

# Virtual Mentor

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## JOURNAL DISCUSSION

### **The Belmont Report's Misleading Conception of Autonomy**

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**National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Bethesda, MD: US Government Printing Office; 1978.**

Practically all human subjects research in the United States is regulated by the Federal Policy for Protection of Human Research Subjects [1]. That policy was formed by the Department of Health and Human Services in the late 1970s and early 1980s, and was later adopted by 14 federal departments and agencies. The policy's ideological foundation had been laid by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [2]. The commission's 1978 report, generally known as the Belmont Report, identified three ethical principles as basic to the ethical guidance of research involving human subjects: respect for persons, beneficence, and justice. This influential analysis has provided the background for ethics policy concerning human subjects research to this day.

Despite its political success, the Belmont Report is not beyond philosophical criticism. In what follows, I will argue that the report makes a philosophical error in its attempt to derive moral requirements for informed consent from the principle of respect for persons. Although neither the principle of respect for persons nor the need for robust informed consent policy will be questioned, I will argue that the report's manner of linking these two is based on a misguided conception of autonomy. Instead of invoking the autonomy of the consentor, the report should have based the duty to seek informed consent on the status of the researcher as an autonomous moral agent.

### **The Belmont Report and Respect for Persons**

Since the publication of the Belmont Report, the standard ethical justification for informed-consent policy has been that obtaining informed consent is a way of respecting persons, which in turn is a fundamental moral requirement. The report states:

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied [3].

Informed consent provides more than an opportunity for choice; it provides choice based on adequate information. But why would it be disrespectful to offer choice without information, and how are we to judge when the provision of information is adequate? The report's answer is that persons with the capacity for self-determination—those capable of deliberation about personal goals and of acting under the direction of such deliberation—must be treated as autonomous agents; *their autonomy must be respected* (emphasis added). The report explains that:

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, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so [3].

Persons with a capacity for self-determination should thus be (1) free to act on their considered judgments as long as they don't harm others, and (2) informed as needed so that they can form a considered judgment concerning how to act. Together, these statements imply that respect for autonomy requires informed consent.

### **Self-Determination and the Duty to Inform**

Respect for persons is surely a fundamental moral principle. It is less clear what to make of the Belmont Report's attempt to derive from that principle a general duty to inform, i.e., a duty not to "withhold information necessary to make a considered judgment." It would be implausible to think that we are all generally obligated somehow to inform each other, out of mutual respect, in every way that might be helpful for the formation of considered judgments. There is simply no such general duty. Instead, a duty to inform out of respect is inherent in specific contexts of personal and communicative transactions [4]. For example, when money is borrowed, the lender and borrower must be mutually informed about terms and conditions. When service is rendered, the provider must similarly inform the client about the service and its cost. The same applies, only with greater moral force, when the service carries substantive risks for the client or is physically or psychologically invasive. It would be disrespectful to expect the client to agree to such services without being informed about their nature or probable risks and benefits.

Such behavior would not only be disrespectful but also potentially harmful and unfair to the client. It is therefore quite possible that informed consent receives part of its justification from considerations of beneficence and justice. This is not the spirit in which it is presented in the Belmont Report, however, which explicitly states that "the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons" [3].

It is beyond the scope of this article to examine the ways in which the principles of beneficence and justice underwrite requirements for informed consent. In the

absence of such examination, however, the report's emphasis on respect for persons as the main foundation for informed consent seems quite unreasonable in the context of human subjects research. Informed consent should not be the primary tool for preventing research subjects from harm and ensuring fairness; instead, ethics governance should ensure that subjects are not exposed to unreasonable risks or treated unjustly. To put the main burden of assessing the risks and benefits of participation on the individual subject through informed consent would indeed be unfair.

The primary role of informed consent seems better understood as a way of respecting each person as a rational agent who enters into agreements as a moral equal based on honest information. In its secondary role, informed consent protects the subject's well-being, because (1) judgments of what is burdensome or beneficial are often relative to the individual's conception of the good, and (2) the experience of being coerced, deceived, or manipulated is generally a strike against one's well-being.

In typical cases of human subjects research, it would clearly be disrespectful and maleficent to omit informed consent. Infamous failures in this regard were indeed a major motivation for the establishment of the National Commission and for the subsequent regulatory framework for research ethics that received its justification from the Belmont Report. The authors of the report, however, made a mistake in the way they chose to justify informed consent. They tried to argue that informed consent is morally required because it promotes self-determination, i.e., informed personal deliberation leading to the formation of a considered judgment. Such deliberation is obviously valuable, but the mere fact that something is valuable, even intrinsically valuable, does not entail a moral requirement to do whatever is necessary to promote it.

Each of us can promote only a limited number of valuable goals. There will always be an infinite number of goals that we might have promoted but didn't, and this does not mean we have failed morally. Similarly, a human subjects researcher might be sufficiently interested in promoting the self-determination of his research subjects to take measures to inform them about the research with its risks and benefits.

