Journal of Medicine and Philosophy, 42: 114–131, 2017
doi:10.1093/jmp/jhw064
Advance Access publication February 13, 2017

Why is Coerced Consent Worse Than No Consent and Deceived Consent?

DAVID WENDLER*
NIH Clinical Center, Bethesda, Maryland, USA

ALAN WERTHEIMER
NIH Clinical Center, Bethesda, Maryland, USA

*Address correspondence to: David Wendler, PhD, Department of Bioethics, NIH Clinical Center, 10 Center Drive, Bethesda, MD 20814, USA. E-mail: DWendler@cc.nih.gov

The Standard View in research ethics maintains that, under certain conditions, investigators may deceive subjects and may enroll subjects without their consent. In contrast, it is always impermissible to coerce subjects to enroll, even when the same conditions are satisfied. This view raises a question that, as far as we are aware, has received no attention in the literature. Why is it always impermissible to undermine the validity of subjects' consent through coercion, but it can be permissible to undermine the validity of subjects' consent through deception, and it can be permissible to enroll subjects without any consent at all? The present analysis suggests that the answer traces to the conditions on the appropriate treatment of subjects. This conclusion suggests that some requirements for human subjects research, and for valid consent more generally, trace not to the protection of subjects per se but to the proper behavior of agents.

Keywords: *clinical research, coercion, deception, valid consent*

I. INTRODUCTION

Research participation sometimes offers subjects potential benefits that compensate for the risks and burdens they face. In other cases, to which we will refer as *net risk* research, subjects face risks and burdens without a compensating potential for benefit. To collect data to benefit future patients, researchers inject subjects with various substances, draw their blood, and withdraw medications. In addition, and often of greater importance, participation in

research places a range of burdens on subjects—waiting for the investigators, lying in the scanner, and filling out surveys.

Net risk research gives rise to a classic collective action problem. The knowledge generated by research is a public good—it is available to everyone (assuming appropriate promulgation), whether they personally contribute to its generation or not. At the same time, it may be contrary to the interests of any given individual to participate in net risk research. Better to have others face the risks and enjoy the benefits of their efforts. This dilemma can make it difficult for researchers to recruit a sufficient number of subjects. And even when researchers eventually meet their recruitment targets, accrual can be painfully slow, delaying the benefits of the research to the detriment of patients.

We use coercion to solve collective action problems in many contexts. We penalize manufacturers who do not equip their cars with catalytic converters. We fine those who do not pay their taxes. In contrast, we do not even consider the use of coercion to motivate individuals to enroll in research, much less allow for or endorse it. One might assume that this absolute prohibition on coercion follows from the more general principle that valid consent is necessary for ethical research. In the words of the Nuremberg Code: "The voluntary consent of the human subject is absolutely essential" (Department of Health and Human Services, 2015; first principle). The problem with this explanation is that, under certain conditions, research without valid consent is widely permitted. Most notably, some studies are permitted without any consent at all, and investigators are sometimes permitted to deceive potential subjects about material aspects of the study in question.

What we will call the *Standard View* in research ethics endorses this perspective. It maintains that research with no consent and research with deceived consent are permissible under certain conditions, but the use of coercion is always impermissible. The Standard View looks plausible to the extent that one focuses on coercion. Coercion undermines the voluntariness of potential participants' decision whether to enroll in research and, therefore, is frequently inconsistent with valid consent. The Standard View becomes puzzling once we compare coercion to research without consent and research involving deception. Research using deception often involves intentionally misdescribing material aspects of the study in question and is, in those cases, inconsistent with valid consent. Moreover, research without consent does not obtain *any* consent from subjects, much less valid consent.

Despite almost universal endorsement, it is not obvious why it is always unethical to conduct research that is inconsistent with valid consent in virtue of using coercion, but it can be permissible to conduct research that is inconsistent with valid consent in virtue of using deception or as the result of not obtaining consent at all. To begin to appreciate this puzzle, consider a potential subject, Mary, who has been invited to enroll in a research study. To obtain Mary's valid informed consent, at least two conditions must be

satisfied: (1) Mary understands the material aspects of the study, and (2) Mary voluntarily agrees to enroll. Coercion is inconsistent with valid consent because it violates condition #2: it undermines the voluntariness of Mary's decision. Deception regarding material aspects of a study is inconsistent with valid consent because it violates condition #1: it undermines Mary's understanding of the study. Because understanding and voluntariness are, in most cases, both necessary conditions for valid consent, it is not obvious why undermining voluntariness through coercion is never permissible, whereas undermining understanding of the material aspects of a study through deception can be permissible. And, it is even more puzzling that enrolling Mary without any consent at all can be permissible, but undermining the voluntariness of Mary's consent through coercion is always impermissible, even with respect to the same study.

