamp's *A History and Theory of Informed Consent*. They define manipulation as "a catch all category for any intentional and successful influence of a person by non-coercively altering the actual choices available to the person or by non-persuasively altering the person's perception of those choices."[12] Faden and Beauchamp's definition locates manipulation as nonpersuasive and noncoercive. However, it would include in the category of manipulation forms of influence that respect autonomy, such as offers. The forms of influence that we define as manipulation therefore constitute a subset of those that would fall under Faden and Beauchamp's definition. Since our interest is in analyzing the wrong of different forms of motivation, our moralized account is better suited to our purposes.

Deceptive manipulation, motivational manipulation, and circumstantial manipulation all disrespect autonomy.[13] They are therefore pro tanto wrong. However, identifying manipulation as a pro tanto wrong is not enough to tell us how to evaluate the use of manipulation to encourage people to enroll into research. First, disrespecting someone's autonomy does not necessarily invalidate her consent. Under what conditions does manipulation into research participation invalidate consent? Second, we are interested in finding out if the use of manipulation to increase participation in socially valuable research is ever ethically permissible. Are there conditions under which the pro tanto wrong of using manipulation to recruit participants can be outweighed by countervailing reasons?

Manipulation and Consent

Five conditions must be met for informed consent to be valid: the person giving consent must have the capacity for autonomous action, certain information must be disclosed to her, she must understand certain facts about the act consented to, her decision must be voluntary, and she must indicate consent.[14] We are interested in situations in which manipulation may invalidate consent from an autonomous person—that is, someone with the capacity to consent. We therefore focus on whether and when manipulation affects disclosure, understanding, or voluntariness to such a degree that consent is invalidated.

The fact that manipulation is a pro tanto wrong implies that it cannot be justified only in virtue of resulting in a sufficiently good outcome; it must also be that other ways of achieving that outcome without similar or worse wrongs are not available.

In the case of consent to research enrollment, appropriate disclosure requires at least that the researcher must tell the prospective participant information about the research that she has good reason to think may be dispositive of his decision regarding participation. The criterion of understanding the act requires at least that the person who gives consent must know what act or acts she is consenting to. Voluntariness in this context, however, requires more detailed analysis.

Faden and Beauchamp analyze voluntariness in terms of control. They present a spectrum of control, with coercion at one end and persuasion at the other. In addition to these two extremes, Faden and Beauchamp

suggest, there are thresholds for "substantial control" and "substantial non-control." They argue that in order for a decision to qualify as autonomous, it must be "substantially non-controlled" by any party other than the person giving consent. According to Faden and Beauchamp, manipulation is a form of influence that extends across the entire spectrum of control: some forms of manipulation are substantially controlling and therefore invalidate consent, and some are substantially noncontrolling and therefore do not.[15] They provide no criteria with which to determine which forms of manipulation are substantially controlling and which are not.

One way to work out the criteria for substantial control is to draw an analogy from the case in which we are confident that the degree of control is sufficient to invalidate consent—that is, the case of coercion. If we can determine what it is about coercion that invalidates consent—independent of features that distinguish coercion from manipulation by definition, such as threats—then we can investigate whether there are cases of manipulation that also have this feature or features. This will tell us whether and when manipulation invalidates consent by rendering the consenter's action substantially noncontrolled.[16]

Not all threats are powerful enough to be controlling. For example, a threat to splash someone's shoes with water is so weak that we would expect it to be laughed off. When is a threat controlling, such that it would invalidate consent? We suggest that it reaches this point when we would no longer consider the threatened person morally responsible for her actions. In cases of duress, we do not blame the person acting under duress, but (if anyone) the agent who put her there. Likewise, in cases of coerced consent, we do not attribute the act of consenting to the coerced person. In the case of duress, the point at which someone is no longer responsible for her actions is, roughly, where she has no reasonable alternative but to comply.[17] For example, a cashier who hands over the contents of the register to an armed robber who credibly threatens to shoot him has done nothing wrong. The same criterion can be applied to consent. Thus, someone who agrees to sex at the point of a knife is the victim of rape.

