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## II. MEANING AND ELEMENTS

To define “informed consent” properly, appropriate criteria of information and consent must be identified. If overdemanding criteria such as “full disclosure and complete understanding” are adopted, then an informed consent becomes impossible to obtain. Conversely, if underdemanding criteria such as “the patient signed the form” are used, then an informed consent becomes too easy to obtain and loses its meaning (as informed) and its moral significance (as valid consent).

Many interactions between a physician and a patient or an investigator and a subject that have been called informed consents have been so labeled only because they rest on underdemanding criteria. Underinformed consents are often referred to as informed consents when they are not morally valid consents. For example, a physician’s truthful disclosure to a patient has often been declared the essence of informed consent, as if a patient’s silence following disclosure could constitute a valid informed consent. Similarly, a signed consent form has often been regarded as an informed consent, as if a signature on a legal form constitutes an informed and valid consent.

### ASSUMPTIONS IN MEDICINE

The existence of such inadequate understandings of informed consent can be explained in part by empirical information about physicians’ beliefs about informed consent. Data about the relevant beliefs of physicians in the United States were gathered in an influential survey of physicians conducted by Louis Harris and Associates. One question asked physicians, “What does the term informed consent mean to you?” In their answers, only 26 percent of physicians indicated that informed consent has something to do with a patient’s giving permission, consenting, or agreeing to treatment. In a related question, only 9 percent indicated that it involves the patient’s making a choice or stating a preference about his or her treatment (Louis Harris and Associates 1982). Similar results have been found in surveys of Japanese physicians (Hattori et al. 1991; Gabbay et al. 2005).

Physicians have widely regarded disclosure as the primary (and perhaps sole) element of informed consent. That is, they conceive of informed consent as explaining to patients the nature of their medical conditions together with a recommended treatment plan. But if physicians

regard informed consent as nothing more than an event of conveying information to patients, rather than a process of discussion with and obtaining an informed permission from the patient, then claims that they regularly “obtain consents” from their patients before initiating medical procedures are vague and unreliable.

### THE DEFINITION AND ELEMENTS OF INFORMED CONSENT

Academic and policy literature on informed consent often analyzes the concept in terms of its basic elements. The strategy is to first divide the concept into an information component and a consent component. The information component is then divided into disclosure by a professional and understanding of the information by a patient or subject. The consent component is divided into a voluntary decision and an authorization to proceed. Using this strategy, legal, regulatory, philosophical, medical, and psychological literatures have come together to support the following elements of informed consent: (1) disclosure, (2) understanding, (3) voluntariness, (4) competence, and (5) consent (see National Commission 1978; Meisel and Roth 1981; President’s Commission 1982; Levine 1988; Eyal 2012; Beauchamp and Childress 2013).

This analysis is sometimes joined with a corresponding thesis that these elements collectively *define* informed consent. The postulate is that a person gives an informed consent to an intervention if and only if the person is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to a proposed plan. This definition is attractive because it both integrates the elements of informed consent and prepares the way for delineating moral and legal requirements of informed consent. It is not, however, the best way to conceptually analyze the *meaning* of informed consent. Requirements for consent and conceptual elements do not amount to a definition.

The US Supreme Court addressed the definition of informed consent in *Planned Parenthood of Central Missouri v. Danforth* (1976, 67) as follows: “One might well wonder ... what ‘informed consent’ of a patient is. ... We are content to accept, as the meaning, the giving of information to the patient as to just what would be done and as to its consequences.” The essential element or part of informed consent, as described here, is again *disclosure*, an analysis that recalls the flawed assumptions made by physicians in the Louis Harris poll. Nothing about an informed consent requires disclosure as part of its *meaning*, and this element alone is not even close to an adequate definition. To make disclosure the sole or even the major condition of informed consent incorporates questionable assumptions about medical authority,

physician responsibility, and legal liability. These norms delineate an obligation to make disclosures so that consent can be informed, not a meaning or definition of informed consent. Even if all five of the above elements are merged as a set, they do not satisfactorily capture the meaning of informed consent.

Both the elements and the meaning of informed consent need a more comprehensive treatment. The following seven categories are needed to express the component parts of the concept of informed consent more adequately than the above five categories—although even this sevenfold list does not adequately express either the *meaning* or the *definition* of informed consent (Appelbaum, Lidz, and Klitzman 2009; Nelson, Beauchamp, and Miller 2011; Beauchamp and Childress 2013):

- I. Threshold elements (preconditions)
  1. Competence (to understand and decide)
  2. Voluntariness (in deciding)
- II. Information elements
  3. Disclosure (of material information)
  4. Recommendation (of a plan)
  5. Understanding (of information from 3 and 4)
- III. Consent elements
  6. Decision (in favor of a plan)
  7. Authorization (of the chosen plan)

Critics of legal requirements of informed consent have often held that medical or research procedures commonly have so many risks and benefits that they cannot be disclosed and explained in a reasonable period of time or in an understandable framework. However, an informed consent is better understood in terms of having adequate (or material) information, as many courts and authors in bioethics have pointed out. Material risks are the risks a reasonable patient needs to understand in order to decide among the alternatives. Only these risks and benefits need to be disclosed and understood, although other information beyond risk-benefit information will usually be needed.

