The Concept of Voluntary Consent

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Abstract:

Our primary concern is analysis of the concept of voluntariness, with a secondary focus on the implications of our analysis for the concept and the requirements of voluntary informed consent. We propose that two necessary and jointly sufficient conditions must be satisfied for an action to be voluntary: intentionality and substantial freedom from controlling influences. We reject authenticity as a necessary condition of voluntary action, and we maintain that constraining situations may or may not undermine voluntariness, depending on the circumstances and the psychological capacities of agents. We compare and evaluate several accounts of voluntariness and argue that our view, unlike other theories, is not value-laden. We also discuss the empirical assessment of individuals’ perceptions of the degrees of noncontrol and self-control. We propose use of a particular Decision Making Control Instrument. Empirical research using this instrument can provide data that will help establish appropriate policies and procedures for obtaining voluntary consent to research.

Keywords: voluntariness, informed consent, intentionality, authenticity, decision making, control
Voluntary informed consent is arguably one of three foundational notions in literature on the protection of human research participants, the other two being fairness in the selection of research subjects and appropriate balance of risk and potential benefit. Since the 1970s, legal, regulatory, philosophical, medical, and psychological literatures have generally favored the following elements as the analytical components of informed consent: competence, disclosure, understanding, voluntariness, and consent (National Commission 1979; Meisel and Roth 1981; President's Commission 1982). Voluntariness and consent are the least carefully examined of these elements in regulatory frameworks and in the literature of biomedical ethics.

Discussions in psychological literature on intentionality and reasoned action correspond to some features of informed decision making in the biomedical ethics literature, but little empirical research has been devoted to the voluntariness of decisions specifically, and few writers in any field have investigated the voluntariness of decisions to participate in research (Lidz 1984; Sugarman et al. 1998; Appelbaum et al. 2009). A 2002 literature review found no shared or well developed model of voluntariness useful for bioethics in either the empirical or the ethics literature (Nelson and Merz 2002).

Our goal is to fill the gaps left by inadequate and incomplete conceptual analysis. We provide both a conceptual account of voluntariness and a discussion of the need for an empirical instrument that addresses individual perceptions (by contrast to actions) of voluntariness in decision making. We first present the regulatory and philosophical issues that center on voluntariness (Section I). We then address basic conceptual issues about the nature of voluntariness (Section II), as well as related ethical issues about voluntariness (Section III). We propose that the concept of voluntary action be understood in terms of two
necessary and jointly sufficient conditions: intentional action (Section IV) and the absence of controlling influences (Sections II and V). We reject authenticity as a necessary condition of voluntary action in Section VI and then evaluate the differences between a value-laden analysis of voluntariness and our non-value-laden analysis (Section VII). Finally, we outline a program for empirical projects that use an instrument to measure individuals’ perceptions of voluntary choice (Section VIII).

The question, “what is voluntariness?” is not, we argue, inherently a moral question and voluntariness is not a value-laden concept. However, voluntariness is not adequately addressable as a practical notion in bioethics (for example, as a way of understanding informed consent) without due consideration to ethical issues. We argue that moral norms are intimately connected to various ways in which the concept of voluntariness plays a role in bioethics. Paul Appelbaum and colleagues recently proposed a well-crafted conceptual model of voluntariness of consent for research that is based on, and inseparable from, the legal doctrine of informed consent (Appelbaum et al. 2009). We regard this model of voluntariness as unnecessarily tied to legal doctrines and and as derivative from the more basic concept of voluntariness that we discuss. We examine the differences between their approach and our starkly different conceptual model.

I. The Regulatory and Philosophical Background

Current approaches to voluntary informed consent in research often follow a regulatory framework traceable to the Nuremberg Code, which emphasizes that a research subject “should be so situated as to be able to exercise free power of choice, without the
intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of *constraint or coercion*” (Nuremberg Code 1949, emphases added). In 1966, the Food and Drug Administration included the ability to “exercise free power of choice” as a necessary condition of informed consent (Goddard 1966). In 1974, the Department of Health, Education, and Welfare employed language similar to the Nuremberg Code in response to comments on a 1973 proposed policy (Weinberger 1973; Weinberger 1974).

Voluntary consent as “the free power of choice without undue inducement or . . . coercion” entered U.S. research regulations only six weeks before the single most influential commission on research ethics in U.S. history. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was assembled in 1974 (National Research Act 1974; Brady and Jonsen 1982) and was charged by the U.S. Congress to identify the ethical principles and to develop guidelines that should govern the conduct of research involving human subjects (National Research Act 1974; Grady 1995; Levine 1996; Cassell 2000; Beauchamp 2008). The Commission made the principle of respect for persons the moral basis for requirements of informed consent in research (National Commission 1979) and stated that it was attempting to protect both autonomous persons and those with "diminished autonomy." The Commission analyzed the practice of informed consent in terms of the elements of information disclosure, comprehension of material information, and voluntariness. The Commission had almost nothing to say about voluntariness, though the notion was meant to apply to decision making free from undue influence and coercion (National Commission 1979). Still today nothing in U. S. regulations governing research approximates a close analysis of the nature of voluntariness.
II. The Absence of Controlling Influences

We begin with the following minimal assumption: A person acts voluntarily if he or she wills the action without being under the controlling influence of another person or condition. The primary notions here are influence, control, and intentional action. In this and the next two sections we will consider, in order, (1) the meaning of and the relevant types of influence; (2) the nature of external noncontrol by individuals positioned to influence the action; (3) the nature of internal noncontrol as a result of conditions such as debilitating disease, psychiatric disorder, or drug addiction; and (4) intentional action.