We now return to the three types of influence that fall under the umbrella of manipulation, and apply the conditions of disclosure, understanding, and substantial noncontrol in order to evaluate the validity of consent in each case.

Deceptive manipulation. Deceptive manipulation typically violates both the disclosure and understanding requirements for informed consent because the recipient of consent does not disclose relevant facts, and the giver of consent does not therefore understand what he is consenting to.[18] For example, in the case of the broken bicycle, Bill fails to disclose something that he has good reason to think is relevant to Anne's decision about buying the bike. Both Anne and Bill then know that Anne takes herself to be consenting to buying a working bike, but Bill knows that the bike he is giving her is not working. Deceptive manipulation therefore renders consent invalid. In research, it is well accepted that deceiving prospective participants about aspects of a study that are likely to be relevant to a decision about enrollment is ethically problematic for exactly that reason. It would be impermissible, for example, for a researcher to lie about the expected side effects of an experimental treatment in order to increase enrollment. Whether deceiving participants about the methods or purpose of a study is ever permissible and under what conditions remains a matter of debate.[19]

Motivational manipulation. In motivational manipulation, one agent causes another agent to act on desires that, upon reflection, he would reject as reasons to pursue a specific action. However, while the manipulator changes the other person's preferences in ways that he would not or does not endorse, she may still disclose everything that she ought to about the act, and he may still understand everything that he needs to about the act. As the example of the Hare Krishna who solicits a passerby for money shows, it is perfectly possible to know that one is being motivationally manipulated and yet for the manipulation to be successful. Moreover, motivational manipulation leaves the manipulated person with the same alternatives to the act as he had prior to the manipulator's interference. His consent to the act can therefore be the result of motivational manipulation but still meet the disclosure, understanding, and noncontrol requirements, and so still be valid.

In the example of the Hare Krishna, the woman passing by knows that she is being asked for a donation, and knows what her money would be going toward. She also has reasonable alternatives that are plainly and clearly available to her, such as simply walking away without donating. Her consent to give money to the Hare Krishna is therefore valid—we would not say that she could legitimately take it back after walking away and thinking about the donation more carefully.

Amanda Leach and colleagues studied the informed consent process in an influenza vaccine trial in the Gambia. Some of the women they spoke to explained that they consented to enroll their children in the trial because "they were influenced by the group pressure of seeing other mothers joining."[20] Suppose a research team were to use this information about the likely effects of peer pressure in order to maximize enrollment in a new study with women in the Gambia. They might design their information sessions so that potential participants are asked to talk to the group about how they feel about enrollment, and they might select women who they know are enthusiastic about the research to speak first.

The researchers involved in this study would know that their

potential participants tend to overweigh the visible desire of their peers to participate when making their own decisions about participation. Outside of the context of the group dynamic that the researchers have created in the information session, a potential participant would not desire so strongly to emulate the choices of other women in the community. By constructing the recruitment process in this way, the researchers would therefore be engaged in motivational manipulation. However, their tactics would not inhibit their disclosure of relevant information or the women's ability to understand it, and they would not remove the reasonable alternative of refusing to participate.[21] The women could therefore still give valid consent, although the motivational manipulation would be disrespectful of their autonomy.

Circumstantial manipulation. In circumstantial manipulation, one agent illegitimately interferes with another in order to alter the options available to him, such that a specific action becomes the most reasonable action to pursue. The wrongful means that the manipulator uses to alter the other person's situation makes her control over his decision disrespectful of his autonomy. However, when faced with the decision about whether to pursue the specific action, the manipulated person may well have been told and understood everything he needs in order to make an informed decision. (Indeed, since that act is now the reasonable thing to do, it may be in the manipulator's interests that the manipulated person has a good understanding of the choice he is presented with.) Thus, circumstantial manipulation does not preclude the fulfillment of the disclosure and understanding requirements.