We argue that standard justifications for research regulations which focus on protecting subjects and respecting their autonomy, what we call *subject-centric* justifications, are not sufficient to justify the Standard View. We then argue that widening the analysis to take into account the researcher–subject relationship, and the way that researchers ought to treat subjects, what we will call *researcher-centric* justifications, can provide an ethical justification for the Standard View. While this analysis focuses on a specific question—the justification for the Standard View—it points to a broader thesis about research regulations and informed consent in general, namely, not all requirements on valid consent are justified by reference to subjects alone. Some requirements are justified by the extent to which they prevent agents from treating subjects inappropriately and, thereby, ensure an appropriate relationship between agent and subject.

II. THREE TYPES OF RESEARCH WITHOUT VALID CONSENT

Valid consent is often described as being morally transformative in the sense of enabling a subject to waive his or her right against the action in question. By providing valid consent, a research subject waives his right to bodily intrusion and permits the investigator to insert a needle in his arm for research purposes. To achieve this moral transformation, the individual must understand the action in question and must voluntarily agree to it. Yet, the prevailing emphasis on respect for individuals' rights and valid consent notwithstanding, some biomedical research, and a good deal of social and behavioral research, proceeds without valid consent.

A book on people's propensity to lie and cheat relies heavily on experiments in which investigators lied to subjects about the purpose of the research (Ariely, 2012). "Mystery shopping" studies involve both deception and failure to obtain consent. For example, researchers evaluate whether clinicians have a bias against patients with Medicaid by posing as Medicaid

patients and asking when they can get an appointment. Research on the placebo effect sometimes uses Deceived Consent: subjects are told that they will receive an active drug but instead are given a placebo. While accounts vary, most commentators and regulations permit these and many other types of human subjects research without valid consent.

Briefly summarizing, then, under certain conditions, investigators may deceive potential subjects about material aspects of the study in question and may enroll potential subjects without their consent. In contrast, investigators are not permitted to coerce potential subjects to enroll in the very same studies. This gives us three types of research that might be conducted without obtaining valid informed consent:

a) No Consent
b) Deceived Consent
c) Coerced Consent

The Standard View in research ethics maintains that the first two types of research can be permissible, but the third type is never permissible.

One might attempt to justify this view by pointing out that the permissibility of No Consent and Deceived Consent renders Coerced Consent unnecessary. Why should investigators go to the trouble of coercing potential subjects to enroll when they can deceive them instead or enroll them without any consent at all? Granting the strategic virtues of this response, it begs the question. It assumes that No Consent and Deceived Consent are morally less problematic than Coerced Consent, and that is the assumption in question.

III. AN EXAMPLE OF COERCED RESEARCH

Briefly, A makes a coercive proposal to B when A proposes to set back B's interests if B does not perform some action. In the classic case, A coerces B when A puts a gun to B's head and proposes to shoot B if B does not give A his wallet. This proposal constitutes coercion because A proposes to render B (significantly) worse off if B does not do what A wants. It is not at all puzzling why commentators and regulations prohibit investigators from threatening to shoot potential subjects if they decline to enroll in research. It is less obvious why commentators and regulations uniformly prohibit coercion by subtler means. For example, commentators and regulations allow investigators to deceive potential subjects about material aspects of a study yet prohibit the investigators from threatening potential subjects with a $50.00 penalty if they decline to enroll in the same study. Consider an example.

A researcher plans to assess how accurately individuals evaluate their own health status and whether the accuracy of these evaluations varies by

gender. He identifies a clinic that asks patients to complete a health assessment questionnaire as part of their routine medical care and proposes to assess the accuracy of these self-assessments by comparing them to the physician's assessment of the individuals' health status. Imagine that the researcher considers three different designs for this study:

No Consent Information Sheet: The researcher accesses the self-assessment sheets after they have been completed, without informing the patients.
Deceived Consent Information Sheet: The researcher solicits the patients' consent to use their completed self-assessment sheets for research, but tells them that he is evaluating whether the questions are clear.
Coerced Consent Information Sheet: The researcher gives the patients the option of allowing their completed self-assessment sheets to be used for the research (accurately described) or paying a $50 fine that is added to their bill.

The Standard View in research ethics maintains that, if certain conditions are satisfied (e.g., the research is valuable and poses no greater-than-minimal risk), the investigator may use No Consent. Moreover, if the investigator chooses to obtain consent, he may deceive the subjects, even about material aspects of the study. In contrast, even when these same conditions are satisfied, the investigator may not violate the requirement on the voluntariness of subjects' consent by means of Coerced Consent.