The category of influence includes offers of payment, threats, education, deceit, manipulative public advertising, emotional appeals, and the like, all of which can have impact. Voluntariness requires that an influence not control action, but not all influences exerted on a person are controlling. If a physician orders a reluctant patient to undergo a diagnostic examination and coerces the patient into compliance through a threat of abandonment, the physician's influence controls the patient's choice. If, by contrast, a physician presents reasons that persuade the patient to undergo the procedure when the patient is at first reluctant to do so, the physician's actions influence, but do not control. Many influences are resistible, and many are welcomed by the person influenced. The three pertinent categories of influence for our purposes are persuasion, coercion, and manipulation (Faden and Beauchamp 1986; Cialdini 1993; Greenspan 2003).

*Persuasion* means rational persuasion, which is consistent with voluntariness. When persuaded, a person believes something through the merit of reasons proposed by
another person. This is the paradigm of an influence that is both noncontrolling and warranted. It is in part warranted *because* it is noncontrolling.

*Coercion* occurs if and only if one person intentionally either forces another person or uses a credible and severe threat of harm to control another person (Nozick 1969; Gert 1972; Wertheimer 1987). The control exerted in involuntary commitments to institutions for psychiatric treatment is an example of the use of physical force. Even if a person agrees to be committed to such an institution, he or she still may have been under a dominating and threatening influence. Some threats will coerce virtually all persons, for example, a credible threat to kill the person. However, other credible threats will coerce a much smaller set of persons, for example, a wife’s threat to leave her husband unless he stops working at night. Whether coercion occurs depends, in part, on the subjective responses of the intended target. For example, a threat of abandonment by a physician will cause some patients to comply with the physician's demands, but will not have this effect on other patients. However, a subjective response in which persons comply because they *perceive* themselves as threatened, although no threat has actually been issued, is not coercion. True coercion by threat requires that a credible and intended threat disrupts and reorders a person's self-directed course of action. Under such coercive conditions even intentional and well informed actions are nonvoluntary. Being coerced does not entail that the person coerced lacks voluntary decision making capacity in deciding to comply with the threat, nor does it mean that the coerced person did not choose to perform the action. However, it does mean that the action performed was not a voluntary action because it was a controlled action.

*Manipulation* encompasses several forms of influence that are neither persuasive
nor coercive. It involves the use of nonpersuasive means to alter a person's understanding of a situation and motivate the person to do what the agent of influence intends. In recruitment for clinical studies, manipulation may include (1) informational manipulation that alters a person's understanding through means other than persuasion, and (2) offers of rewards or potential benefits such as health care. Critics of various recruiting practices have suggested that informational manipulation can occur through withholding critical information and through misleading exaggeration. Other critics note that offers of money and health care can be manipulative when made attractive.

The manipulation of information through different communication techniques, communication of early trial results, or the format and method of risk disclosure all may influence decisions (Ubel et al. 1997; Albrecht et al. 1999; Grant et al. 2000; Wragg et al. 2000). Similarly, the manipulation of options may include compensation or financial incentives, access to drugs or medical care, or presentation of limited choices following pre-consent randomization (Zelen 1979; Chang et al. 1990; Snowdon et al. 1999). Investigators also may manipulate trust to increase enrollment (Brown et al. 1989); re-approach, with new techniques, subjects who have previously refused (Bucholz et al. 1996); or employ intensive retention methods to keep participants in research (Morrison et al. 1997).

Many, but not all, forms of manipulation are incompatible with voluntary decision making, regardless of whether the person manipulated is aware of the influence. For example, lies, withheld information, and misleading exaggeration all may compromise and even eradicate voluntariness. Negatively stated, action that is controlled to a significant degree by another is not voluntary, though how to discover and understand the
degree of influence exerted in some circumstances is notoriously difficult. Positively stated, a significant degree of noncontrol by others is a necessary condition of voluntariness. Total control by others, as in coercion, always renders an action nonvoluntary. We will analyze the key notion of degrees of control and noncontrol in Section V.

We have thus far focused entirely on external controlling influences that are either influences by a second party or accidents, natural disasters, and the like. No less important are internal influences on the person, such as those caused by mental illness. These conditions too can deprive a person of voluntariness. Examples include severely brain-damaged patients, patients with schizophrenia, mania or dementia, and some alcoholics. Such internal influences can render an apparent action nonvoluntary. Whether we would or should hold the individual responsible for the consequences of a nonvoluntary action is a separate question. For example, we might not hold a schizophrenic person responsible for a homicide “by reason of insanity,” but we might hold an alcoholic responsible for deaths that occur while driving under the influence. The action that resulted in the death of another person may be nonvoluntary, but the assessment of both legal and moral responsibility is independent of factual questions about whether “internal” controlling influences governed an individual’s actions. We will not attempt to resolve these vexing problems of lack of internal self-control. We simply specify that an adequate condition of voluntariness must take both internal and external controlling influences into account.