Corresponding to each of the above elements, one could construct informed-consent *requirements*. That is, there could be disclosure requirements, comprehension requirements, noninfluence requirements, competence requirements, authorization requirements, and so forth. These requirements would presumably specify the conditions that must be satisfied for a consent to be valid (Beauchamp and Childress 2013; Nelson, Beauchamp, and Miller et al. 2011).

## TWO MEANINGS OF INFORMED CONSENT

Translating the above seven elements directly into a definition or meaning of informed consent invites confusion, because the term *informed consent* has subtleties not captured by these elements. One subtlety that has generated misunderstanding is that two entrenched and irreducibly different meanings of “informed consent” have been at work throughout its history and still today cause confusion about the meaning of this term in law, policy, medicine, and research.

In the first meaning, an informed consent is an autonomous authorization by individual patients or subjects of a medical intervention or of involvement in research by individual patients or subjects. An autonomous authorization requires more than merely acquiescing in, yielding to, or complying with an arrangement or a proposal made by a physician or investigator. A person gives an informed consent in this first sense if and only if the person, with substantial understanding and in substantial absence of control by others, intentionally authorizes a health or research professional to do something. Here, informed consent is fundamentally a matter of autonomous (or self-determining) choice by a patient or subject.

In the second meaning, informed consent is analyzed in terms of institutional and policy rules of consent that collectively form the social practice of informed consent in institutional contexts. An approval of a procedure is an informed consent, and therefore effective or valid, if it conforms to the rules that govern specific institutions. In this sense, unlike the first, conditions and requirements of informed consent need not be truly autonomous authorizations. “Informed consent” refers to an institutionally or legally effective authorization, as determined by prevailing social rules. This second meaning is driven by demands in the legal and health care systems for a generally applicable and efficient consent mechanism by which responsibilities and violations can be readily and fairly assessed (Faden and Beauchamp 1986).

Under these two contrasting understandings of informed consent, a patient or subject can give an informed consent in the first sense, but not in the second sense, and vice versa. For example, if the person consenting is a minor and therefore not of legal age, he or she cannot give an effective or valid consent under the prevailing institutional rules; a consent is invalid even if the minor gives the consent autonomously and responsibly. (“Mature minor” laws sometimes make an exception and give minors the right to authorize medical treatments.)

Literature in bioethics has increasingly maintained that a justifiable analysis of informed consent cannot be

limited to the second sense and must in some respect be rooted in autonomous choice by patients and subjects; otherwise, there is no truly informed consent. For an action to be classified as either voluntary or nonvoluntary and informed or uninformed, cutoff points on the continua from control to noncontrol and from full information to zero information must be provided. Yet in order to classify an action as voluntary and informed, only a *substantial* satisfaction of the conditions of control and information is needed. A line drawn to distinguish between substantial and insubstantial might seem arbitrary, but thresholds marking substantial control and substantial information can be fixed in light of specific objectives of decision making. There will, of course, be different theories about how to establish the needed degrees of control and information and how to set threshold lines.

The second sense is heavily influenced by law and institutional policy, in contrast to the deep influence of moral theory on the first sense. The law has been more influential historically as an authoritative set of statements than any other body of thought on the subject, and “the doctrine of informed consent” is the legal doctrine. But law and policy cannot, from a moral viewpoint, be accorded determinative authority on the matter of the meaning and criteria of “informed consent.” American legal scholar Jay Katz was unrelenting, throughout his career, in criticizing court decisions that used only a thin legal model. He regarded the declarations of courts as filled with overly optimistic moral rhetoric lacking in substantive moral force. The problem, in his view, is that the law has little to do with fostering morally required forms of real communication and effective decision making in the clinic and in the research environment (Katz 1984).

#### THE RELATIONSHIP BETWEEN THE TWO MEANINGS

Rules governing effective authorization have often not been premised on a carefully delineated conception of autonomous decision making, but arguably a justifiable analysis of informed consent must be rooted in autonomous choice. An act is often accepted in much of contemporary bioethics as an informed consent only if (1) a patient or subject agrees to an intervention based on an understanding of material information; (2) the agreement is not controlled by influences that engineer the outcome; and (3) an authorization for an intervention is given by the patient or subject with the understanding that it is an authorization to proceed.