One might try to justify imposing stronger protections on subject voluntariness compared to subject understanding by arguing that coercion leaves subjects with no choice but to comply. Coercion does increase, sometimes dramatically, the costs of declining. But, it does not eliminate choice altogether. The coercion involved in the third Information Sheet example increases the costs of declining by $50 but allows patients to make this choice. By contrast, individuals in the No Consent option are not given a choice at all. Their self-assessment sheets are simply used for research without their knowledge or consent. Individuals in Deceived Consent have a choice but only under a false description of the purpose of the study.

This analysis suggests that there is at least one way in which Coerced Consent is ethically *less* problematic than No Consent and Deceived Consent—it allows potential subjects to make a choice based on accurate information. This difference is emphasized by the fact that the normative preference embedded in the Standard View can switch in the case of high net risk research. Consider a case, contrary to regulation and ethics, in which an investigator proposes to conduct a high net risk study without valid consent. Suppose that researchers want to demonstrate the importance of hand washing as a way to reduce hospital-acquired infections. They propose a cluster randomized trial in which some hospitals require hand washing among their clinicians and other hospitals instruct their clinicians not to wash their hands. In this case, enrolling subjects without their consent and placing half of them in a hospital that does not practice hand washing seems

worse than giving individuals the choice of enrolling in the study or paying a fine of $50. At least in the case of Coerced Consent, individuals can decide for themselves whether to participate (or pay the fine). No Consent does not even give potential subjects this choice; they are simply enrolled.

In general, regulations and ethical requirements for human subjects research are justified by the protection they offer subjects. For example, the U.S. federal regulations describe their included requirements as "relating to protection of human subjects" (Department of Health and Human Services, 2009, 45 CFR 46). The U.S. regulations also state that complying with the regulations requires institutions to protect "the rights and welfare of human subjects" (Department of Health and Human Services, 2009, 45 CFR 46.103). Similarly, the Declaration of Helsinki states that researchers are obligated to protect subjects' "life, health, dignity, integrity, right to self-determination, privacy, and confidentiality" and that the collection of data should "never take precedence over the rights and interests of individual research subjects" (World Medical Association, 2013, paragraph 8). These are what we call subject-centric justifications in the sense that they justify research requirements on the grounds that they protect and respect subjects. In the next section, we consider whether it is possible to justify the Standard View on subject-centric grounds. Specifically, we consider whether protection of subjects' interests or respect for subjects' autonomy provides a justification for the Standard View.

IV. POSSIBLE SUBJECT-CENTRIC JUSTIFICATIONS FOR THE STANDARD VIEW

Being Coerced Involves a Greater Setback to Subjects' Interests

One might argue that Coerced Consent is morally worse than No Consent and Deceived Consent because it sets back subjects' interests to a greater extent. In particular, the experience of being threatened typically feels worse than the experience of being deceived or not asked for one's consent. Consider a set of nonresearch examples that might be used to support this view:

Larceny: A secretly takes B's necklace
Fraud: A offers B $500 in counterfeit money for her necklace
Robbery: A threatens to shoot B if B does not hand over her necklace

Robbery, which relies on coercion, seems worse than Larceny and Fraud, which rely on no consent and deception, respectively. A plausible explanation for this difference is that the experience of being robbed is likely to feel worse. In Larceny, B loses her necklace and suffers the comparatively minor harm of having a stranger rummage through her personal belongings without her consent and possibly without her knowledge. In Fraud, B loses her necklace and suffers the comparatively minor additional harm of being

tricked or played for the dummy. In Robbery, B loses her necklace, is threatened with serious harm, and likely experiences profound fear.

Granting the likely experiential difference in this case, things look substantially different when we consider "threats" more analogous to small fines. Imagine a white-collar criminal who threatens to electronically remove $250.00 from B's bank account unless she hands over her necklace (valued at $200). It does not seem obvious that this threat is worse or that the experience of it will be more negative than being tricked in Fraud or having a stranger rummage through one's personal belongings in Larceny. In the case of research, awareness of being deceived usually occurs after the study at the time of debriefing. The present justification thus assumes that individuals will often find being threatened by investigators with a fine at the time of study enrollment to be more unpleasant than being informed, after having contributed to a study, that the investigators lied to them. More importantly, the proposed justification assumes that the experience of being fined will be so much worse than the experience of being lied to that it justifies prohibiting coercion in all cases but allowing deception under some conditions.

To us at least, neither of these assumptions seems compelling. For example, it does not seem that being threatened with a fine upfront will be experientially so much worse across a broad range of cases, compared to being lied to upfront and finding out later, to justify a complete ban on the former but permit the latter in some cases. Similarly, it is not clear that individuals will systematically find being threatened with a small fine to be worse than being enrolled in research without any consent at all. This analysis suggests that protection of subjects' experiential interests does not provide a justification for the Standard View. What about subjects' interests more broadly?

