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Deception in Clinical Research

Testing research hypotheses and answering scientific questions are sometimes accomplished by deceiving research participants. Deception is most commonly associated with psychological and social science research, in which data suggest that investigators often deceive participants. However, deception also occurs in a broad range of clinical research.[1] For example, clinical trials designed to assess the impact of expectancy on drug-craving and drug-taking behaviors sometimes deceive participants. One testing paradigm involves asking research participants to perform various manual tasks, for instance, responding to a red light on a computer screen, after receiving an injection of a drug such as cocaine. To distinguish drug effects from expectancy effects, this paradigm administers the drug in only half of the testing sessions and administers saline in the other sessions, but tells participants that they will receive the drug in all the sessions.

In some cases, clinical investigators may deceive research participants for what is perceived to be the good of the participants themselves, for instance, suggesting that an individual's disease has not progressed to the point that research testing reveals. Such deception raises obvious ethical concerns, but not issues that are unique to clinical research, and we will not address them here. We will instead focus on the question of whether and under what conditions it might be ethically acceptable to deceive research participants for scientific purposes.

Most commentators agree that deceiving research participants for scientific purposes is prima facie unacceptable. Most commentators also agree that the deception of research participants for scientific purposes can be justified in some cases—that is, that such deception is not, in practice, always ethically unacceptable. Much of the debate, then, focuses on the conditions under which deception might be acceptable. Not surprisingly, the extent to which one finds deception in clinical research acceptable depends on how problematic one takes deception to be, which, in turn, depends in large measure on the extent to which one thinks that deception harms or wrongs research participants.

Many researchers assume that deception typically is relatively harmless and conclude that any restrictions on its use should be modest. These individuals would allow deceptive research for a broad range of studies, and would allow deception in cases in which nondeceptive methods are possible but would be more burdensome or onerous, perhaps requiring more participants or a longer study. Many commentators assume, in contrast, that deception is seriously unacceptable, and should be permitted only in extraordinary circumstances, if at all. These commentators often conclude that deception should be allowed for scientific purposes only when the research has very significant social value and would be impossible to conduct using nondeceptive methods.

Behind much of the debate over the ethical acceptability of deception in clinical research is the assumption that the use of deception necessarily conflicts with respect for participant autonomy. Either participants can provide valid informed consent, or investigators can rely on deception, but not both.[2–5] Against this assumption, some writers have argued that investigators can conduct deceptive studies while respecting the autonomy of the research participants by prospectively informing them that will be deceived, but not informing them of the nature of the deception. For example, in the deceptive studies of drug-craving and drug-taking behaviors, participants might be informed that the study has not been described accurately in all its details, without telling them which details have been misdescribed. Here too, as in a good

deal of the deception debate, more data would be instructive, data on how deception and its alternatives affect participants and the validity of scientific findings.

The Nature of Deception

Deception occurs when investigators communicate—understood broadly to include written, spoken and behavioral communication—in ways that can reasonably be expected to result in some participants developing false beliefs. For example, investigators might tell participants that they will all receive active medication when only half of them will receive active medication and the other half will receive placebo. Deception in the clinical setting typically is intentional. That is, the investigator intends to deceive the participant and communicates in a way that is expected to lead to false beliefs on the part of participants. Moreover, the investigators rely on the fact that the participants are likely to develop false beliefs. It is the fact that the participants develop false beliefs in the drug testing paradigm mentioned previously that allows the investigators to distinguish expectancy effects from drug effects. Typically, we consider deception especially problematic when it involves the deceiver intentionally deceiving another person and then relying on the deception for the benefit of individuals other than those deceived.

Deception typically occurs as the result of investigators providing false information to participants. For example, in a study of continuous positive airway pressure (CPAP) versus placebo in sleep apnea, participants were told that the inert placebo pill was "intended to improve airway function."[6] The investigators used a misdescribed placebo pill as the control out of concern that those familiar with CPAP would have been able to distinguish CPAP from sham CPAP.

Investigators also may deceive participants by withholding pertinent information from them. In a study of chronic obstructive pulmonary disease (COPD), investigators attached a chronolog to participants' inhalers to measure whether they were "dumping" study medications.[7] To ensure accurate measurements, participants "were not informed of the chronolog's date- and time-recording capabilities."[7]

Whether a given instance of communication or failure to communicate constitutes deception depends upon what it is reasonable to expect individuals to conclude on the basis of the communication (or lack thereof). For this reason, reasonable people may disagree on whether a given instance of communication constitutes deception. To assess the impact of expectancy, one research design tells participants that a light will appear on their computer screen and then they will receive an injection of a drug. The design assesses expectancy by delaying the injection of drug for some time after the light appears. This design relies on the fact that participants expect to receive the injection just after the light appears. Is this design deceptive?