In the case of Peter's dinner, John may not initially realize that Peter intends to leave his wallet at home. However, once the bill comes, John understands fully what has happened and that what is being proposed is that he pay for the meal. John also has reasonable alternatives, such as paying his half and leaving. These alternatives are reasonable, even if John might strongly prefer not to choose them. His consent to pay for dinner is valid—Peter has not robbed him.[22]

Duncan Ngare describes a situation in which medical students helped to conduct the consent process for a malaria treatment trial. In the community in which they were recruiting:

> The culture also dictates that it is good practice to welcome visitors into the community and discourages disappointing them. Therefore, visitors are received warmly and almost anything they request will be provided without resistance. . . . Whenever [the students] arrived at a household they would introduce themselves and seek informed consent. . . . The research assistants were surprised that, even before completing their explanations of the project, individuals would consent to join the study. . . . Moreover, although some women were reluctant to be interviewed, they did not say that they were unwilling because their culture does not allow them to show disrespect to visitors.[23]

How would we judge them if the students had continued to ask people for consent in their homes after discovering these cultural norms? It might be that the norm of hospitality is not only deeply ingrained in the members of this community but that it is also endorsed by them—that they would consider, on reflection, that the custom of being agreeable to guests is a good one, even if sometimes it risks making an irrelevant factor (hospitality) relevant to a decision about an activity like research. If the medical students were to have continued their house-to-house recruiting, and perhaps delayed explaining the purpose of their visit until they had been invited inside, then they would be engaged in circumstantial manipulation and would therefore be disrespecting the autonomy of their potential participants.

As in the case of using peer pressure, however, the potential participant's consent could still be valid: the research team could disclose everything that they ought to, the participants could understand what was being proposed, and refusal would still be a reasonable option—albeit one that the potential participants' value system would strongly dispose them against. Thus, although the students would have acted wrongly in manipulating the potential participants, they would not have invalidated the participants' consent.

Motivational and circumstantial manipulation make use of potential participants' decision-making tendencies in ways that undermine their autonomy. However, there are ways to make use of such tendencies and preserve respect for autonomy.

Outweighing the Wrong of Manipulation

Having analyzed the circumstances under which manipulation invalidates consent, we can now address our second question: when manipulation does not invalidate consent, is it ever permissible? Motivational manipulation and circumstantial manipulation disrespect autonomy even though they do not

invalidate consent and so are pro tanto wrong. However, if the pro tanto wrong of manipulation were outweighed by some other good consequence of the manipulation, then it could be ethically permissible, all things considered.

In a variety of everyday situations, the use of manipulation is intuitively judged to be ethically permissible. Consider, for example, government-backed antismoking strategies. In November 2011, the Australian Parliament passed legislation mandating that cigarettes may be sold only in plain olive green packages, which research had shown is the most unappealing color in the eyes of young people.[24] The Australian government's packaging legislation is an attempt at motivational manipulation. If effective, it will prevent people from buying cigarettes by playing on the aversion they feel toward the olive green packets. However, no one would say that the color of cigarette packets is a genuine reason to smoke or not to smoke. By interfering with the potential smoker's existing alignment of desires and preferences, the Australian government makes her decision-making process less rational without her permission, thereby engaging in motivational manipulation. However, while this is manipulative, it appears to be widely considered that such strategies are acceptable ways to reduce the prevalence of unhealthy behaviors like smoking.

If strategies like the Australian government's are ethically permissible, then sometimes the use of manipulation is justified by the outcome. However, the fact that manipulation is a pro tanto wrong implies that it cannot be justified only in virtue of resulting in a sufficiently good outcome; it must also be that other ways of achieving that outcome without similar or worse wrongs are not available. For example, if there were a morally innocent way to prevent adults from smoking, then that would be ethically preferable to manipulating them. As it turns out, straightforward education to inform people about the risks of smoking does not significantly lower smoking rates, and more extreme measures that would achieve the desired outcome, such as criminalizing tobacco, are not currently feasible and might be even more morally fraught.