Some may object to the distinctions we have introduced between persuasion, manipulation, and coercion. We have said that persuasion occurs by a presentation of reasons and the acceptance of those reasons, but what are we to say about a context in
which an offended spouse is threatening to leave a philandering spouse? The dialogue between them, involving a threat, might be a case of persuasion in some circumstances, but might constitute manipulation or coercion in other cases. Whether the philandering spouse is, in fact, persuaded by reasons, manipulated by the threat attempt, or coerced depends on how the threat of leaving is presented and how it is received. If it is a declaration of intent to inflict harm of punishment, then there is an attempt to manipulate or coerce even if it fails to manipulate or coerce. Such a context is not one of persuasion. However, if the threatened spouse interprets the threat attempt as merely a warning of a probable breakdown in the relationship, then the context could be one of persuasion. It matters whether the “threatened” spouse perceives what is intended to be a threat as actually constituting a threat (to financial stability, reputation, loss of companionship, or whatever). The “threatened” spouse may respond positively to the threat attempt, viewing it as a wake up call about the spouse’s feelings. Thus, depending on the circumstances, the threatened spouse may receive the threat attempt as either persuasive (offering good reasons), manipulative (using a nonpersuasive and noncoercive means of control such as minor punishment), or coercive (using a credible and severe threat of harm that controls). The spouse’s perception does not, of course, determine whether there actually is persuasion, manipulation, or coercion, because these concepts have conditions not reducible to the way statements are perceived. Coercion, e.g., requires a force or credible and severe threat of harm that actually controls another person.

III. The Problem of Constraining Situations
Many seriously ill patients qualify for clinical trials. Patients or surrogates often must make hard choices about participation. Their decisions are sometimes classified as coerced when the patient feels forced by circumstances to participate in a trial. This usage of the term “coercion” is too broad and wrongly suggests that experiences such as the fear of losing health care benefits (Karim et al. 1998) and fear of retribution for refusal to participate (Weissman et al. 1972) can render a decision coerced, regardless of the researcher’s intention, whether there is a credible threat, and the patient’s powers of resistance to influence. There is no coercion if an alleged agent of coercion has no intention to coerce. Mere perception of being coerced by an actual or potential subject never justifies the belief that the actions taken by those conducting a trial are coercive.

Setting aside such improper usage of "coercion," many subjects report feeling heavily pressured by circumstances to enroll in clinical trials (Hewlett 1996; Kass et al. 1996). The pressure and sense of constraint may be felt as intensely as they are felt by truly coerced persons. Even voluntary enrollment in a clinical trial may be accompanied by a dominant perception of a heartbreaking, unwelcome, and forced choice. Offers of promising “treatments” that are primarily research investigations can leave a person with a sense of having no meaningful choice. Also, influences that many individuals easily resist and perhaps even welcome are felt by some persons as heavily or even totally constraining.

Constraining situations, by contrast to truly coercive situations, are those in which nonintentional coercion-like conditions cause a person to feel controlled situationally, rather than controlled by the design of another person. A person may feel controlled by severe illness, lack of a basic resource, or the offer of a high risk procedure. Sometimes
people unintentionally make other persons feel threatened by their actions, and sometimes illness, powerlessness, and lack of resources are perceived as threats of harm. The prospect of another day fearing that a young son or daughter will die without treatment can powerfully constrain a parent to accept an offer of research involvement. Here the parent can understandably profess, "I had no choice; it was unthinkable to refuse the offer." These situations are momentous constraints on choice, though not ones that involve either threats or physical force by another.

A perceived absence of options does not render a choice nonvoluntary, but constraining situations can lead to deprivations of voluntariness that are morally problematic. The most significant such problem is undue inducement or, more generally, undue influence. This moral category springs from concerns about the effects that certain actions and incentives have on choices. The federal regulations governing research in the United States require investigators to “minimize the possibility of” undue inducement, but they do not define, analyze, or explain this notion (Emanuel 2004) or make an explicit connection to voluntariness. Analysis of the moral categories of exploitation of persons, and of undue inducement itself, has generally been as impoverished as the analysis of the underlying and more basic notion of voluntariness. This is true of the bioethics and public policy literatures, though several contributors show vital insights into some problems (McNeill 1997; Wilkinson and Moore 1997; Dickert and Grady 1999; Wilkinson and Moore 1999; Grady 2001; Casarett et al. 2002; Halpern et al. 2004; Appelbaum et al. 2009).