In White-Collar Robbery, B can decide whether it is worse for her personally to lose her necklace or pay $250.00. This suggests that, in a range of cases, White-Collar Robbery will set back B's interests less than Larceny or Fraud. Imagine that the sentimental value to B of the necklace is greater than $250.00. Under these conditions, White-Collar Robbery offers B the option of limiting her loss to $250. In Larceny, B loses the entire value of the necklace. In Fraud, B is offered the option to keep her necklace but only under the false description of the money being worth $500. Thus, if the sentimental value of the necklace is between $250 and $500, B's interests will be set back less under White-Collar Robbery than Fraud.

Similarly, Coerced Consent allows individuals to decide whether to participate in the research or pay the fine. This offers individuals who oppose research in general or the specific study more than they value the amount of the fine to avoid the lesser option. No Consent does not offer this possibility but instead makes the decision for subjects that they will contribute to the research. Because waivers of consent are permitted only in cases where the risks are low and the research is judged to be relatively unproblematic,

this will be a concern largely for individuals who oppose research per se, or those with idiosyncratic preferences regarding the study in question. For example, imagine someone who is fundamentally opposed to research that investigates possible gender differences. Coerced Consent Information Sheet offers these individuals the option of paying the fine rather than contributing to research which conflicts with their fundamental values. Deceived Consent and No Consent do not offer this option, thus setting back to a greater extent the interests of individuals who would be better off paying the fine rather than contributing to the research. The point here is not to argue that subjects often will be *better off* with Coerced Consent compared to No Consent and Deceived Consent. The claim is the more modest one that protection of subjects' interests generally does not seem to provide a reason to allow No Consent and Deceived Consent under some conditions but to prohibit Coerced Consent in all cases.

Coercion Violates Subject Autonomy

It is frequently argued that the "underlying principle and justification of informed consent requirements . . . is a moral principle of respect for autonomy" (Faden and Beauchamp, 1986, 216). With this in mind, one might argue that Coerced Consent is more problematic than No Consent or Deceived Consent because coercion violates respect for autonomy to a greater extent than does the use of deception or simply using people without their knowledge. To assess this justification, consider the Belmont Report's summary of respect for autonomy:

> To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974, part B 1).

This passage suggests that respect for individuals' autonomy involves allowing them to act on their own considered judgments. When we are used for research purposes without our knowledge or consent, as in No Consent, we are not free to act on the judgment that we prefer not to participate. There is no choice whatsoever. Deceived Consent allows subjects the "freedom to act" but without accurate information regarding the alternatives among which they are choosing. In Coerced Consent, the prospective subject's freedom is constrained in the sense that the option of declining to participate without incurring a penalty is eliminated. Yet, in this case, the subject retains the freedom to choose between participation and paying the penalty based on his own judgment. Thus, while coercion does constitute a violation of autonomy, it does not seem to constitute a *greater* violation of autonomy than No Consent or Deceived Consent.

V. A RESEARCHER-CENTRIC JUSTIFICATION

To this point, we have considered possible subject-centric justifications for the Standard View which focus on threats to subjects' interests or violations of their autonomy. Specifically, we considered the claims that coercion poses a greater risk to subjects' experiential or more general interests or represents a greater violation of their autonomy compared to deception and no consent. The analysis suggests that these claims do not hold across a sufficiently broad range of cases to justify the Standard View. This conclusion suggests that any exclusively subject-centric justification is unlikely to succeed. From the perspective of protecting subjects' welfare interests and respecting their autonomy, Coerced Consent, No Consent, and Deceived Consent seem to stand or fall together.

In this section, we argue that a researcher-centric justification for the Standard View is more likely to succeed. A researcher-centric justification is but one form of what might be called *agent-centric* moral principles. To illustrate the latter notion, consider the claim that it is wrong for physicians to perform voluntary active euthanasia, even when patients request it and doing so is in the patient's interests (e.g., it puts an end to great and untreatable suffering). For present purposes, we need not assess whether this claim is true or false. Instead, the point is that this claim is plausible, and its plausibility points to the possibility of agent-centric limitations that do not trace exclusively to the protection of individual subjects.

First, let us consider a point of terminology. There are conditions on the appropriate behavior of researchers that have little, if anything, to do with their subjects. Researchers should not misappropriate hospital funds; they should treat their support staff with respect. However, by a researcher-centric justification, we do not intend a justification of this sort. It would be odd to attempt to justify the Standard View based on considerations that are wholly independent of subjects. Instead, by a researcher-centric justification, we intend a justification that does not trace exclusively to the protection of individual subjects.