Franklin G. Miller and Alan Wertheimer (2011) have challenged the idea that the first sense of “informed consent” is the best model for judging the moral adequacy of institutional understandings and rules of informed

consent. They propose instead a “fair transaction” model of informed consent in which, for example, investigators and their research subjects are treated fairly while also giving due consideration to (1) the reasonable limits of an investigator’s responsibilities to ensure adequate understanding on the part of subjects who consent to research, (2) the modest levels of comprehension expectable of some subjects, and (3) the overall interests of subjects in participating in research. This approach is an insightful way of interpreting the second sense of institutional informed consent, but it loses sight of the moral importance of the first sense of autonomous authorization in its substitution of a “fair transaction” model.

In principle, although less clearly in practice, the conditions of informed consent as an individual’s autonomous authorization can function as model standards for fashioning the institutional and policy requirements of effective consent. The model of autonomous choice would then serve as the basic benchmark against which the moral adequacy of prevailing rules and practices should be evaluated. The postulate that policies governing informed consent in the second sense should be formulated to conform to the standards of informed consent in the first sense is grounded in the premise that the primary goal of informed consent in medical care and in research is to enable potential subjects and patients to make autonomous decisions about whether to grant or refuse authorization for medical and research interventions (Katz 1984; Faden and Beauchamp 1986).

It does not follow that institutional policies regarding informed consent are justifiable only if they rank the protection of autonomous decision making above all other values. Consent requirements imposed by institutions should be formulated and evaluated against a range of social and institutional considerations. The preservation of autonomous choice is a major but not the only consideration. For example, a patient’s need for education and counseling in order to achieve a substantial understanding of a medical situation must be balanced against the interests of other patients and of society in maintaining a productive and efficient health care system. Accordingly, institutional policies must consider what is fair and reasonable to require of health care professionals and researchers and what the effect would be of alternative consent requirements on efficiency and effectiveness in the delivery of health care and the advancement of science.

#### IS BROAD CONSENT INFORMED CONSENT?

Problems of broad consent—also called global consent and blanket consent—with regard to future uses of biological samples, surplus biological material, and

research data have received an increasing presence in the informed consent literature because of a need for public and institutional policies to protect individuals and groups from harms when samples and data are stored and then used in previously unanticipated ways. Advances in science have introduced new areas of concern about how to both efficiently promote research and protect the rights of donors of data to give informed consent for future research using the data (Buchanan 2000; Pentz, Billot, and Wendler 2006; Maschke 2010).

Using stored samples, materials, or data to achieve goals other than those initially disclosed to subjects can negate even an originally valid consent process and also may threaten relationships of trust between subjects and investigators. The content of disclosures will be determined by anticipated future uses of the samples, but the future uses are often not well understood even by investigators. At a minimum, research subjects should be reliably assured that sensitive personal information and data will be protected in a way that will not cause harms, violate privacy and confidentiality, or lead to discriminatory treatment.

If an investigator seeks to use a sample for purposes not originally stated in an informed consent form, the subject in principle would have to be re-contacted in order to renew consent. There may, however, be legitimate exceptions—such as when only minor departures are made from an original protocol and consent form and when samples cannot be linked to a donor. Allowing such exceptions is nonetheless not free of moral problems. Some cases of broad consent have raised questions about whether research scientists have taken advantage of vulnerable populations even if, from a scientific perspective, only minor departures were made from the original protocol. Broad consents are inherently risky in this regard (see Mello and Wolf 2010 for analysis of the Havasupai Indian tribe case).

#### SHOULD THE MEANING, ELEMENTS, AND REQUIREMENTS OF INFORMED CONSENT BE DIFFERENT IN CLINICAL MEDICINE AND CLINICAL RESEARCH?

The distinction between clinical research and clinical medical practice has long been thought to be canonical and has shaped ways in which informed consent is considered. It has been thought since the early 1970s that research is risky, whereas accepted practice is aimed at the best interests of the patient and relies on standard, accepted therapies. Requirements of informed consent and review of consent forms have therefore been more stringent in research settings than in clinical settings as well as more carefully reviewed. That is, the threshold of an adequate informed consent has been higher in research and relatively lower in medical practice. But are there still

good reasons to warrant higher standards of consent and the scrutiny of consent in research?

As health care systems (hospitals, military medical care, rehabilitation centers, cancer centers, etc.) become reorganized as learning health care systems, as is now occurring, the knowledge generated and the uses of information typically associated with research will become embedded into the core of medical practice, so that research and improvements in practice will be natural outgrowths of the health care delivery process itself, leading to constant improvements in both the delivery of information and care (Institute of Medicine 2007, 2012). This change in the ways that learning occurs and health care is delivered calls for a rethinking of the roles that the traditional elements and requirements of informed consent should play in learning health care systems. One central question will be, Why should there be a moral system in which there is a close ethical review of consent forms and consent processes in research protocols and no directly parallel attention given to consent forms in medical practice? And why should there be government regulatory systems for the oversight of research, but no comparable system for the regulation of standards of consent in practice?