Offers of payment for research and offers of involvement in clinical research are not morally problematic if the offers are welcome, persons do not want to refuse, and the
risks are fairly low (e.g., at the level of everyday activities). Offers become morally problematic as (1) risks are increased to an elevated level, (2) more attractive inducements are introduced, and (3) the subjects’ economic disadvantage, or lack of available alternatives or resources, is increased. If risks, inducements, or disadvantage are elevated beyond a morally acceptable threshold, the term "exploitation" is appropriately used. If some one of these conditions is not elevated, problems of exploitation and voluntariness diminish, but may not vanish; if all three are not elevated, these problems likely will fade away. This standard of what is morally problematic facilitates our understanding of situations in which deprivations of voluntariness are caused by elevated risks, excessive inducements, or material disadvantage.

The condition of an irresistibly attractive offer is a necessary condition of undue inducement, but this condition is not by itself sufficient to make an inducement exploitative (or to render a response involuntary). Claims of exploitation require that there also be a risk of harm of sufficient seriousness that the person’s welfare interest is negatively affected by assuming it. Further, it must be a risk the person would not ordinarily assume. If an irresistibly attractive payment in the increased risk situation is involved, these offers almost certainly should be categorized as manipulative, and probably as unjustifiable.

Locating the threshold of irresistibility, where an offer deprives a person of being in control of decision making, is a critical issue. Here we should ask, irresistible by what standard? The same offer in identical circumstances may manipulate one person into acceptance, yet be resistible, or even welcome, by another. How an offer is perceived and whether it will be accepted depend on the subjective responses of those who receive the
offer. Nonetheless, the perception of feeling threatened or being forced into a choice is not per se voluntariness-depriving. A person might be exploited and manipulated by an offer and still retain a significant degree of voluntariness. To suppose that these conditions are altogether voluntariness-depriving is to mistake a moral problem about undue inducement for a psychological problem of voluntariness.

Wertheimer distinguishes between “harmful” and “mutually advantageous exploitation” in which both parties are reasonably expected to gain from the transaction (compared to the pre-transaction status quo). He further distinguishes between “nonconsensual” and “consensual exploitation.” Nonconsensual exploitation occurs if the exploited party does not give sufficiently voluntary, informed, or competent consent. (Wertheimer A, 2008). Here again we see a link between morally problematic behavior and inadequate voluntariness, as we noted in discussing the deprivation of voluntariness caused by “undue inducement.” We agree with Wertheimer that nonconsensual exploitation is problematic to the extent that it reflects “moral defects in the transactions that occur within the situation” rather than the potential expolitee’s “background situation.” (Wertheimer A, 2008) We likewise agree that the background situation of the potential exploitee (which we refer to as a “constraining situation”) does not establish that the consensual exchange is per se exploitative. Whether an offer, however advantageous to both parties, constitutes nonconsensual exploitation requires an assessment of the threshold of irresistibility under which an offer deprives a person of being in control of decision making, and so deprives the person of voluntariness. Some may object that the distinction between irresistible and merely not resisted cannot be brought under adequate conceptual and empirical analysis. We disagree. In Section V we
offer an account of degrees of voluntariness, and in Section VIII, we consider how to empirically assess the perception of control on the part of the potential expolitee, which is to be understood within the context of the circumstances surrounding that choice.

We could say more about the moral issues surrounding constraining situations, but the current inquiry into voluntariness does not require further investigation. Instead, we comment, in concluding this section, on only one point about the moral dangers inherent in prohibiting research with the goal of avoiding undue influence. Even if the degree of voluntariness is lower for some persons than for others in different communities or situations, to deny individuals with a capacity to act voluntarily the right to make choices about participation in clinical research on grounds that the choice might be rendered nonvoluntary as a result of their circumstance of deprivation is morally questionable. The possibility of the exploitation of subjects does indeed constitute a danger, but to deny these subjects the opportunity of research participation can also be paternalistic or at odds with the principle of equality in access to research and medical care. Denial of research opportunities to desperate persons would be to refuse them, in many cases, the very conditions they seek to increase their degree of control and to make voluntary choice meaningful.

**IV. Voluntary Action as Intentional Action**

We have thus far concentrated on conditions of noncontrol, but this condition is not sufficient for voluntary action, because it is likewise essential that an agent be in control. We analyze this agency in the performance of actions as a form of intentional action.
When this analysis is extended to voluntary persons, by contrast to their individual actions, capacity for intentional action is the proper category. Our general thesis is that intentional action—or, as some might prefer to say, intending, willing, and performing—and the absence of controlling influences are individually necessary and jointly sufficient conditions of voluntariness.

We perform intentional actions when we act in accordance with plans proposed for the execution of an action. An intentional act must correspond to the actor's conception of the act in question. Unintended acts, such as accidentally dropping a medication on the floor, are not voluntary, even if the agent is responsible for the action.