But suppose, hypothetically, that he is not? Merely to point out the value of self-determination, as the Belmont Report seems to do in its arguments for informed consent, may not be enough to persuade him. Why should he value these subjects' self-determination more than, say, the maximum cost-effectiveness of his research? Where's the argument that says he must, morally, weigh these values in one way rather than the other? And what if he can argue that omitting informed consent in this instance would ultimately lead to greater benefits to society or mankind? Simply to assert that self-determination is intrinsically valuable is insufficient because any measures to promote self-determination will come at a cost to some other intrinsic value that might then just as well be presented as a ground for an opposing moral duty. The value of self-determination can only be ranked in relation to that (or those) other value(s). (Interestingly, it is even possible to imagine, as Sarah Buss has, a

person who genuinely values self-determination and yet, without contradiction, sees nothing wrong in manipulation and coercion [5].) So valuing self-determination will not alone get us very far in the direction of justifying requirements for informed consent.

### **An Alternative Approach**

Fortunately, there are alternatives on the philosophical menu. The term “autonomy” was first introduced to ethical theory by German philosopher Immanuel Kant [6]. Kant’s conception of autonomy differs greatly from the one indicated in the Belmont Report [7, 8]. The Belmont definition of autonomy (as self-determination) describes a psychological capacity for personal deliberation and action, a capacity that individuals may enjoy and exercise to various degrees. For Kant, by contrast, our autonomy is the free exercise of our practical reason in accordance with the good, and consists in the fact that the practical reason we all possess has direct implications for how we should act, no matter what our individual desires might be. More specifically, practical reason demands of all of us that *we never use humanity in our own person or that of another merely as a means but always at the same time as an end in itself* [6]. This principle, often referred to as Kant’s Formula of Humanity (FH), is indeed relevant to the morality of informed consent, because it implies a prohibition against coercing and deceiving human beings, as well as an obligation to benefit others and avoid harming them.

In addition to providing this promising lead toward a normative principle, the Kantian conception of autonomy puts us in a better position to address the hypothetical researcher who valued cost-effectiveness more than the self-determination of his research subjects. If we assume that the researcher has true autonomy, in Kant’s sense of the word, it follows that he has an obligation not to deceive or coerce his human research subjects.

### **Implications for Informed Consent**

With the Formula of Humanity in hand, we are in a better position to consider when informed consent is required and what should count as “adequate standards of informed consent.” Kant scholars generally agree that the most plausible candidates for Kantian duties are the duties not to coerce or deceive rational agents [8]. According to Wood, for example, “coercion and deception obviously violate FH because they achieve their end precisely by frustrating or circumventing another person’s rational agency and thereby treat the rational nature of the person with obvious disrespect” [9]. Granting this, informed-consent procedures are justified by FH to the extent that they serve the purposes of noncoercion and nondeception.

The remaining question is which standards of informed consent are likely to serve these purposes. O’Neill claims that “informed consent is ethically important because it adds a tough safeguard by which individuals can protect themselves against coercion and deception” [8]. At the same time, she warns that the tendency to increase the amount and specificity of information and to insist on informed-consent procedures in every possible context is not warranted by this goal and can be

contrary to other morally important purposes, such as beneficence, public health, trust, and trustworthiness. Her suggestion is that, instead of inflating informed consent in a misguided attempt to solve all moral problems through one instrument, we should try to make sure that patients, research subjects, and tissue donors have control over the amount of information they receive and whether or not to go along with a proposed course of action (therapy or research). The danger of their being deceived or coerced is effectively limited when they “know that they have access to extendable information and that they have given rescindable consent” [10].

This suggestion seems plausibly motivated by Kant’s FH, and it implies that research ethics is not reformed by every additional demand placed on the informed-consent process. All such demands must serve the purpose of minimizing deception and coercion, and it is possible to imagine requirements for more information processing after that purpose has been served. On the Kantian view, the ultimate point of informed consent policy is not to increase endlessly the incidence of personal deliberation on the subject’s part, but rather to decrease the incidence of manipulation, deception, and coercion on the researcher’s part; the demands of autonomy bind the researcher. In fact, insisting that patients or potential subjects engage in extensive deliberation and information processing may arguably have the effect of frustrating their self-determination if they are neither willing nor able to engage in such efforts. Attempts to implement inflated informed-consent procedures may thus bespeak inadequate respect for persons who would rather not have the responsibility of deliberating and reflecting on the pros and cons of what they are being offered.

### **Conclusion**

The Belmont Report rightly insists that informed-consent policy is justified by respect for persons and considerations of autonomy. The justification, however, should be along the lines of Kantian autonomy, basing informed consent on the Formula of Humanity and not on the value of self-determination. Informed consent may of course have unrelated benefits, such as helping individuals protect themselves from harm and exert control over their lives. These benefits will not, however, justify the significance informed consent has been given in bioethics in the past few decades. Insofar as that emphasis is justified, it rests on deeper considerations of real respect for persons.

This conclusion is of more than mere academic interest because the Formula of Humanity will guide our judgments about informed-consent policy differently than the Belmont Report does. Policy will no longer be based on how far it goes in the direction of offering people opportunities for personal deliberation. Instead, it will be rated by how well it protects people against deception and coercion. This difference in approach should certainly lead to policies that are different—perhaps less demanding and more flexible—than those that are naturally supported by the Belmont Report.

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