It is deceptive if it is reasonable to expect that participants, told that they will receive an injection of drug after the light appears, will conclude that they will receive an injection *immediately* after the light appears. If it is reasonable to expect that participants, told that they will receive an injection of drug after the light appears, will conclude that they will receive an injection at some time relatively soon but not necessarily immediately after the light appears, then the design may not be deceptive, depending upon how long the delay happens to be. Because our expectations regarding the beliefs reasonable individuals will develop may not be clear in this case, it may be unclear whether this design involves deception.

To consider a more prominent example, what does the present analysis imply about whether placebo-controlled studies are inherently deceptive? A typical blinded placebo trial randomly assigns some to receive drug and others to receive placebo, while withholding from participants information regarding which they are receiving. Furthermore, active steps are taken, such as double blinding and placing drug and placebo in identical capsules, to ensure that participants do not discern whether they have been assigned to receive drug or placebo. Clearly, then, placebo trials withhold important information from participants, and as a result participants often end up with false beliefs about what they are taking. Some end up with the belief that they are taking drug when, in fact, they are receiving a placebo. Are these trials therefore inherently deceptive? (Critics of placebo trials claim that participants typically are able to discern whether they are receiving active drug or placebo, allaying one's concerns regarding the potential for deception, but raising concerns regarding the scientific usefulness of placebo-controlled studies.)

Placebo-controlled trials in which all participants are told that they will receive an active drug clearly are deceptive. A trial that simply withheld any information regarding the contents of the research "tablets" would arguably be deceptive as well. In the absence of information to the contrary, one expects that tablets provided in the context of a clinical trial contain active medication. It is less clear that placebo-controlled trials are deceptive when participants are informed that placebos are being used, and that they will not be told whether they are receiving active medication or placebo. If participants are provided this information, it seems the reasonable response would be to remain agnostic over whether they are receiving medication or placebo, implying that standard placebo-controlled designs are not inherently deceptive.

Trials involving sham procedures, in contrast, sometimes involve an element of deception. In these trials, researchers manipulate the sham procedure, not so that participants will remain agnostic over whether they are receiving the real or the sham procedure, but in such a way as to engender the false belief in the participants that they are receiving the real procedure. Thus, even though participants are informed in advance that they will receive either a real or a sham intervention, active steps are taken to convince all the participants that they are receiving the real treatment.[8]

The Milgram Experiments

The contemporary debate about deception in clinical research was fueled by Stanley Milgram's experiments on obedience in the early 1960s.[9] In the wake of the disclosure of horrific acts during World War II, perpetrated by ostensibly ordinary Germans who claimed simply to be following orders, Milgram designed a series of experiments to assess the extent to which ordinary Americans would likewise obey authority figures.

Milgram recruited participants and paired them with a second individual who was identified as another participant, but in fact was working with Milgram. The "confederate" was placed in what was described as an electric chair and given a series of tasks to perform. This individual intentionally made a series of mistakes.

At each mistake, the participants were instructed by a researcher in a white coat to administer shocks of increasing severity to the individual. The accomplices in the chairs would feign increasing levels of agony as the participants were instructed to give, and often complied with giving, greater and greater shocks.

Milgram's widely criticized experiments were clearly deceptive. Participants were told that they were delivering actual shocks, and the actors strapped in the chair reacted in ways to reinforce this belief. Milgram's experiments led to widespread discussion on what precisely are the harms of deception in clinical research. Milgram responded to his critics on several occasions, and even conducted follow-up research on the participants to assess the extent to which they had been harmed.[10] Many of the participants reported to Milgram that they did not experience long-term harm as a result of their participation and were supportive of the research. Critics have questioned whether long-term harms are the relevant metric and whether participants can be trusted to report accurately whether they experienced serious trauma, especially when asked by the very individual who perpetrated the deception in the first place, raising further questions about the best methods for empirically assessing the possible harms of deception for scientific purposes.

What Makes Deception in Scientific Investigation Ethically Problematic?

At the outset, it is useful to appreciate the conflict between the ethos of science and the use of deceptive techniques. Science aims to discover and communicate the truth about the natural world and human conduct. There are sound methodological reasons for using deception to probe the truth about human attitudes and beliefs, and their effects on behavior. It follows, however, that when deception is used, a conflict between the means and ends of scientific investigation ensues: The end of discovering the truth is pursued by the means of deliberate untruth.

It might be argued that deception in scientific investigation is no more problematic than the pervasive and accepted use of deception in daily life and social contexts.[11] In a 2004 news article reporting advances in the design of computers to simulate human responsiveness, Clifford Nass, a professor of communication at Stanford University, is quoted as endorsing the use of deception in research: "We spend enormous amounts of time teaching children to deceive—it's called being polite or social. The history of all advertising is about deceiving. In education, it's often important to deceive people—sometimes you say, 'Boy you are really doing good,' not because you meant it but because you thought it would be helpful."[12]

Deception in ordinary life typically is justified on the grounds that it is for the benefit of the individual who is being deceived. For instance, the "polite" and "social" deception that Nass cites is justified on the ground that it is better to deceive someone slightly than criticize them or hurt their feelings. Notice, however, that this condition is not relevant to deceiving research participants for scientific purposes and the benefit of society in general, through the development of generalizable knowledge.