The connection between voluntariness and intentional action raises weighty philosophical questions. Harry Frankfurt writes about one key problem: "Whether a person identifies himself with [his] passions, or whether they occur as alien forces that remain outside the boundaries of his volitional identity, depends upon what he himself wants his will to be" (Frankfurt 1999, 137). We cannot here explore the many problems surrounding volitional identity, self-identification, and motivational forces such as passions. We note, however, that one's identification with one's motives and passions could itself be caused, and so governed or controlled by the strength of a passion, disorder, or other condition. Any resultant action, so caused, is not a voluntary act or a form of self-identification that is independent of its causal origins. If a person's identification at any point is the result of conditioning or of a controlling passion, then the identification is not sufficiently independent to render resultant actions voluntary. It is controlled behavior, not behavior in which the agent is in control.

For example, an alcoholic with a passion for red wine who self-identifies with
drinking is acting nonvoluntarily if his volition and desire to drink red wine are causally determined by a desire over which he has no effective control. We say that he "needs help" because he cannot help himself. An alcoholic who reflects at ever higher levels on lower-level desires will not achieve self-control over his or her choices if identification at all levels is causally determined by the same initial desires. An adequate theory of voluntariness must contain a condition that there are no influences or desires that deprive an individual of voluntariness by controlling the choice, even if the person identifies with the choice and intends the actions. Intentional actions are not voluntary if they are controlled by causes the agent does not control. This conclusion brings our analysis in line with our argument in section II concerning the necessity of an absence of controlling influences.

Frankfurt’s theory of willing does not adequately ensure that we are sufficiently free of controlling influences. He seems to address this problem when he argues that voluntary choices require "being satisfied with a certain desire" and having pre-existing "stable volitional tendencies" (Frankfurt 1999, 105, 110). We are unconvinced that this analysis supplies adequate conditions of voluntariness, but we postpone assessment of this idea of "stable volitional tendencies" until our discussion of authenticity in Section VI.

V. Degrees of Voluntariness

We will not attempt to determine precisely the degree of control an agent must have over causal influences in order to act voluntarily, but we will now address related questions
about degrees of voluntariness.

Edmund Wall has argued that “voluntariness is the *degree of control* that an agent has over his own behavior” (Wall 2001, 130). His idea is that individual behavior is shaped by both agents’ intentions and their surrounding circumstances. Although we cannot always control the circumstances that shape our actions, we can “plausibly attempt to control [our] behavior within the parameters of the circumstances” (Wall 2001, 130). “If an agent exercises any amount of control or effective guidance over his own behavior, then he acts, and the degree of that control is the degree of voluntariness with which he acts” (Wall 2001, 131). Wall so introduces the notion of degrees of voluntariness, but he does not provide an account of it. To have an adequate account, he would have to analyze the notions of "parameters of the circumstances,” "amount of control or effective guidance,” and “the degree of that control.”

Of the two conditions of voluntariness we have defended, noncontrol and intentional action, we consider the latter first. There can be degrees of the ability to take control, to remain in control, and to act on one’s intentions. Weakness of the will is one well known phenomenon where there can be such degrees. However, intention is not a matter of degree: Acts are either intentional or nonintentional. While there may be gray cases, such as acting on "automatic pilot," having a confused plan of action, or having a minimal rather than an elaborate plan of action, these cases must be classified as either intentional or nonintentional.

By contrast, acts can satisfy the condition of noncontrol, or the absence of controlling influence, to a greater or lesser extent. There are degrees of control and noncontrol, and, in this respect, degrees of voluntariness as a function of the continuum
from total control to total noncontrol. Each point on the continuum can be conceived as corresponding to a different degree of voluntariness, ranging from lowest to highest.

Children provide a good example of the continuum of being in control and the continuum of noncontrol. In the early months of life children are heavily controlled and exhibit a low-level of the ability to be in control: They exhibit different degrees of resistance to influence as they mature, and their capacity to take control and perform intentional actions gradually increases as they develop.

For an action to be classified as either voluntary or nonvoluntary, cut-off points on the continuum from control to noncontrol are required. To classify an action as voluntary, only a substantial satisfaction of the condition of noncontrol is needed. A line drawn to distinguish between substantial and insubstantial might seem arbitrary, but thresholds marking substantial noncontrol can be fixed in light of specific objectives of decision making, as can gradations on the continuum of voluntariness.

There are certain to be different theories about the degrees of control and noncontrol and about how to set threshold lines. One account might set a high threshold of self-control, rendering many individuals normally regarded as voluntary to be nonvoluntary, or at least questionably voluntary. For example, decisions for ill newborns made by frightened parents who understand almost nothing about clinical research might be classified as substantially voluntary, nonvoluntary, or questionably voluntary, depending on the account (cf. Savulescu 1994). But some theories might require only low thresholds of self-control and of the corresponding ability to resist influence, thus rendering voluntary some individuals who are normally regarded as nonvoluntary. Even certain nonhuman animals could be said to be acting voluntarily in such a theory. These
problems cannot be pursued here, but a comprehensive theory of voluntariness and its degrees would have to address them.