The example of active euthanasia is helpful for clarifying this distinction. One might maintain that it would be good for a patient who is in great and untreatable suffering due to metastatic cancer, say, to die as the result of his disease. At the same time, one might hold that it would be inappropriate for the patient's physician to bring about this patient's death. The second claim is what we are calling an agent-centric claim in the sense that it brings into the analysis considerations that do not trace exclusively to the patient's welfare interests. At the same time, the agent-centric claim has something to do with the patient; it has to do with how the physician ought to treat the patient or what constitutes an appropriate clinician–patient relationship. One could thus redescribe the second claim in subject-centric terms: active euthanasia is problematic in this case because it involves the patient being

treated inappropriately by the physician. And, one might endorse a theory of patient welfare according to which being treated inappropriately (in this way) sets back the patient's interests.

For present purposes, we will not take on this debate. Before pursuing an extended analysis of precisely how (what we are calling) agent-centric considerations fit into a theory of individual welfare and moral theory more generally, we want to try to make the case, through the example of coercion in human subjects research, that these considerations need to be taken into account. Readers who hear researcher-centric considerations as considerations that are wholly independent of research subjects might want to translate these claims into ones regarding the researcher–subject relationship or the manner in which researchers ought to treat subjects.

To begin, then, to identify a researcher-centric justification for the Standard View, consider the four conditions under which US federal regulations allow investigators to conduct research without obtaining subjects' valid consent:

(1) the research involves no more than minimal risk;
(2) failure to obtain valid consent will not adversely affect subjects' rights and welfare;
(3) the research could not practicably be carried out with valid consent; and
(4) whenever appropriate, subjects will be provided with additional information.

The examples we have considered of acceptable research with No Consent and with Deceived Consent satisfy all four conditions. In contrast, the examples we have considered of research with Coerced Consent arguably satisfy (1), (2), and (4) but not (3) what we will call "the practicability condition." What does this difference suggest regarding a justification for the Standard View?

One might assume that the practicability requirement—the research could not practicably be carried out with valid consent—mandates simply that research may be conducted without valid consent only when it is difficult, costly, or inconvenient to obtain a subject's valid consent. Specifically, conducting research without valid consent is pro tanto wrong, but it may be permissible when the cost of obtaining valid consent (e.g., inability to obtain valuable data) is high enough to justify the wrong of conducting research without it. This reading of the practicability requirement offers a relatively straightforward justification for the Standard View. No Consent and Deceived Consent are sometimes permissible because there are cases in which they are necessary to obtain valuable data. In contrast, the essentially blanket prohibition on Coerced Consent is explained by the fact that there are no cases in which coercion of potential subjects is needed to collect valuable data.

To see the problems with this straightforward reading of the practicability requirement, and to begin to develop a researcher-centric account, consider

two alternative versions of No Consent Information Sheet. In the first version, the investigator conceives of the study 10 years after the information sheets have been completed, and he does not have any contact information for the source patients. In the second version, the investigator learns that a physician is going to start asking his patients to complete the information sheets for clinical purposes and designs a study to use the sheets for research purposes. In this second version, the investigator could obtain the patients' informed consent to use their information for research at the time the patients complete the sheets. However, the investigator declines to do so because he regards obtaining informed consent as a nuisance. Instead, he deliberately allows 10 years to pass and then proposes the study, at which point he requests a waiver from obtaining informed consent on the grounds that it is not practicable (given that many of the patients can no longer be located).

The first version of this study seems acceptable, while the second version is problematic. Notice, however, that strictly speaking the impact of the two studies on those who participate is exactly the same. In both cases, the patients fill out the same information, and this information is used, without their consent, for the same research study. In addition, at the time the second example is proposed, it could not practicably be carried out without the waiver of the requirement to obtain valid consent. Thus, on one interpretation, the example seems to satisfy the practicability requirement. Why, then, is No Consent problematic in this case?

In the second version, it would have been practicable to obtain valid consent at the time the study was conceived. Contrast this with standard cases of permissible Deceived Consent. In those cases, the investigator is not misdescribing the study just because he regards it as a nuisance to obtain informed consent or because he is concerned that potential subjects will decline to enroll if he describes the study accurately. Obtaining valid informed consent is impracticable because obtaining valid consent conflicts with the scientific methodology needed to answer the question posed by the study. To take a specific example, if an investigator accurately informs subjects that he is studying their propensity to cheat, they will be less likely to cheat. Hence, the study results will be less likely to reflect cheating behavior accurately. To avoid confounding the validity of the study results in this way, the investigator deceives subjects regarding its purpose.