A major ethical concern with deception in research is its potential to violate legitimate trust. Individuals generally trust that the research in which they are invited to participate is worthwhile, that it will not expose them to undue risks of serious harm, and that they will be treated fairly. When participants discover that they have been deceived, which typically occurs during the process of debriefing at the end of study participation, they may lose trust in scientific investigation. As we argue below, the issue of trust is likely to be especially important for research involving patient subjects conducted in clinical settings.

Deception of research participants also clearly conflicts with the ethical norms governing clinical research.[1,13] First, it violates the principle of respect for persons by infringing the right of prospective research participants to choose whether to participate in research based on full disclosure of relevant information. Second, it may manipulate individuals to volunteer when they would otherwise not have chosen to do so had they been informed accurately about the nature of the research, including its use of deception. For these reasons, deception as it is currently practiced in many clinical research studies is incompatible with informed consent.

Finally, deception in research raises ethical concern because it can be corrupting for the professionals who practice it and for those who witness it. According to an ancient perspective in moral philosophy, moral character depends on habits of conduct.[14] The use of deception in research may interfere with the disposition not to lie or deceive persons. This problem is compounded when the study design requires deception at the initiation of the trial, as well as maintenance of the deception during the conduct of research. Those who witness deception, especially if performed or sanctioned by professionals in positions of authority, may develop skewed perceptions of the ethics of deception, which may have negative consequences for the development of moral character. For these reasons, deception in research is prima facie wrongful.

The Harms of Deception and the Value of Deceptive Studies

The previous section concludes, as most commentators assume, that deception in clinical research is prima facie unethical, but can be justified in some circumstances. Hence, much of the debate concerns the extent to which deceptive studies should be permitted: Should deceptive studies be allowed in a relatively broad range of cases, or in extraordinary circumstances only? This debate over balancing the costs of deception against the value of deceptive studies occurs for two general kinds of studies.

First, in some cases investigators must deceive research participants to answer the scientific questions posed by the study. Earlier, we considered some examples of drug expectancy studies that pose just this dilemma. Assuming that there is no way to assess the effects of expectancy without deceiving the research participants, institutional review boards (IRBs) must determine whether the value of answering these questions justifies the harms of the deception involved. This is a difficult calculation to make; it is an impossible calculation to make unless one has some estimate for the potential harms of deception. It is worth noting that this calculation is made all the more difficult by the fact that an individual study rarely, if ever, definitively answers any given scientific question on its own. Only a series of studies, including future studies that may or may not occur, and which are usually not under the purview of the reviewing IRB, can answer the scientific questions posed by most trials.

A second, less examined need to balance the potential harms of deception against the anticipated value of deceptive research arises with respect to studies in which the use of nondeceptive means is theoretically possible, but is to varying degrees difficult or impractical. For example, one experimental paradigm for studying aggression in humans challenges participants to accumulate points by typing into a computer that, they are told, is connected to another computer operated by someone who may steal some of their points. In fact, the participant's computer is programmed to occasionally, and arbitrarily, subtract points from the participant's accounts. The investigators measure aggression as a function of how participants respond to these "thefts" by attempting to steal points from their "opponents." There are nondeceptive alternatives to this paradigm. Most simply, the researchers could hire assistants to sit at a second computer that is connected to the participants' computer. This person could type in the responses that the computer program now enters, thus producing a nondeceptive study. Should IRBs require investigators to adopt this methodology instead? Is this study feasible and effective? Presumably, the person entering the data will make more mistakes than the computer and may not end up entering truly random responses. It follows that this alternative study design will require more resources. It will require hiring assistants and setting up a second computer in a different room. In addition, given the uncertainty regarding the data entry of the "responding" research assistant, the alternative study design will likely yield somewhat less powerful results.

Whether an IRB should mandate this alternative design depends on the balance of the potential harms of deception against the anticipated value of the study and the costs of requiring an alternative design. Some might argue that the risks of the study amount to the potential harm that might result from the participants' having their points stolen and how they respond to these thefts. The use of deception does not increase the risks of the study, hence there is no reason to require the investigators to pursue a more costly nondeceptive approach. In response, one could just as easily argue that this design offers a clear example of a deceptive study with a feasible, and effective, nondeceptive alternative. Granted, the alternative design introduces an extra variable. But the alternative study is relatively straightforward and the mistakes that the computer operator makes could be isolated and controlled for. Thus, on this view, one might conclude that the investigators should be required to pursue the nondeceptive alternative. To resolve this debate, we need to determine to what extent deception harms research participants.