VI. Authenticity

Authenticity has occasionally been advanced as a necessary condition of voluntary action or, more commonly, as a necessary condition of autonomous action. In a famous passage Aristotle spoke of actions performed “from a firm and unchanging state” (where “state” might also be translated “character”), by which he seems to mean from a stable disposition of the agent (Aristotle 1999, 1105a34-35). Many writers have subsequently placed a high value on the role of a stable disposition or body of reasons in developing philosophical theories that bear on voluntary action. Such an authenticity condition is consistent with and perhaps the functional equivalent of Frankfurt's idea of accepted and stable volitional tendencies. This condition requires that actions be consistent with a person's reflectively accepted values in order to qualify as voluntary (see Faden and Beauchamp 1986).

To be authentic, actions must faithfully represent the values, attitudes, characteristic motivations, and life plans that the individual personally accepts. The authentic part of a person is the repository of the person's second-order reflective preferences, as contrasted with first-order desires and aversions on which the person has not reflected or identified with. According to some accounts, if one’s values are not stable, that is, not “one's own,” then one is not acting as one's own person (Downie and Telfer 1971; Benn 1976; McMahon 1987; Benn 1988). Authenticity is a necessary
condition of voluntary choice in some of Gerald Dworkin's writings on autonomy. For him it makes no difference how one comes to have and to act on desires. For example, one might be socialized or conditioned to have them. The difference comes in whether, on reflection, one accepts them and, in a stable manner, makes them one's own. Desires and motives that are not reflectively accepted are not authentic (Frankfurt 1971; Dworkin 1976; Dworkin 1988; Frankfurt 1999).

We regard all such conditions of authenticity in a theory of voluntariness as overly demanding and misleading. A theory that makes conscious, reflective, stable identification with one's desires and motives a necessary condition of voluntary action would render nonvoluntary many intentional, well understood, and uncontrolled actions that are paradigms of voluntary choice. Persons often make voluntary choices that are not authentic. Anomalous actions sometimes arise from choices that are out of character as a result of surrounding events that are unprecedented in the actor’s experience, such as serious disease. These acts could be well planned, intentional, and free from the control of other persons, yet not authentic. The actions might be conscious and reflective, but if a stable identification with basic values were made a condition of authenticity, these actions would not be authentic.

Some patients who make decisions about so-called "physician-assisted suicide" are examples. They may have been reared with, and perhaps autonomously accepted, the view that all forms of self-killing are wrong, but they may change their minds when faced with the type and degree of suffering involved in a particularly threatening illness. Their deliberations and conclusions can involve a thorough collection of information and even wide consultation, eventuating in a decision at odds with their own decades-old pattern of
beliefs and values. In other cases, persons may have no relevant stable values. In still other cases, decisions to accept or reject physician recommendations or offers of research participation are made by persons who are unaware of the motivational or conditioning history that underlies and prompts their actions and who have made no reflective identification with the values at the roots of their actions.

Authenticity would also be morally worrisome if it were made a condition of voluntariness because it could result in morally unacceptable judgments regarding which actions are worthy of respect and which are not. If reflective identification with one's desires, second-order volitions, and possession of an underlying, stable set of values were made a necessary condition of voluntary action, then many ordinary actions that are almost universally (and rightly) considered voluntary, such as many decisions not to go to a doctor for treatment of a sports injury, would be considered nonvoluntary. This account would unduly narrow the scope of actions protected by a principle of respect for the choices a person makes. It is, then, not only conceptually dubious, but morally risky to make authenticity a necessary condition of voluntariness.

In a related and stimulating analysis, Agnieszka Jaworska has recently argued that choosing contrary to one’s own stable set of values, or one’s “professed values,” need not involve sidestepping or abandoning one’s autonomy. She warns, specifically, that physicians or other parties “tempted toward paternalism must exercise particular caution before they deem a choice to be disengaged from autonomy: even if a choice contradicts the person’s own [professed] values, it might be rooted in caring, and then, despite initial appearances to the contrary, it may still command the highest level of protection against paternalism” (Jaworska 2009, 82). Jaworska argues that a patient may satisfy all of the
necessary conditions of autonomous self-governance and nonetheless make choices that are deeply in conflict with his or her operative and fixed set of values. For example, a patient might request a highly invasive treatment at the end of life against his previous judgment about his best interests because he has come to a conclusion that surprises him: He now cares more about living a few extra days than he ever imagined he would, and despite his longstanding view that he would never accept such invasive treatments. Jaworska’s point is realistic and deserves careful examination in bioethics.

We conclude that authenticity is not a necessary condition of voluntariness (or autonomy) and that making it so is both conceptually unsatisfactory and morally dangerous.

VII. The Place of Values in a Theory of Voluntariness

We have distanced our analysis of the concept of voluntariness from moral concerns about voluntariness, and yet we have occasionally discussed moral problems. These features of our analysis might seem inconsistent. We might seem to be arguing both (1) that the concept of voluntariness is value free and (2) that the absence of undue influence, a moral notion and a moral obligation, is at the heart of our conceptual analysis of voluntariness. If the latter were so, then our analysis of noncontrol would be value laden and our theory could be interpreted as asserting that if a physician unduly influences a patient to become a research subject, the undue influence renders the person’s choice nonvoluntary.