Coerced Consent, in contrast, is unlikely to satisfy the requirement that a waiver of informed consent is acceptable only when obtaining consent is not consistent with the methods needed to obtain valid data. First, and unlike Deceived Consent, it is difficult to imagine research where the scientific methodology needed to answer the question posed by the study is inconsistent with obtaining non-Coerced Consent (but see below). Rather, the most important and plausible justification for using coercion rests on the desire to facilitate recruitment. In principle, this is not a trivial reason to consider

coercion. The research may be of social importance. And, failing to enroll a sufficient number of subjects can undermine the social value of the study just as much as failing to collect valid data. Yet, the need to enroll a sufficient number of subjects alone would not justify a waiver of valid consent. Indeed, the fact that an investigator is having trouble enrolling subjects typically signals that potential subjects have concerns with the study, providing more, not less reason to obtain subjects' informed consent.

One might respond that the use of coercion does not satisfy the practicability requirement because investigators have the ready alternative of obtaining sufficient numbers of subjects by offering incentives to enroll. For two reasons, we doubt that the possible use of incentives provides a justification for the Standard View. First, commentators and regulations on research with human subjects tend to regard incentives as ethically suspect. Indeed, somewhat ironically, many commentators express concern that incentives raise the potential for coercion. Second, the US federal regulations do not stipulate that waiver of valid consent is permissible when obtaining valid consent makes it impractical to enroll a sufficient number of subjects. They state that waiver is permissible when obtaining valid consent makes it impractical to "carry out" the study, that is, when obtaining valid consent is not consistent with the methods that are needed to obtain valid data. Even when it would be practicable to offer incentives, and their use would be sufficient to complete the study, the use of incentives is not necessary to the methods needed to obtain valid data.

This is not to say that it would never be permissible to waive the consent requirement on the grounds that potential subjects who are given a choice may decline to enroll. For example, one could imagine a study of profound national significance which requires a very high response rate. In this case, it might be permissible to waive the requirement to obtain subject consent. While this is possible, it is permissible in exceptional cases only. Precisely what conditions such a study would need to satisfy is complex. For present purposes, we are assuming that the studies we are evaluating do not satisfy these conditions.

Information Sheet may be a valuable study. But, it is not exceptional. In that case, we sometimes allow deception and no consent, but we prohibit coercion. The question, then, is why, from a normative point of view, some reasons for waiving the requirement to obtain valid consent (in the realm of studies that are not of extremely high importance) are legitimate and others are not. Why, specifically, can it be acceptable to conduct research without valid consent when obtaining valid consent poses a significant obstacle to the scientific methodology needed to answer the study question but not when obtaining valid consent poses a significant obstacle to enrolling a sufficient number of subjects? And, what does the answer to those questions tell us about the normative difference between No Consent and Deceived Consent versus Coerced Consent? To try to answer these questions, consider a case in which there *is* a scientific reason to coerce subjects.

VI. SCIENTIFICALLY NECESSARY COERCION

Suppose that a health-care system is considering whether to institute fines to get individuals to live a healthier life, eat better, or exercise more. Prior to instituting this approach, the health-care system wants to systematically evaluate the impact of fines (penalties or coercion) on individuals' behavior to determine whether they would be effective. To collect these data, investigators propose to conduct a study along the lines of Coerced Consent Information Sheet, namely, they propose to give patients the option of agreeing to contribute to research or paying a $50 fine that is added to their bill.

When used as a method simply to get subjects to agree to enroll in research, the use of coercion seems unacceptable. However, when used as a method to answer a legitimate scientific question, it seems that the use of coercion might be ethically acceptable, although the impact on the subjects is essentially identical in the two cases. In both cases, coercion threatens to make individuals worse off (by the financial amount of the fine) if they do not agree to contribute to the research. Moreover, in both cases the investigators are intentionally trying to manipulate the potential subjects' decision whether to enroll in research by threatening them with a fine if they decline. This suggests that whether coercion of research subjects is ethically acceptable depends on more than whether it involves an intentional attempt to manipulate their decision to enroll and whether the ultimate goal of the manipulation is to complete a valuable study. It seems that a subject-centric justification will not be able to account for this difference given that the immediate effect on prospective subjects is the same in the two cases. Specifically, in both cases prospective subjects' experience is one of being threatened with a fine along with any emotions that experience evokes. Because the subjects are not aware of the differences in the reasons for the fines in the two cases, any justification regarding the two cases as normatively different cannot trace to the subjects' experiences alone.

This analysis suggests that the practicability condition allows a waiver of informed consent only when the investigators face an independent challenge such that the requirement to obtain valid consent is incompatible with the methods needed to obtain valid data. When there are scientific or independent practical reasons why obtaining valid consent is not feasible, the explanation for the failure to obtain subjects' valid consent does not trace ultimately to the investigator simply trying to exert influence on potential subjects' decision whether to enroll. Instead, in the case of permissible deception, the investigator is not using deception to exert his Will on the potential subjects. Instead, he is deceiving subjects because the scientific exigencies of the study require it.