Empirical Data on the Harms of Deception

A number of studies have found that deception does not upset most participants.[15–18] In a study of participants who had been deceived in psychology experiments, Epley and Huff found "little negative impact." Indeed, Smith and Richardson report that those who had been deceived in psychology experiments rated their overall experience as more positive than those who had not been deceived. Although these findings seem to suggest that deception itself poses no risk to participants, thus seeming to confirm Milgram's findings that the deception he used did not harm his participants, there are reasons to question the data and their relevance to clinical research. First, the data focus on healthy college undergraduates participating in psychology experiments. Yet healthy college students may have a different attitude toward being deceived than patients participating in clinical trials.[19] Second, it is estimated that approximately one-third to one-half of psychology experiments use deceptive techniques.[20,21] Given the prevalence of deception, combined with widespread debriefing, college students may *expect* psychology experiments to be deceptive.[22–25] Hence, the existing data may reflect the attitudes of participants who expect to be deceived, not the attitudes of those who assume they are participating in nondeceptive research.

Third, the relationship between investigators and participants in psychology studies may minimize the impact of deception. Deception is morally problematic in part because it involves a violation of trust in a relationship. The trusted deceiver manipulates the beliefs of the deceived and thereby undermines their ability to make autonomous decisions. On this analysis of the harm of deception, one would expect that the degree to which individuals are bothered by deception will depend in part on the extent to which they are dependent on the deceiver.[26–28] We expect those we trust and depend on to look out for our interests and support our making decisions for ourselves. As a result, we are more vulnerable to deception by them.

Young, healthy college students are unlikely to rely a great deal on psychology experimenters, whereas patients often invest a great deal of trust and hope in clinical investigators. Thus, deceiving patients in the research setting has the potential for greater harm, especially if it undermines patients' trust in physicians in general. For instance, in a study by Fleming and colleagues concerning alcohol use (discussed below), a majority of the individuals who were upset by being deceived stated that the use of deception would "lower their trust in the medical profession." In this way, investigators deceiving participants seems to conflict with physicians' obligations to earn and maintain the trust of their patients.[29]

Fourth, the majority of these studies assess the impact of deception by deceiving participants, debriefing them, and then asking whether they found the deception troubling. Because people do not like to view themselves as victims, under the control of others, they may downplay the effects of deception, particularly when asked by the individual who deceived them in the first place.[30,31] Finally, some of these studies assessed the impact of the deception after some time had elapsed. This is most clear in the case of Milgram's follow-up studies, which occurred years after the original experiment. It seems plausible to assume that any harms caused by deceiving participants would diminish over time.

These differences suggest that the psychology data provide little insight into the impact of deception on participants in clinical research. Moreover, despite the long history of deceiving participants in clinical research, few clinical investigators have attempted to gather data on its effects. To assess the generalizability of these data, IRBs that approve deceptive clinical studies should consider obtaining data on the impact of the deception, perhaps as part of the debriefing process. Indeed, it seems reasonable to argue that IRBs that approve deceptive studies should require the investigators to collect such data. These studies are being approved on the basis of assumptions about the harms caused by the deception. It seems reasonable for investigators and IRBs to systematically collect data to assess whether the IRBs' assumptions in this regard are accurate. Until such data are collected, assessment of the extent to which deceptive clinical research harms research participants must be based on more theoretical considerations.

It is worth noting a potential conflict between reducing the harms of deception versus reducing its wrongs. One might argue that debriefing remedies the wrong of deception to some extent by informing research participants that they were deceived. Debriefing may also limit the social harms of deceptive research by establishing a clear policy by which deceptive actions are disclosed, thereby notifying research participants in general that deception is not widespread and unreported. Debriefing, however, is likely to increase the extent to which deception harms research participants. Presumably, research participants who never realize and are never told that they were deceived will not experience psychological harm. Hence, some might argue that investigators should err on the side of no debriefing as a way to protect research participants from experiencing harm.

Theoretical Harms of Deceptive Clinical Research

Studies that fail to inform participants prospectively of the use of deception conceal the possibility that participants may experience distress once they are deceived. Those who learn that they were deceived may also lose trust in investigators, reducing the pool of potential research participants. Research participants may be harmed even when they are not upset by the use of deception. Being in control of one's life is central to human dignity and self-respect; hence, the fact that investigators fail to respect the autonomy of research participants by deceiving them may be harmful. The knowledge that medical researchers are sometimes deceptive may undermine the public's trust in the research enterprise. Finally, deceiving participants may have an adverse effect on clinicians, who are trained to promote the best interests of their patients.[32,33] These burdens may be exacerbated when participants inadvertently inquire about the misdescribed aspects of the study. To avoid such situations, researchers may minimize the opportunity for participants in deceptive studies to ask questions, further vitiating the informed consent process.

These concerns, although genuine, are largely theoretical. Hence, they leave IRBs in the position to choose, in the absence of sufficient data, whether to allow deceptive clinical research or not. Stopping all deceptive clinical research until sufficient data are collected would halt important research. Moreover, the effects of deception may be impossible to assess in the absence of deceptive studies that deceive participants and then assess the effects. Continuing to conduct deceptive clinical research also seems problematic, especially given social norms against deception and the possibility that use of deception may cause serious distress to some participants.