The problem is this: On the one hand, the concept of voluntariness seems morally
infused because acting voluntarily requires that other persons abstain from *undue* influence. On the other hand, our analysis understands the link between undue influence and nonvoluntary action in terms of conditions under which one person has come under the *control* of another, and *the key condition of noncontrol* is not a moral notion. Neither control nor noncontrol is a moral notion, and therefore voluntariness and nonvoluntariness per se are not morally infused notions.

Our account in previous sections implies that intention, noncontrol, and voluntariness are all *not* moral notions, and we take the value free rather than the value laden interpretation to be the correct conceptual account of voluntariness. But are we justified in taking this position? The recent work of Paul Appelbaum, Charles W. Lidz, and Robert Klitzman (2009) might be interpreted as maintaining that we are not right, though these authors do not actually *argue* that a position such as ours is incorrect. They frame conceptual issues about “voluntariness and its impairment” in a significantly different light than we do (Appelbaum et al. 2009, 30). They start with the correct assumption that today’s concerns about voluntariness, as found in much of the bioethics literature, are embedded in “policy and practice regarding human subjects research,” where concerns about voluntariness are about proper compensation, whether physicians should be allowed to recruit their own patients, and the like. It is in this environment that these authors seek “a valid way of conceptualizing voluntariness,” especially “voluntariness to consent to research.” In examining this situation, they offer “a model of voluntariness rooted in the doctrine of informed consent” as well as a theory powerful enough to “be operationalized to detect problematic restrictions on voluntariness in consent to research.” “Problematic restrictions” seems to mean morally and legally

These authors develop a powerful model of voluntariness. However, the model is grounded from the start, as they state, in the “legal doctrine of informed consent,” a clearly normative concept. They thus presume from the outset that voluntariness and involuntariness are inherently value-laden notions. The authors then pursue an argument that remains throughout closely aligned with the legal doctrine that a choice is voluntary unless it is unduly influenced or coerced. When they present the conditions of involuntariness in their conceptual analysis, they theorize that “a decision is involuntary only if it is subject to a particular type of influence that is [1] external, [2] intentional, [3] illegitimate, and [4] causally linked to the choice of the research subject.” (see Appelbaum et al. 2009, 33) These conditions, when properly analyzed, express their full account of the concept of involuntariness and, derivatively, voluntariness. They do not argue that these conditions are both necessary and jointly sufficient conditions of involuntariness, though they imply that they are. The authors clearly do hold that all four are necessary conditions. No doubt conditions (2) and (4) are necessary conditions of involuntariness, as is consistent with our analysis. However, their conditions (1) and (3) are more properly about involuntariness under the legal doctrine of informed consent than they are appropriate for an independent analysis of voluntariness and involuntariness. That is, their analysis is dependent upon their inclusion of this legal doctrine as the basis of the theory, and it is therefore not a general theory of voluntariness and involuntariness.

These authors assert rather than argue for the claim that each condition is necessary, but they are careful to explain why certain conditions “do not negate voluntariness” in their account. For example, they regard internal forces on a person, such
as psychiatric conditions, as not voluntariness-depriving because in their conception one can be deprived of voluntariness only by “external influences” involving the “deliberate actions of another person.” This claim renders their account significantly different from ours, but the most prominent difference between their account and ours is their condition of “illegitimate influence.” This is a key notion in their analysis and one we exclude from ours. We hold, for example, that it is not the condition of being *unduly influenced* that renders an action involuntary; rather, involuntariness is caused by the *controlling effect* exerted in the circumstance of undue influence. By contrast, Appelbaum and colleagues analyze illegitimacy, including undue influence, as follows: “The person exerting the influence does not have the right to act in this way according to generally accepted moral norms” (Appelbaum et al. 2009, 33). In our account, whether an external influence is morally legitimate is conceptually and morally distinct from whether the action taken in response to that influence is voluntary or involuntary.

We are not arguing that the account of Appelbaum and colleagues is wrong or lacks merit. In the context of valid informed consent and legal liability, it is a strikingly interesting analysis that builds on important moral and legal principles. We are arguing only that this analysis takes a markedly different approach than ours. Their approach situates interest in these notions, at least in bioethics, exclusively under the umbrella category of valid informed consent. Although we too are interested in voluntary consent, our account treats these evaluative concepts as themselves building on a more basic concept of voluntariness.
We have argued that for an action to be voluntary it must be intentional and not under a substantial controlling influence. That which is voluntary in fact is to be distinguished from that which is perceived as voluntary by the person who decides or acts. Controlling influences are sometimes unobservable to a decision maker, and voluntariness is sometimes perceived as present when it is not. For instance, if a researcher deceived a potential study participant regarding the risks and potential benefits of an intervention, this deception would create a controlling influence that would not be perceived as such, and the choice would therefore be perceived as voluntary by the potential participant. Because the individual providing the information manipulated the other’s decision through intentional falsification, the decision itself was controlled and rendered in fact not voluntary, despite the perception of voluntariness. Also, some decision makers may be vulnerable to influences that ordinarily are consistent with voluntary choice. These influences include, for example, constraining situations with pressures to decide so intense that they block voluntary choice.

