Formal Assessment of Voluntariness With a Three-Part Consent Process

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Informed consent that is voluntary and made by an individual who is knowledgeable and competent is a foundational requirement for protecting human subjects from harm and exploitation that could result from research participation. In 1974 Miller and Willner proposed a two-part consent process that involved disclosure of information and assessment of comprehension. The authors propose a brief third component to the consent process: assessment of voluntariness. Three steps are involved: generate a list of potential coercive influences on the basis of the research population and the study context, develop a set of questions to assess the presence and intensity of the impact of these influences, and identify alternative courses of action should coercion be identified. (*Psychiatric Services* 62:87–89, 2011)

For more than a half-century, there has been considerable interest and activity in the United States in developing guidelines to protect human subjects from harm and exploitation that might result from research participation. In 1952 the first published code of ethics written for the behavioral sciences proposed that researchers secure truly informed consent from participants that does not capitalize on potential feelings of obligation or desires to please (1). In 1966 the Surgeon General issued a policy statement that required human subjects research funded by the federal government to undergo review by a committee to ensure protection of the rights and welfare of participants, to evaluate the balance of risks and benefits, and to review the methods used to obtain informed consent, thereby giving birth to institutional review boards (IRBs). In the late 1970s the Belmont Commission made voluntary informed consent the cornerstone upon which ethical research rests and made researchers responsible for ensuring that participants understand information disclosed during the consent process (2).

According to the U.S. Department of Health and Human Services (45 CFR 46), the basic elements of an informed consent include, among other things, a statement that the study involves research, an explanation of the purposes of the research, a description of the study procedures and identification of any procedures that are experimental, a description of any reasonably foreseeable risks and benefits to participants, and statements that participation is voluntary, that refusal to participate is without penalty, and that subjects can discontinue participation at any time without penalty.

How are informed consent requirements met?

The informed aspect of consent is related to the disclosure by the investigator of relevant information in a form that can be comprehended so that the prospective research participant can make a knowledgeable decision about enrolling in a proposed study. IRBs hold researchers accountable for ensuring that consent processes include the federally required elements and, with limited exceptions, require researchers to obtain written consent before research participation. In addition, consent must be given voluntarily without controlling influences (for example, coercion). However, federal regulations provide no explicit guidelines for assessing the extent to which a research participant is actually giving autonomous consent.

Investigators have explored a variety of factors related to the comprehension of research consent disclosures. Some have examined the impact of cognitive or mental disorders on comprehension (3,4). Others have investigated potential mechanisms for improving comprehension, such as alternative modes of presenting consent disclosure information and remedial teaching interventions (5,6). Some have proposed safeguards designed to demonstrate that persons with severe mental illnesses are capable of providing meaningful informed consent (7). A small body of literature addresses the potential effects of undue amounts of compensation (8) and discusses potential contextual influences on certain vulnerable populations (for example, prisoners) (9). One empirical study has examined coercion to participate in research in a prison setting. Moser and colleagues (10) indicated that prisoners with mental illness demonstrated adequate capacity to consent to re-

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search, although to a lesser degree than a control group, and that prisoners cited a desire to cooperate, avoidance of boredom, the opportunity to meet someone new, and a desire to help others as motivations to participate. The authors stated that the prison setting may have influenced the prisoners' decisions but that the prisoners did not feel coerced into participation. Similarly, a study that polled medical patients who were participating in various studies found that patients cited such motivators as the possibility of better care, a serious need for help, the research institution's reputation, and a desire to help others; very little evidence suggested that patients felt coerced (11).

More recently researchers have focused on the concept of voluntariness to consent to research. Appelbaum and colleagues (12) noted that the limited empirical work on voluntariness provided few if any answers about the nature and constraints on this construct. They stated that whether consent is voluntary "depends on the extent to which subjects are actually exposed to external, intentional, and illegitimate influences that causally impact their decision" and theorized that inducement (for example, incentives), persuasion (for example, interpersonal pressure), and force (for example, nonconsensual intervention and threats) might be mechanisms that would unduly influence a person's decision to participate in research, thereby making his or her decision coerced and involuntary.

Two-part consent: a test of comprehension

In 1974 Miller and Willner (13) proposed a two-part consent process. The first part involves the disclosure of relevant information (such as the purpose of the research, required tasks, and risks and benefits). The second part involves use of a brief, objective test of the potential participant's comprehension of the disclosed information. Others have since proposed the use of structured measures to assess decision-making capacity, conceptualized to include an understanding and appreciation of information, the ability to use the information in making a decision, and the ability to express a choice. A review by Dunn and colleagues (2) suggested that several such measures may be useful in the assessment of comprehension, although these authors cautioned that there is currently no consensus on the definitions of the domains of capacity and therefore no gold standard by which to measure them.

Similarly, others have lamented the lack of consensus on conceptualizing voluntariness and the absence of accepted measures of voluntariness in research settings (12,14). Most IRBs do not require an explicit or systematic documentation of voluntariness. To our knowledge, there has been no formal movement toward incorporating assessments of comprehension and voluntariness during the informed consent process, nor is there any consensus on how documentation should be secured.