Regulations and Guidelines Governing Deception in Research

National and international guidelines regarding research with humans uniformly require participants' informed consent in most cases. Guidelines that mandate informed consent without exception may inadvertently prohibit deceptive research. For example, guidelines that require participants to be informed of the purpose of the research may effectively prohibit research whose validity depends on participants not being prospectively informed of the study's purpose.

Many guidelines do not address deception explicitly, but allow investigators to alter some or all of the elements of informed consent in some circumstances, typically when the risks are minimal. For example, U.S. research regulations allow IRBs to approve research that "does not include, or which alters, some or all of the elements of informed consent" provided that several conditions are satisfied, including the requirements that the risks are minimal and the research could not "practicably" be carried out without the alteration.[34] Hence, IRBs may approve deceptive studies provided they find that the studies pose no greater than minimal risk to participants.

Other guidelines address the issue of deception explicitly, typically leaving the decision of whether to approve the deception up to the reviewing IRB or research ethics committee. The research guidelines from Nepal state, "A special problem of consent arises when informing participants of some pertinent aspect of research that is likely to impair validity of the research. Such circumstances should be discussed with the [ethical review boards] who will then decide on the matter."[35] Similarly, the Brazilian regulations state that "when the merit of the research depends on some restriction of information to the subjects, such facts should be properly explained and justified by the research and submitted to the Committee of Ethics in Research."[36] And according to the Tanzanian guidelines, participants must be informed that treatments will be allocated at random, although "[e]xceptional cases are where there is an argument for not telling the patient the truth, and must be subject of the IRECs [institutional research ethics committee]."

Some guidelines draw a distinction between deception by lying to participants versus deception as the result of withholding pertinent information. The Indian guidelines state that "[d]eception of the subject is not permissible. However, sometimes information can be withheld till the completion of the study, if such information would jeopardize the validity of the research."[38] Guideline 6 of the guidelines produced by the Council for International Organizations of Medical Sciences (CIOMS; see Chapter 16) has one of the most extensive discussions of deception in research, arguing, "[a]ctive deception of subjects is considered more controversial than simply withholding certain information."[39] The CIOMS guidelines further state, "[d]eception is not permissible, however, in cases in which the deception itself would disguise the possibility of the subject being exposed to more than minimal risk" and stipulate that the "ethical review committee should determine the consequences for the subject of being deceived." The same approach is suggested by the Belmont Report (see Chapter 14), which allows investigators to "indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded." Importantly, the Belmont Report allows withholding information only when necessary and does not allow it in "cases in which disclosure would simply inconvenience the investigator."[40]

One of the most detailed guidelines regarding deception in research is the *Ethical Principles of Psychologists and Code of Conduct* produced by the American Psychological Association.[41] The *Principles* allow investigators to deceive subjects when the following four conditions are satisfied:

1. The use of deception is justified by the study's significant value.
2. Any equally effective, nondeceptive approaches are not feasible.

3. Deception is not reasonably expected to cause physical pain or severe emotional distress.
4. Any deception is explained to participants, preferably at the conclusion of their participation, but no later than the conclusion of the research, and participants are allowed to withdraw their data.

The second condition's requirement of *equal* effectiveness seems to conflict with the assumption that deception is prima facie unacceptable. If this assumption is correct, it follows that we might prefer a nondeceptive study even if it is somewhat *less* effective, because the harm incurred by the decrease in effectiveness might be outweighed by the good that is achieved in avoiding the deception.

The third condition attempts to address the concern that deception conflicts with respect for participants' autonomy by requiring that participants are not deceived in the context of studies that are reasonably expected to cause physical pain or severe emotional distress.

Briefly, we can think of harms as states of affairs that conflict with the interests of the individual harmed. For instance, physical integrity is in most individuals' interests. Therefore, states of affairs that involve destruction of physical integrity harm the person in question. States of affairs that conflict with individuals' moral interests, in contrast, are standardly understood not as harms, but as "wrongs." The third condition attempts to ensure that, as long as the use of deception does not conceal the potential for physical pain or severe emotional distress, it will not alter the enrollment decisions of prospective participants. In other words, as long as this condition is met, one might assume that participants who consent to a deceptive study would have consented even if that study had not been deceptive. This then leaves IRBs with the task of determining whether the social value of the research justifies the use of deception. One might assume that as long as the deception does not conceal risks of physical pain or severe emotional distress, then studies with essentially any social value can justify the deception, because the use of deception will not increase the risks to participants. This line of reasoning, however, ignores the possibility that the deception itself might pose a risk to participants.

Assessing Participants' Desire for Control

There are some data relevant to assessing the extent to which deception itself harms individuals. One example comes from alcohol research. Gathering accurate data on alcohol abuse is complicated by the fact that alcoholics often provide misleading information when asked direct questions about their alcohol use. To address this problem, some investigators have studied the acceptability of concealing the intent of alcohol abuse questionnaires by including questions about smoking, weight, exercise, and drug use. Under this design, participants are provided with "general health" questionnaires without being informed that the investigator's research interests are limited to the alcohol use questions.