Cases of justified manipulation may arise in the context of research, too. For example, in communities where it is customary to ask the permission of local chiefs or elders before conducting research, researchers may reasonably be concerned about manipulation. Even if the permission of the chief does not mean that he coerces people into participation, it may still be very influential and potentially manipulative. For example, in their qualitative study of recruitment and informed consent in the Kassena-Nankana District of northern Ghana, Paulina Tindana and colleagues describe the gatekeeping role played by traditional chiefs.[25] Although some informants, including several chiefs, stated that community members are free to say no even when the chief has given the research his stamp of approval, the authors note that the approval of the chief has a powerful influence on whether people agree to enroll. It might be that the approval of the chief has this influence because community members infer that he has assessed the costs and benefits of the research and decided that it is in the community's interests. Alternatively, community members might simply feel internal pressure to conform to social norms of respecting the requests of the chief. In the latter case, getting the chief's approval before asking people to enroll would be a form of motivational manipulation. It would therefore be pro tanto wrong.

However, Tindana and colleagues also suggest that in this region it would not be possible to conduct the research at all without going through the chief.[26] In contrast to the cases described in the previous section, in which it seemed likely that the research could proceed without using manipulation, the pro tanto wrong of manipulation could therefore be overridden in this case. When nonmanipulative alternatives are genuinely impractical, the use of manipulation can be justified if the study is sufficiently important. For example, a study that is expected to substantially benefit participants or host communities (on whose behalf participants are asked to take on risks and burdens) might be important enough to justify manipulation. In cases where the direct benefits of the study are nonexistent or uncertain—such as a phase I oncology trial in the United States—the social value of the knowledge expected to result would have to be extremely high in order to justify manipulating potential participants into enrolling.

Heuristics for Decision-Making

Motivational and circumstantial manipulation make use of potential participants' decision-making tendencies in ways that undermine their autonomous decision-making. However, there are ways to make use of such tendencies and preserve respect for autonomy. One important example is the use of heuristics.

Consider trust. When trust is warranted, it is a legitimate reason to rely upon another person's opinion as a reason to pursue a particular action; it therefore provides a helpful shortcut or heuristic for decision-making. However, when trust is unwarranted, it can be illegitimately leveraged to motivate individuals to make decisions that they would not, upon reflection, endorse. Its use is then manipulative.

Tindana and colleagues describe the relationship between the residents and the local research institution as follows:

> to some extent the longstanding relationship between the NHRC [Navrongo Health Research Centre] and the community has contributed to the latter's willingness to participate in research. . . . Several participants voiced a belief that

> the NHRC has always brought interventions that have improved the health status of the people in the district. They therefore assume that anything the NHRC proposes is in their best interest.[27]

Suppose a new researcher were to join the NHRC and that his new colleagues advised him: "Always emphasize your affiliation. That way, people will trust you, and will agree to join your study." Suppose this particular researcher's intentions and plans did not mirror the beneficial work of the local research institution. Although he emphasized his affiliation in order to encourage people to enroll, his research program was designed to generate publications that would further his career, and it was unlikely to lead to findings that would benefit the community. The researcher's emphasis on institutional affiliation would mean that he was playing on the tendency of potential participants to trust studies that emerged from the local research institution in order to motivate them to join a study that bears no relation to the reasons they have for trusting the institution. He would be using manipulation (either deceptive or motivational manipulation, depending on exactly how we understand the way trust motivates).

However, if the researcher's intentions and plans were in line with the work of the institution, then a potential participant who relied on her trust of the institution to make a decision about participating in this particular study would be using a legitimate decision-making shortcut. Because community members' trust of the institution is warranted in such a situation—that is, because the institution actually does what the community members trust them to do and because this particular study actually does what the institution generally does—the researcher's leveraging of that trust would not make their decision-making process worse. Potential participants' trust in the research institution would be a valid heuristic for good decision-making, so the researcher's use of this trust would not disrespect their autonomy.

What Should Researchers Do?

It is often advantageous for a researcher to design her recruitment and consent processes in ways that make potential participants more likely to enroll. She may be confident that her strategies do not involve threatening potential participants and so she is not in danger of coercing them. Nonetheless, the researcher may be concerned that her methods are manipulative and therefore unethical.

Our analysis suggests several steps that concerned researchers should take when they design their enrollment processes. First, they should examine the effects of their use of knowledge about the decision-making processes of potential participants. If their use of this knowledge is improving the decision-making process—as when potential participants are persuaded by a clear presentation of the facts or are being encouraged to use a valid heuristic—then they will not thereby disrespect people's autonomy.