The third element of the process: assessment of voluntariness

In this brief report we describe a process that researchers may use to inform their judgment of whether a prospective research participant is making a voluntary decision to participate. This process may be especially valuable in settings that many consider inherently coercive (for example, prisons and forensic psychiatric hospitals) because of administrative or peer power differentials that might affect an individual's sense of autonomy (9). Adding an explicit assessment of voluntariness to the Miller and Willner model (13) results in a three-part consent process—disclose information, assess comprehension, and assess voluntariness—that more systematically informs a researcher's judgment regarding the validity of the consent provided by a potential participant.

Currently no standardized measure exists for assessing voluntariness in the research context, although there have been some recent efforts toward this end (15). We offer an approach here that is simple and efficient (that is, it adds little time to the consent process) and that informs the researcher about salient issues related to the targeted populations and the study context that could have an impact on the voluntariness of consent. This information can inform the researcher's judgment regarding the voluntariness of an individual's decision about participation. If undue incentives or coercive influences are identified, the investigator may then be able to offer alternatives that protect the potential participant from illegitimate sanctions.

Our assessment of voluntariness involves three steps. First, a list of potential coercive influences relevant to the research population and study context should be generated. Second, the researcher should develop a set of questions to assess the presence and intensity of the impact that these influences may have on the prospective participant's decision-making autonomy. Finally, the researcher should identify alternative courses of action should coercion be identified (that is, when the consent does not appear voluntary).

Frameworks like that of Appelbaum and colleagues (12) can be useful in identifying potentially coercive influences. Investigators should seek to identify inducements, persuasions, or forces that are salient within the targeted recruitment population or the context or location of the study. For example, in a family context there may be concerns about the coercive effects of the level of compensation (inducement) on parents who are consenting for their children or concerns about whether a vulnerable individual could be talked into participating to prevent someone else from being embarrassed (persuasion). In a prison context, issues of control or force might be relevant for the assessment of voluntariness.

The second step involves creating simple assessment questions that address the areas identified in the first step. The questions and approach to collecting the information should capture both the presence of the coercive influence and the intensity of the influence. This line of inquiry could take several forms. For example, for a study we are currently conducting in a prison setting, we first ask questions about the presence of several potential coercive influences and then follow up with questions about the prospective participant's perceived intensity "In deciding to take part in this study, were you threatened with harm by

other inmates or inmate groups—gangs for example—if you would or would not agree to sign up for this study?" Four response options are provided, and for responses other than 1, the interviewer inquires about the nature of the threats: 1, No, not at all. It was just my own decision; 2, A little bit, but it was mainly my decision; 3, Yes, somewhat. I felt somewhat forced by others' threats; 4, Definitely. I wouldn't have signed up if I didn't feel forced to.

Another question that we include is, "In deciding to take part in this study, did the staff, like the warden or corrections officers, offer you any incentives, like more privileges or better living or work conditions, to get you to sign up or not sign up for this study?" Four response options are provided, and the interviewer follows up as above for answers other than 1: 1, No, not at all. It was just my own decision; 2, A little bit, but it was mainly my decision; 3, Yes, somewhat. My decision was influenced by things they offered me; 4, Definitely. I wouldn't have signed up if they hadn't offered me incentives."

Several questions similar to those listed can provide good information on which to base a judgment about whether coercive influences may have rendered the person's consent not voluntary and thus invalid.

The third step focuses on protecting potential participants who indicate that they would not participate except for the coercive influence. Such individuals cannot ethically be enrolled in the study; however, depending on the type of coercive influence involved, the individual may face negative consequences for failure to participate. For example, if a prison inmate reports that staff threatened adverse consequences for failure to enroll (for example, placement in isolation or administrative segregation), the investigator may need to create options that attempt to protect such inmates from harm. In this example and in other protocols that involve only brief interview or questionnaire procedures (for example, one hour), one option is to allow the inmate to stay with the researcher for a period of time equal to that required to complete the protocol, even though no data are collected. Indeed in our own research with prison inmates this option has been exercised by some inmates who feared consequences for nonparticipation. A second and more broadly applicable alternative is for the investigator to "officially determine" that the potential participant does not meet eligibility requirements. This transfers the responsibility for failure to participate from the person to the researchers, thus providing an acceptable excuse for nonparticipation.

Although an individual's perception of risk of sanctions may be inaccurate (that is, he or she may wrongly anticipate that the staff will sanction nonparticipation), in our view the ultimate result should be the same: the individual should not participate, and he or she should be protected. It should be noted that we recognize that this approach has important legal and ethical implications including minor deception of others at research sites; however, such a discussion is beyond the scope of this brief report.

Conclusions

Some researchers have adopted a two-part consent process whereby comprehension of consent disclosures is specifically and separately assessed. In many settings in which coercion and control are concerns, a distinct "third part" of the consent process may be appropriate and even ethically advisable to ensure that individuals give voluntary consent. We have described here a simple and flexible approach that focuses the voluntariness inquiry on areas of potentially coercive influence that are perhaps more salient and relevant in the context of a particular research study. That is, the context determines the focus. Nevertheless, whether one uses a standardized instrument (which still needs to be developed) or a semistructured interview such as the one proposed here to help inform the researcher's professional judgment, a three-part consent process is perhaps a future trend in the ethical recruitment of research participants.

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