At the end of one study, the investigators debriefed the participants and assessed the impact on them of the deception itself.[29] The data reveal that one-third of the participants were upset by the deception, but of these, two-thirds supported the study and said that they would be willing to participate again. The authors regard the relatively high number of participants who were willing to participate again, combined with the importance of accurate information on alcohol abuse, as showing that these kinds of deceptive studies are ethically acceptable.

But as previously noted, there are reasons to question whether individuals, once deceived, will accurately report how much the deception bothered them. Leaving that concern to the side for the moment, these same results tell us that one-ninth of the participants were upset by the deception to the point of refusing future participation. Importantly, these individuals had been told in advance the truth about the nature of the study, including its risks, the lack of expected benefit, the procedures involved, and the possible alternatives. The deception involved the minor point that the researchers were interested in a specific aspect of the participant's health, rather than the participant's health in general. And yet, a significant percentage of the participants were bothered enough to be unwilling to participate in such research again.

Presumably, many of these participants were upset not by the fact that the researchers were interested in alcohol use, but by the use of deception itself. This conclusion supports a piece of common sense: At least some people are upset by the mere fact of being deceived, independent of the nature of that deception, especially when the deception is for the benefit of others. It follows that no matter how carefully we minimize the *extent* of deception, for example along the lines of the American Psychological Association's *Principles,* deception still poses risks to some participants without their consent. Of course, most guidelines allow the use of deception only when the risks are minimal. However, this assessment is typically made by considering whether the deception conceals any significant risks from the participants, thus ignoring the possibility that the use of deception itself may pose risks to some participants.

Individuals who are upset by the use of deception per se are, presumably, those who place a high value on being in control of their lives. Therefore, taking control of these individuals' lives by deceiving them without their consent involves a contradiction of one of the values that is most important to them as persons. The fact that at least some are upset by deception per se establishes that even if the deception involved in a particular study does not conceal any risks that are present independently of that deception, the deception itself introduces a new risk into the study. And allowing studies that fail to inform participants of this risk contradicts the requirement that participants may not be put at risk without their consent. The most obvious way of avoiding this harm would be to treat the risk presented by the use of deception in exactly the same way that we treat all the other risks involved in research participation: Inform participants of the presence of that risk. The possibility suggests the need for "authorized" deception.

The Principle of Authorized Deception

It is widely assumed that deceptive clinical studies force investigators and IRBs to choose between respecting personal autonomy and collecting valid data. This assumption neglects the possibility that prospective participants can be informed of the deception and asked to consent to its use, without being informed of the nature of the deception. For instance, investigators who conduct deceptive research could include the following statement in the informed consent document:

> You should be aware that the investigators have intentionally misdescribed certain aspects of this study. This use of deception is necessary to conduct the study. However, an independent ethics panel has determined that this consent form accurately describes the major risks and benefits of the study. The investigator will explain the misdescribed aspects of the study to you at the end of your participation.

For studies designed to deceive participants by *withholding* information, as opposed to providing false information, the first sentence might read: "You should be aware that the investigators have intentionally left out information about certain aspects of this study."

We have seen that deception per se presents a risk to participants; at least some are harmed when they are deceived, and others may have relevant idiosyncratic concerns that never get revealed because of the deception. Authorized deception warns participants of these risks. Therefore, potential participants who are bothered by deception per se will be able to avoid deceptive studies, those with idiosyncratic concerns will have the opportunity to reveal them, and others will have the opportunity to consent to being deceived. Authorized deception also removes any harm to the research team that is incurred when members of the team are required to deceive participants without their consent.

By alerting participants to the use of deception, authorized deception goes as far as possible in respecting the autonomy of research participants while permitting deception needed to generate scientifically valid data. Authorized deception also blocks the undermining of participants' and the public's trust in science and medicine by flagging those studies that are deceptive, and it justifies exposing participants to deception not in terms of the potential benefit to others but in terms of the participants' consent to that deception.

Objections to Authorized Deception

There are a number of possible objections to the use of authorized deception in clinical research. We raise and respond to three broad areas of concern below.

Concerns About Informed Consent

Some might argue that valid consent requires that participants know the exact nature of all the procedures they will undergo. On this view, people cannot provide valid consent, even when informed of the use of deception, because they do not know the true nature of the misdescribed procedures. In order to provide fully informed consent, they would have to know the nature of the deception as well. They would have to know what they are being deceived about.