If, however, the recruitment process is designed to encourage people to enroll in a way that is likely to make their decision-making process worse—by deceiving them about facts relevant to their decision, by causing them to make a decision based on immediate desires instead of considered preferences, or by illegitimately changing their choice situations—then the researchers are engaged in manipulation. If the manipulation involves deception about facts that are relevant to a potential participant's decision to join a trial, then the manipulation will render consent invalid. In general, therefore, researchers should not engage in deceptive manipulation. However, if the manipulation does not involve deception about the enrollment decision, then further analysis is required. The researcher might leverage someone's weakness of will to motivate him to join the trial, thereby using motivational manipulation. She might illegitimately change a potential participant's circumstances so that joining the study becomes the most reasonable choice, thereby using circumstantial manipulation. If the researcher uses these types of manipulation to motivate participants to join a trial, then she will not prevent potential participants from giving valid consent. However, this does not mean that the manipulation is ethically unproblematic. Since manipulation is still a pro tanto wrong, its use must be the least bad way to achieve a sufficiently valuable outcome—for example, great benefits to participants or the production of research results that are extremely socially valuable.

When nonmanipulative alternatives are genuinely impractical, the use of manipulation can be justified if the study is sufficiently important—for example, it provides great benefits to participants or produces research results that are extremely valuable to society.

This framework can be illustrated by applying it to the case with which we began. Dr. Khan is not threatening his patients, and he is not deceiving them about the study. It seems unlikely, however, that capitalizing on patients' propensity to agree to physicians' requests will be making their decision-making better. Rather, by playing on potential participants' desires to please high-status individuals, Dr. Khan would be engaged in motivational manipulation. Moreover, it is hard to imagine that enrolling this

group of people in a trial of a hypertensive medication is both important enough to justify manipulating them into it *and* requires such manipulation in order to get them to consent. If, for example, trial participation would provide substantial individual benefits to participants—say, because they would receive ancillary care that they could not otherwise afford—then we might expect that a less manipulative presentation of the facts would suffice for enrollment. We therefore judge that the recruitment strategy proposed by Dr. Khan's colleague is unethical.

Disclaimer

The opinions expressed are the authors' own. They do not reflect any position or policy of the National Institutes of Health, U.S. Public Health Service, or Department of Health and Human Services.

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3. For an analysis of the concept of coercion applied to the context of clinical research, see A. Wertheimer and F.G. Miller, "Payment for Research Participation: A Coercive Offer?" *Journal of Medical Ethics* 34 (2008): 389-92. For analysis of undue inducement, see Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva, Switzerland: CIOMS, 2002), Guidelines 4, 6, and 7; and E.J. Emanuel, "Ending Concerns about Undue Inducement," *Journal of Law, Medicine and Ethics* 32 (2004): 100-105.

4. The term "persuasion" gets used to describe all sorts of attempts to motivate others, including acts that are clearly manipulative or coercive. Here, we follow the usage of Ruth Faden and Tom Beauchamp by defining persuasion narrowly as "restricted to influence by appeal to reason"; R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), at 261.

5. A detailed analysis of what constitutes deception is outside of the scope of this paper. J.E. Mahon gives the following definition: "to intentionally cause another person to have or continue to have a false belief that is truly believed to be false by the person intentionally causing the false belief by bringing about evidence on the basis of which the other person has or continues to have that false belief"; J.E. Mahon, "A Definition of Deceiving," *International Journal of Applied Philosophy* 21 (2007): 181-94, at 189-90.

6. Adapted from R. Cialdini, *Influence: The Psychology of Persuasion*, rev. ed. (New York: Quill, 1993), at 32.

7. Note that one person's causing another to do something does not entail that the other did not engage in the action freely. For example, if I offer twenty dollars to Mudit to wash my car, my offer has caused him to wash my car when he would not have done so otherwise. Yet Mudit has still freely chosen to wash my car. This suggests if ethical analysis is to determine the effect of different types of cause on the validity of consent, it needs to distinguish between different ways in which one person can cause another to do something.