Having clarified the concept of voluntariness in previous sections, we shift now to methodological considerations about a construct that facilitates empirical measurement of the degree to which a choice is perceived by an actor as voluntary. “Constructs” are characteristics or attributes that cannot be observed directly; therefore, only indirect measures or indicators of the constructs can be employed. A construct and its measure are not synonymous, but we can study the construct based on observed indicators (DeVellis 1991). Absent a measure of the perception of voluntary choice, we would be ill-equipped
to assess empirically the conditions under which choices are made, and especially whether the conditions surrounding a particular choice are perceived as controlling that choice.

Although voluntary action cannot be measured, a person’s perception of whether his or her action is voluntary can be measured with the proper method of grasping the construct. We can then test for perception of both intentionality and control (and noncontrol). Because the first condition, intentionality, does not admit of degrees, we need only assess whether a person perceives that he or she has made an intentional choice. Intentionality should be considered a categorical variable with the value of either yes or no. We have analyzed the second condition of noncontrol as admitting of degrees, and we now carry this conceptual point into the present discussion. A measure of this feature of the construct of voluntary action assesses an individual’s perception of the degrees of noncontrol and self-control. We hypothesize that perception of noncontrol is on a continuum (continuous scale), which allows for fractional amounts (or degrees) of the attribute being measured (perception of control).

Accordingly, the first step in assessing a person’s perception of voluntariness is to ask, “Did you intentionally choose as you did?” Absent a perception of intentionality, a person can be said to perceive that whatever occurs is nonvoluntary on his or her part. The perception that an action was unintentional, and so nonvoluntary, is in many cases morally unproblematic, as when one accidently spills a cup of coffee on a neighbor’s ivory colored rug. Such an unintentional action may be thoughtless and irresponsible, and for this reason morally problematic, but there is nothing inherently problematic about its being perceived as nonvoluntary. If a person answers to a question about his or her
perception, “No, I did not choose intentionally,” in a setting such as research participation, in which voluntary action is to some degree expected, this categorical response is an assertion of nonvoluntariness and raises concern that something may be ethically problematic about the conditions under which consent to participation was obtained. (In some settings, persons may report that they did not make the decision because they delegated it to another party. If a person intentionally delegates decision making, the intentional action was one of delegating, and the perceived voluntariness of this action can be assessed in the same way as any other form of decision making.)

The second step in assessing perception of voluntariness is to measure the person’s perception of the extent of control exerted by other persons or conditions, including the person’s perception of absence of such control. The perceived degree of control can be assessed using a measure that, in multiple ways, contains self-report items that assess aspects of perceived self-control and/or noncontrol over an intentional action. We have developed such an instrument: the “Decision Making Control Instrument,” or DMCI, as we call it. The DMCI combines an assessment of the intentionality of action with a measure of perceived self-control or noncontrol over any intentional action. As such, the DMCI measures the degree to which an individual perceives his or her intentional choice to be voluntary on a scale of control. The DMCI is an important new tool that can be used to inform our understanding of the voluntariness of treatment and research decisions in medical settings. (Miller et al. 2011).

The DMCI for measuring perception of control or noncontrol in decision making opens to empirical exploration the conditions under which persons perceive themselves as vulnerable to a controlling influence, even when they perform an action intentionally.
We can measure, for example, the extent to which attractive financial incentives for research participation are perceived as controlling and whether certain socioeconomic conditions more frequently lead to reports by a person of being vulnerable to influence by these conditions. As another example, many patients receive a request for research participation directly from their personal physician. The DMCI allows us to determine whether some individuals perceive the request as causing them to act out of fear that their access to health care services will be restricted or that their physicians will no longer respect their decisions. We can assess the effectiveness or ineffectiveness of template consent-document wording in reassuring potential subjects about not losing access to health care benefits if they decline research participation. The DMCI also allows exploration of whether the involvement of family members is perceived to undermine or to support an individual’s voluntary choice.

The DMCI also should enable us to identify characteristics of individuals who feel vulnerable to external influences that, under ordinary conditions, would not generally render a person vulnerable. We can identify, for example, the circumstances under which an investigator may unintentionally create a situation in which some persons perceive their choice to be nonvoluntary. The use of the DMCI to measure the ways in which an individual perceives his or her intentional choice to be voluntary, together with an empirical assessment of the external conditions under which that choice was made, should allow investigators to identify and examine the circumstances that are conducive to voluntary choice, or, at least, to a perception of voluntary choice.

**VIII. Conclusions**
We have proposed two necessary and jointly sufficient conditions that must be satisfied for an action to be voluntary. The action must be both intentional and substantially free of controlling influences. Both conditions are free of evaluative notions such as undue influence. We have rejected authenticity as a necessary condition of voluntary action, and we have noted that constraining situations may or may not undermine voluntariness, depending on the circumstances and the psychological capacities of agents in those circumstances. In the final section we discussed a program for empirically measuring the degree to which an action is perceived by an actor as voluntary. Empirical research using this instrument can provide data that will help establish appropriate policies and procedures for obtaining voluntary consent to research participation and other interventions.

References