We can grant that participants cannot provide fully informed consent as long as they are unaware of the nature of the deception and as long as we understand "fully" in a literal sense. However, as is widely acknowledged, participants never know everything there is to know about any study. There is simply too much to know. Therefore, in order to argue that authorized deception precludes informed consent, one would have to show that the information participants fail to obtain as the result of deception casts doubt on their consent in a way that the other information they never receive does not.[42] For instance, prospective participants need to be informed of the risks and potential benefits of study medications because most people care about this information and it might affect reasonable persons' willingness to participate; however, they typically need not be informed of the precise doses of the medication because this is a technical detail that is unlikely to affect their willingness to participate. This widely accepted analysis suggests that investigators can conduct deceptive clinical studies and still obtain valid consent as long as they do not deceive participants about any aspects of the study that would affect their willingness to participate or aspects of the study that individuals are likely to want to know prospectively.

To implement this approach, IRBs must decide which aspects of a given study might affect participants' willingness to participate. Because enrollment decisions depend upon the risks and benefits of the research, IRBs should approve deceptive studies only when the deception does not conceal significant risks or misleadingly promise significant benefits. The burden of proof should be on investigators to show why any deception regarding risks or benefits is necessary. In some cases, it may be acceptable to deceive participants about minimal risks.

When reviewing deceptive clinical research, IRBs should also consider whether the potential participants have idiosyncratic concerns that might affect their willingness to enroll. For instance, deceiving participants about the ingredients in a study drug typically would not affect their willingness to enroll. Yet such deception might be problematic if it conceals ingredients to which the participant population would strongly object, such as bovine-derived products for a Hindu population.

Authorized deception requires IRBs to use their judgment to assess what aspects of a given study might affect participants' willingness to participate. Of course, IRBs might get these judgments wrong in certain cases, and allow investigators to deceive subjects about aspects of the study that would have affected their willingness to participate. Given this possibility, IRBs should err on the side of caution, requiring investigators to accurately inform participants of all aspects that, in the judgment of the IRB, might affect their willingness to enroll.

Granting the potential for mistakes, it is important to note that this potential is not unique to deceptive studies. Informing participants of every aspect of a given study, including all the ingredients of every drug and every remote theoretical risk, would only confuse participants and undermine their informed consent. For this reason, investigators and IRBs must decide which aspects of the study might affect participants' willingness to participate every time they decide what information should be included in a consent form.

Similarly, most regulations allow IRBs to waive the requirement for informed consent when the research poses no greater than minimal risk and there are good reasons not to obtain informed consent. Assuming it can be ethical to conduct clinical research that the IRB deems to pose only minimal risks without consent at all, it seems acceptable to conduct otherwise ethically appropriate, deceptive research when the IRB judges that the use of deception poses no greater than minimal risks to participants.

Some might respond that this analysis ignores the fact that deceiving participants is different from withholding information from them. In cases of deception, participants fail to have certain information not because there is too much information to convey,

but because they are being deceived. As a result, participants end up with false beliefs about the studies in which they are participating. Clearly, there is a difference between the two cases. However, it is not clear that this difference makes an ethical difference. Authorized deception informs participants of the use of deception, and provides them with the opportunity to consent to its use. Therefore, the deception per se will not make an ethical difference between the two cases. The participant, not the researcher, is in control of deciding whether the person participates in a deceptive study. In addition, the fact that the participant ends up with false beliefs, rather than no belief at all, does not seem to make an ethical difference either. It all depends on whether the issue in question is relevant to providing informed consent. And, as we have seen, relevance to informed consent gets decided using the same method in both cases: Is the information relevant to the participant's decision to enroll? If the answer is "no," then in both cases withholding that information does not cast doubt on the person's informed consent.

In some cases, however, there may be an important difference between a study that uses authorized deception and one that that simply does not inform participants of particular aspects of a study, on the assumption that the aspect is irrelevant to the decision of whether to enroll. In the latter case, investigators can solicit from prospective participants any individual concerns that might be relevant to the research. Of course, it may not occur to participants that a particular concern of theirs is relevant to the research. Hence, this approach is not guaranteed to uncover concerns. Yet some participants would likely reveal concerns. For instance, some Jehovah's Witnesses might present their views regarding receipt of various blood products.

In the case of research using deception, however, individuals might not reveal idiosyncratic concerns that happen to coincide with the aspects of the study relevant to the deception. If the study's informed consent form explicitly and inaccurately stated that participants would not receive any blood products or bovine-derived products, it seems unlikely that participants would reveal these concerns. The use of authorized deception might partly address this concern. When told that they are being deceived about some aspects of the study, potential participants might think to reveal these concerns. When it is felt that some participants might be especially bothered by some aspects of the study over which they are being deceived, the IRB could consider requiring a focus group of relevant participants to assess their views. For instance, a recent study of the impact of direct-to-consumer advertising on physician prescribing behavior failed to state in specific terms the purpose of the study.[43] It is unclear whether this is something that would bother these participants, a question that could be addressed by conducting a preliminary focus group of similar physicians.

Concerns About Study Data

Others might object that authorized deception could confound a study's data if informed participants tried to discover which aspects of the study have been misdescribed. Granting this possibility, the fact that many participants currently recognize the existence of deceptive studies suggests that this possibility may already be present.[44] Just as participants in placebo-controlled trials may try to guess whether they received the study drug or placebo, so informing participants about the use of deception might stimulate them to try to guess the nature of that deception.