The claim that the scientific justification for the practicability requirement is central to our concerns regarding coercion can be seen on standard

accounts of coercion according to which we can be coerced by other people, but we cannot be coerced by nature (Wertheimer, 1988). Consider an individual who chooses to enroll in a research study because she has no good clinical options available to her. Whether this involves a case of valid consent depends on *why* there are no clinical options available. In Case 1, there are no clinical options because the individual has developed kidney failure which precludes her from receiving standard clinical care (e.g., standard treatment is excreted by the kidneys). An alternative form of treatment is available only as part of a clinical trial with which the individual's physician is not involved. This is a straightforward case in which the individual can give valid consent to participate in research although she has no reasonable alternative to doing so. She is not coerced to participate by her physician or the investigator.

In Case 2, the patient's physician says that he will not offer her standard clinical care unless she enrolls in a clinical trial. In this case, the physician has coerced or at least wrongfully pressured her into enrolling in research by threatening not to treat her if she does not enroll. Here, it is false to say that it was impracticable to conduct the research without consent. And, the patient's consent is not valid, although she faces the same choice situation as in Case 1, namely, that she will not receive treatment unless she participates in clinical research.

One might argue that it is acceptable to enroll individuals in research without their consent when the four conditions on waiver are met because, when these conditions are satisfied, there is no right against being enrolled. This explains the Standard View that it can be acceptable to enroll individuals in some trials without any consent at all. Now, consider the possibility of obtaining consent for the same trial but using coercion. The Standard View maintains that this is inappropriate. In other words, it suggests that, in some cases, there is no need to obtain valid consent. However, if researchers decide to engage with subjects and ask their agreement to enroll in the study in question, then the investigators are obligated to do so in a way that satisfies some of the procedural requirements on obtaining valid consent.

At first glance, this looks puzzling. One might have thought that in an important sense the value of valid consent is instrumental. That is, valid consent is a means for individuals to decide for themselves whether to waive their relevant rights in a given case. Hence, if there are no relevant rights, then there is no need to obtain valid consent and, therefore, no need to satisfy the procedural requirements on obtaining valid consent. Put differently, one might assume that satisfying the procedural requirements on valid consent (e.g., don't coerce) is important only in circumstances where it is important to obtain valid consent.

The Standard View seems to suggest that there are independent normative considerations on obtaining somebody's consent. Even when an individual does not have a right against being enrolled in a trial, it is impermissible,

if one decides to ask for his consent, to manipulate his decision. Why might it be problematic to violate this condition on valid consent in cases in which valid consent is not necessary, indeed no consent is necessary at all? The comparison to deception increases this puzzle. In these cases, it can be permissible to violate the condition on understanding by deceiving potential subjects about material aspects of the study in question (e.g., the purpose of the study is to assess cheating behavior).

The way to make sense of this is to recognize that the harm of manipulating individuals' decision-making process is not exhausted by the extent to which it interferes with their ability to decide whether to waive the relevant right or not. There is a more direct harm involved, namely, that of trying to control them or impose one's own Will on them. Recall how the preference for no consent over coercion switches in the case of high-risk research. We saw this previously with respect to the hand washing study that posed very high risks to subjects and offered them no potential for benefit. In that case, threatening to fine individuals if they did not enroll seemed better than enrolling them without consent or deceiving them about the nature of the study.

When there is no, or perhaps a very weak, right against being enrolled in a study, then the individual may be enrolled without consent. However, coercion is still impermissible because it involves the researcher inappropriately trying to control the individual or exert his Will over the individual. As noted previously, depending on one's account of subject welfare, one might describe this case as involving the direct harm to the subjects of manipulation or inappropriate treatment by a researcher. In the case of possible coercion with respect to very high risk research, this (direct harm of) manipulation of the subject remains. However, it is outweighed by the strong right that the individual has against enrollment (or perhaps by the strong interest that would be set back by being enrolled). This gives us a rough way to estimate how problematic it is to manipulate someone else's decision through coercion: it is worse than exposing him to a low risk without his consent but not as bad as exposing him to a substantial risk without his consent.

This analysis suggests that there is an independent concern that arises when agents try to coerce subjects or manipulate their decision-making, and this concern does not arise when the agent bypasses the subject's decision-making altogether. It is also not present when the manipulation is mandated by the science rather than the investigator (although a subject who is not aware of the scientific justification for the manipulation may feel that it is present). This suggests that valid consent is not simply a matter of whether subjects have a say in whether they are enrolled. There is also a claim that, if subjects are going to be asked, they have to be asked in what one might think of as a proper way or manner.

Finally, manipulation of the subjects' decision is frequent in cases of deceptive research. As noted, researchers often do studies on lying and cheating.