8. Whether a particular proposal constitutes a threat depends on the baseline from which we measure. A normative baseline will judge a proposal to be a threat only if carrying it out would make the victim worse off than she ought to be. A predictive baseline will judge a proposal to be a threat only if carrying it out would make the victim worse off than she would otherwise be in the normal course of events. See S. Anderson, "Coercion," in *The Stanford Encyclopedia of Philosophy*, ed. E.N. Zalta, winter 2011, at http://plato.stanford.edu/archives/win2011/entries/coercion.

9. Since the publication of Nozick's classic analysis, philosophical discussion of coercion has focused on the type of coercion described here; R. Nozick, "Coercion," in *Philosophy, Science, and Method: Essays in Honor of Ernest Nagel*, ed. S. Morgenbesser, P. Suppes, and M. White (New York: St. Martin's Press, 1969), at 440-72. However, there are two other types of action that might also be described as coercive. First, there are cases in which one agent is physically controlled by another, so that his movements are not voluntary under any description. For example, if I were to push you into a man by the train tracks so that you knocked him onto the tracks, your knocking him onto the tracks would be involuntary on your part. Second, Harry Frankfurt describes coercion in terms of its psychological effect, so that the coercee is incapable of resisting the threat; H. Frankfurt, "Coercion and Moral Responsibility," in *The Importance of What We Care About* (New York: Cambridge University Press, 1988), 26-46.

10. There is some debate in the philosophical literature about whether there can be offers one cannot refuse, and whether such offers disrespect autonomy or qualify as coercive; D. Zimmerman, "Coercive Wage Offers," *Philosophy and Public Affairs* 10, no. 2 (1981): 121-45; O. O'Neill, "Which Are the Offers You Can't Refuse?" in *Bounds of Justice* (Cambridge, U.K.: Cambridge University Press, 2000), at 81-96; A. Wertheimer, *Coercion* (Princeton, N.J.: Princeton University Press, 1987), at 204-6. If there can be coercive offers, then they should simply be classified as coercion for the purposes of our analysis. One could imagine, further, that there might be noncoercive offers that disrespect autonomy, for example, in cases where an offer is made with the intention that it be so tempting that the recipient will accept it against her better judgment. Such offers would, however, be best analyzed as a form of motivational manipulation.

11. Compare Joel Rudinow's account, according to which manipulation involves the "complex motivation of a person by means of deception or by playing on a supposed weakness." Our account builds on Rudinow's means of manipulation ("deception or by playing on a supposed weakness") in its analysis of ethically problematic ways in which one person can play on another's weakness through motivational and circumstantial manipulation; J. Rudinow, "Manipulation," *Ethics* 88 (1978): 338-47, at 346.

12. Faden and Beauchamp, *A History and Theory of Informed Consent*, at 236.

13. Cf. Patricia Greenspan, who identifies the wrong of manipulation as an "interference with self-governance"; P. Greenspan, "The Problem with Manipulation," *American Philosophical Quarterly* 40 (2003): 155-64, at 164. In contrast, Sarah Buss argues that the wrong of manipulation does not lie in its disrespect of autonomy. She cites the example of Johannes's seduction of Cordelia in Kierkegaard's *The Seducer's Diary*. Buss argues that Johannes's manipulative seduction is wrong, but not because he disrespects Cordelia's autonomy. In fact, Buss argues, Johannes's manipulation

of Cordelia is carried out in an attempt to increase Cordelia's capacity for autonomous action, and therefore his manipulation ultimately respects her autonomy. Buss argues that Johannes's manipulation is wrong for reasons unrelated to autonomy: it prevents Cordelia from governing herself with an accurate understanding of her situation, it prevents her from relating to her manipulator as an equal, and it may be incompatible with her welfare. Johannes may well respect Cordelia's future autonomy in that his manipulation builds her capacity for future autonomous action. However, in manipulating Cordelia, Johannes disrespects her autonomy in the present by exerting illegitimate control over the choices that Cordelia would make now if she were in control of her situation. In fact, two of the wrongs of manipulation that Buss identifies as unrelated to autonomy—including the fact that Johannes's manipulation makes Cordelia unable to govern herself with an accurate understanding of her situation, and the inequality that Johannes's manipulation creates between them—are actually ways in which Johannes disrespects her present autonomy; S. Buss, "Valuing Autonomy and Respecting Persons: Manipulation, Seduction, and the Basis of Moral Constraints," *Ethics* 115 (2005): 195-235.

14. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*, 5th ed. (Oxford, U.K.: Oxford University Press, 2001), at 79-98.

15. Faden and Beauchamp, *A History and Theory of Informed Consent*, 258-59.

16. Faden and Beauchamp argue that coercion is always wholly controlling. However, *threats* may be more or less controlling depending on what is threatened and what the alternative options are. The harder (or less reasonable) it is to resist a threat, the more controlling it is.

17. S.I. Benn and W.L. Weinstein put it this way: "A plea of duress in criminal law works in the same way; the accused excuses himself by claiming that he was not free to obey the law, on account of some more immediate threat that he could not reasonably have been expected to disregard. . . . Corresponding to the standards presupposed by the plea of duress in contract . . . , there is here a kind of reasonable rate of exchange between the importance of a given law and what damage a man might reasonably be expected to risk or to suffer . . . rather than break that law"; S.I. Benn and W.L. Weinstein, "Being Free to Act, and Being a Free Man," *Mind New Series* 80, no. 318 (1971): 194-211, at 208-9. A complete account of the relationship between threats and consent or duress would require some analysis of "reasonable." However, as the following paragraphs should make clear, our argument about whether the control involved in manipulation is sufficient to render consent invalid does not require this level of precision.

18. Cases in which information is deliberately withheld or deception is attempted, but where the person giving consent nevertheless understands what he is consenting to (for example, from other sources), would still violate the disclosure requirement.

19. See D. Wendler, "Deception in Medical and Behavioral Research: Is It Ever Acceptable?" *Milbank Quarterly* 74 (1996): 87-114; M. Kemmelmeier, D. Davis, and W.C. Follette, "Seven Sins of Misdirection? Ethical Controversies Surrounding the Use of Deception in Research," in *Handbook of Professional Ethics for Psychologists*, ed. W.T. O'Donohue and K. Ferguson (Beverly Hills, Calif.: Sage, 2003).

20. A. Leach et al., "An Evaluation of the Informed Consent Procedure Used during a Trial of a *Haemophilus influenzae* Type B Conjugate Vaccine Undertaken in The Gambia, West Africa," *Social Science and Medicine* 48 (1999): 139-48.

21. One could imagine a case in which the emotional stress from the peer pressure that the women experienced was so strong that it rendered them incapable of weighing the pros and cons of participation. Their consent would not then be valid. In this case, however, the consent would be invalidated because the capacity of the women to act autonomously would have been undermined, not because of the control exerted through manipulation.

22. Contrast this with a case where his options are not reasonable: Peter demands dinner at gunpoint. Here Peter's threat is controlling in a way that making use of John's strong desires not to cause a fuss in public or desert a friend would not be.

23. D. Ngare, "Malaria Drug Trial in Kenya," in *Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-Poor Settings*, ed. P. Marshall (Geneva, Switzerland: World Health Organization, Ethics and Health Unit, Division on Ethics Special Programme for Research and Training in Tropical Diseases, 2007), at 41.

24. N. Bryant, "Big Tobacco Takes Another Big Hit," *BBC News*, Nick Bryant's Australia, April 2011, at http://www.bbc.co.uk/blogs/thereporters/nickbryant/2011/04/big_tobacco_takes_another_big.html; S. Cohen, "Australia Passes 'Plain Package' Law for Cigarettes," *National Public Radio News*, November 2011, at http://www.npr.org/2011/11/11/142232709/australia-passes-plain-package-law-for-cigarettes.

25. P. Tindana, N. Kass, and P. Akweongo, "The Informed Consent Process in a Rural African Setting: A Case Study of the Kassena-Nankana District of Northern Ghana," *IRB: Ethics and Human Research* 28 (2006): 1-6.

26. Ibid., 5.

27. Ibid., 4.