The goal in learning health care institutions will increasingly be to ensure that scientific research is not unduly delayed, even if some requirements of informed consent must be adjusted to allow for rapid learning. One major issue rarely confronted in research ethics and government oversight rules is whether patients have a moral *obligation* to participate in learning activities in health care systems given that they reciprocally receive the benefits of the system that derive from participation by previous patients. The issue is whether the moral framework of respect for autonomy and consent created since the 1970s gives informed consent an undue deference or overriding importance unsuited to the development of better care. Not all health care decisions are likely to be attached to a significant autonomy or consent interest of patients, and burdensome consent requirements that block progress in science and medical care can amount as much to a moral failure to take adequate care of patients as to a showing of respect for their autonomy. Many decisions in health care, such as the repetition of routine tests during hospitalization and decisions regarding which medications will be dispensed by which qualified professionals, are unlikely to be of importance to the patient (Faden et al. 2013).

Activities such as randomized controlled trials of an investigational new device will undoubtedly continue to require patients' informed consents, but how many learning activities in health care contexts can be validly undertaken by health professionals and institutional officials without receiving explicit informed consents?

What is reasonable and legitimate in the way of physicians proceeding with certain kinds of tests, collection of data, and treatment without specific authorization? (Joffe and Truog 2010; Faden et al. 2013).

One possibility is that there should be a more pervasive level of participation in research in health care institutions without requiring explicit consent. In this conception, a moral presumption is set in favor of learning, in which health professionals and institutions have an affirmative obligation to conduct learning activities and patients have affirmative obligations to contribute to these activities whether or not they give an explicit informed consent to do so. The health care institution might be structured so that patients routinely become subjects. This idea is grounded in theses that all parties benefit from this arrangement and that the societal goals of health care quality, just health care, and economic well-being require continuous learning that should not be retarded by overly demanding standards of informed consent (Orentlicher 2005; Faden et al. 2013).

Critics will maintain that this proposal amounts to the end of informed consent. In upcoming years, however, a rethinking of the scope of informed consent requirements and related human subjects regulations along these lines is almost certain to occur. The history of informed consent is still unfolding and new moral challenges undoubtedly lie ahead.

**SEE ALSO** *Autonomy; Competence; Epistemic Injustice; Information Disclosure, Ethical Issues of; Informed Consent; Professional-Patient Relationship*

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### III. CONSENT ISSUES IN HUMAN RESEARCH

"The voluntary consent of the human subject is absolutely essential." This, the first sentence of the Nuremberg Code, signals the centrality of the consent requirement in research involving human subjects (Germany [Territory under Allied Occupation] 1947, 181). Before the Nuremberg Code was written in 1947 as a response to the atrocities committed in the name of science by Nazi physician-researchers, statements of medical and other professional organizations apparently made no mention of the necessity of consent. Ironically, the only nations known to have promulgated regulations that established a requirement for consent to research were Prussia and Germany (Perley et al. 1992). Subsequently, the tendency to focus on informed consent was reinforced by public outcry over the inadequacy of consent in certain landmark cases in the United States, such as the Willowbrook Studies (1963–1966), the Jewish Chronic Disease Hospital Study (1963), the Tea Room Trade Study (1970), and the Tuskegee Syphilis Study (1932–1972) (Katz, Capron, and Swift 1972; Levine 1986, 69–72). Indeed, the issue of informed consent has so dominated recent discussion of the ethics of research that one might be led to think erroneously that other ethical issues (e.g., research design, selection of subjects) are either less important or more satisfactorily resolved.

This entry is concerned with the conceptual aspects of informed consent. For an extensive review of empirical studies of informed consent, see the 1999 article written by Jeremy Sugarman and Douglas C. McCrory.

#### GROUNDING OF INFORMED CONSENT

The requirement for informed consent has philosophical, religious, and legal foundations.

**Philosophical Basis.** The philosophical foundations of the requirement for informed consent may be found in several lines of reasoning (Veatch 1981; Faden, Beauchamp, and King 1986; Brock 1987). Based on the Hippocratic admonition "to help, or at least, to do no harm" (Jonsen 1978), one can justify seeking consent for the benefit of the patient; to do so provides a mechanism for ascertaining what the patient would consider a benefit. Allowing individuals to decide what they consider beneficial is consistent with the perspective affirmed in US public policy that competent persons are generally the best protectors of their own well-being (Brock 1987). A focus solely on patient benefit, however, would allow physicians and scientists not to seek consent when they judge that doing so might harm patients or subjects. Thus this justification alone does not suffice to establish a requirement to seek consent.