Informing individuals that the study involves cheating would almost certainly make them less likely to enroll. Hence, deceiving them about the goal, describing the purpose in innocuous terms, increases the chances that they will enroll. Why then is this not an impermissible transgression on the process of decision-making in the way that coercion is? Again, the key involves whether the researcher is imposing his Will. In some cases, when the investigator simply chooses to deceive, the deception involves exertion of Will. However, in other cases, when the science requires deception—when informing subjects about the goals of the study would change the results—the investigator is not imposing his Will on the subjects. In effect, it is not the investigator but the science that is doing it. It follows that the puzzle posed by the Standard View cannot be solved simply by distinguishing between the process of decision-making and the content of the decision. Instead, we need to appeal to the concept of researcher-centric wrongs. The picture we have in mind, then, is roughly the following.

There is a division of moral labor with respect to the conduct of ethical research. Investigators are charged with designing studies to answer valuable scientific questions. Respect for autonomy implies that individuals should then be able to decide for themselves whether to enroll in the studies thus designed. The problem is that these two goals can conflict when the scientific design needed to obtain valid data is inconsistent with obtaining valid consent. Waiver of valid consent can be acceptable in these cases, provided the risks are low, because the failure to obtain consent does not trace to the investigator trying to force potential subjects to enroll; it traces to the investigator attempting to collect valid data. In these cases, individuals are not being subject to the Will of the investigators, just as the physician is not imposing his Will on the patient when an alternative therapy is only available in a clinical trial. In contrast, in standard cases of Coerced Consent this is precisely what is happening. The investigator is using coercion, not because it is needed for scientific reasons but in order to influence potential subjects' decisions whether to enroll in the study.

It can be difficult to distinguish between cases in which obtaining valid consent is "merely inconvenient" or "costly" and those in which it is inconsistent with the plan of research. Still, it will generally be clear enough. In some cases, it will be impracticable to obtain consent because doing so is inconsistent with the methods needed to answer the scientific question. In other cases, it will be impracticable to obtain consent because of factors that are beyond the investigator's control, such as the fact that the data were collected 10 years before the study was conceived.

Finally, the conclusion that the Standard View is based, in part, on researcher-centric rather than exclusively subject-centric considerations raises, for future research, the question of the extent and strength of researcher-centric limitations on human subjects research. In the present case, the claim that (nonscientifically necessary) coercion involves

investigators inappropriately subjecting participants to their Will raises the question of the strength of the prohibition on treating research subjects in this way: is subjecting participants to the investigators' Will a side constraint that should never be violated? Or, is it rather a pro tanto wrong that may be justified in some cases?

To consider a very different example, children bullying other children (e.g., at school) causes significant acute and long-term harms. Interventions to minimize these harmful effects would be extremely valuable. With this in mind, imagine that an investigator develops an intervention that may protect bullied children if applied soon after the bullying incident. To test the intervention, the investigator identifies a cohort of children who experience regular bullying at school. The investigator proposes to bring the children to the laboratory, bully them one time, and test the experimental intervention. Because the children are taken out of school, this experiment does not increase and may well decrease the extent to which the subjects experience bullying. Imagine further that the subjects agree and their parents give permission. Is this research paradigm one that institutional review boards should even consider? Or, should they reject it in all cases on the ground that it is always impermissible for *investigators* to bully subjects, even when conducting the research reduces the amount of bullying to which the subjects are exposed? We do not have answers to these questions. However, they strike us as interesting and important, and they illustrate the need for future work to identify and consider the implications of what we have been calling researcher-centric limitations on clinical research.

VII. CONCLUSION

We began with a puzzle regarding an almost universally endorsed view in research ethics: it is sometimes permissible to conduct research with No Consent and with Deceived Consent, but it is always impermissible, even under the same conditions and for the same study, to conduct research with Coerced Consent. We argued that exclusive subject-centric justifications for this view—the difference in treatment of these three approaches is justified by protection of subjects' interests or respect for subject autonomy—do not succeed. We then offered a researcher-centric justification that is grounded in appropriate treatment of subjects by investigators or the conditions on appropriate researcher–subject relationships. In sum, we have argued that the Standard View is correct, albeit for different and (we think) deeper reasons than are thought to account for the requirements governing research with human subjects. Future research will be needed to determine the theoretical basis and to identify the range and strength of researcher-centric limitations.

ACKNOLWEDGMENTS

This work was completed as part of the authors' official duties as employees of the U.S. NIH Clinical Center. The NIH had no role in the analysis, writing of the manuscript, or the decision to submit it for publication. The views expressed are the authors' own; they do not represent the position or policy of the NIH, DHHS, or US government. The authors have no conflicts of interest with respect to the present work.

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