There are several ways in which this effect can be reduced. First, researchers should make a clear offer of debriefing at the study's end. Knowing ahead of time that they can eventually learn the nature of the deception should reduce participants' desire to discover it for themselves. In addition, by disclosing the use of deception and explaining that it is necessary to generate valid data, researchers might enlist participant cooperation in maintaining the deception. For instance, participants can be asked ahead of time to focus on the procedures specifically asked of them, and researchers can explicitly limit any probing questions.

Some experimental evidence indicates that authorized deception would not necessarily bias the responses of research participants. For example, two groups of psychology students were exposed to a deceptive experiment in which they were falsely informed that they would receive two to eight "painful electric shocks" at random times after a red signal light appeared.[45] No shocks were actually administered. Measures of self-reported anxiety and physiological arousal (pulse and respiration rates) were obtained. Prior to the deceptive shock intervention, one experimental group was informed that deception is occasionally used in psychology experiments to assure unbiased responses. The other group exposed to the deceptive shock intervention did not receive any information about the possibility of deception. No outcome differences were observed for participants informed of the possibility of deception versus those not informed.

The information about deception in this experiment, however, falls short of the authorized deception approach that we recommend. It disclosed to prospective participants that deception is a possibility in "a few experiments" rather than informing them that deception would actually be employed for all or some participants in the particular experiment in which they were invited to enroll. In contrast, Wiener and Erker directly tested the authorized deception approach, described as "prebriefing," in an experiment evaluating attributions of responsibility for rape based on transcripts from an actual rape trial.[46] Participants (68 undergraduate psychology students) were either correctly informed or misinformed about the jury verdict regarding the defendant's guilt. Half of participants received an informed consent document stating "You may be purposefully misinformed." The other participants were not alerted to the possibility of deception. No differences on attribution of responsibility were observed depending on whether or not the participants were prebriefed about the use of deception.

The results of studies that use authorized deception, however, may not be comparable with the results of previous studies that did not use this approach. This is a genuine methodological concern, which must be weighed against the countervailing ethical concern. When preservation of data comparability is an issue, IRBs should decide whether it is of sufficiently compelling value to warrant waiving the requirement for authorized deception.

The use of authorized deception also may reduce accrual if people refuse to participate in studies they know to be deceptive. This possibility could undermine the generalizability of the data, especially if particular groups are more likely to avoid deceptive studies. Conversely, the use of authorized deception may increase the available pool of research participants in the long run, by reducing the number of those who refuse to participate in future research after being deceived. Currently, there are no data to make

this assessment either way. On the other hand, there is clear evidence that deception upsets at least some people, violates respect for personal autonomy, and may cause problems for the research team. In addition, even if it turns out that authorized deception adversely affects accrual, it does not necessarily follow that authorized deception should be rejected. A finding that authorized deception substantially decreased accrual would suggest that people are especially bothered by the use of deception. Hence, we would have even more reason to argue that the use of deception *should* be revealed during the consent process.

Concerns About Harms

The argument for authorized deception assumes that people accurately gauge the extent to which being deceived will bother them. If this is not so—if, for instance, awareness of the use of deception concerns participants far more than actually being deceived would bother them—then authorized deception would make research less effective without making it significantly less harmful. In general, participants are more likely to be upset by the prospect of deception if they think that the deception might be concealing some risks involved in the study. The solution (to the extent that this is actually a problem) would be to explicitly state that the deception involved in the study does not conceal any risks. In the end, which alternative we should adopt depends upon how participants react to the use of authorized deception. Thus, a final decision will have to await the appropriate studies called for previously.

Conclusion

Deception in clinical research and valid informed consent are not necessarily incompatible, as is widely assumed. However, IRBs should consider allowing deceptive research only when the following conditions obtain: (1) the use of deception is necessary to achieve the goals of the study; (2) the use of deception is justified by the study's social value; (3) people are not deceived about aspects of the study that would affect their willingness to participate, including risks and potential benefits; (4) people are informed of the use of deception and consent to its use; and (5) people are informed of the nature of the deception at the end of their participation. To be sure, deception about the purpose of a study that is authorized in advance by participants is not *strictly* compatible with informed consent, because accurate disclosure about a study's purpose is a basic element of informed consent. However, if there is no reason to think that prospective participants would decline to participate if they knew the true purpose of the research, then authorized deception is compatible with respect for autonomy and thus with the spirit, if not the letter, of informed consent.

The use of authorized deception—an approach that generally has been neglected by researchers and IRBs—respects personal autonomy by putting participants in control of whether they are deceived; it minimizes the harms of deception to the participants; it removes the possibility that the use of deception will undermine one's willingness to participate in clinical research; it minimizes the possibility that the use of deception will undermine public trust in research; and it minimizes the burdens of conducting deceptive research on the research team.

Disclaimer

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