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# *The Concepts of Informed Consent and Competence*

Covered by the account of autonomous action in Chapter 7, we now turn to analysis of the concepts of informed consent and competence. We argue that "informed consent" has two distinct senses or general uses. In the first sense, an informed consent is a special kind of autonomous action: an autonomous authorization by a patient or subject. The second sense of "informed consent" is analyzable in terms of rules governing informed consent in public policy and institutional contexts.

The policy dimensions of this second sense of informed consent require that attention also be paid to the concept of competence, especially the competence to consent. Competence is analyzed in later parts of the chapter in terms of criteria of autonomous *persons*, as distinct from autonomous *actions*. Judgments of competence, we argue, primarily serve a gatekeeper function by identifying persons from whom it is appropriate to obtain informed consents.

## Two Concepts of Informed Consent

Legal, philosophical, regulatory, medical, and psychological literatures have generally discussed informed consent in terms of its "elements." The following elements have been identified as the concept's analytical components:[1]

1. *Disclosure*
2. *Comprehension*
3. *Voluntariness*
4. *Competence*
5. *Consent*

The fifth element is labeled "consent" in only a few analyses. Some commentators omit it entirely as an element; others prefer to call this element *decision*,[2] and still others prefer to emphasize *shared decisionmak-*

*ing* or *collaboration*[3] as a substitute for the consent of a patient or subject. Whatever the precise formulation, the fifth element refers to the final stage in the act of giving an informed consent.

Disagreements such as those over the proper label for "consent" are minor, and there is otherwise more agreement than disagreement over the appropriateness of these five elements. Indeed, there may be more consensus on this analysis of informed consent into its elements than on any other topic in the literature on informed consent. These elements are also extensively used in this literature as the conditions in a *definition* of informed consent—or, as some prefer to say, as the conditions in a definition of *valid* consent.[4] According to this mode of definition, X is an informed consent if and only if some of the elements 1–5 above are conditions that are satisfied in the circumstances. Precisely which of the five elements is used varies from theory to theory. Transformation of all five elements into a definition of informed consent yields the following:

> Action X is an informed consent by person P to intervention I if and only if:
> 1. P receives a thorough *disclosure* regarding I,
> 2. P *comprehends* the disclosure,
> 3. P acts *voluntarily* in performing X,
> 4. P is *competent* to perform X, and
> 5. P *consents* to I.

Although this schema is at first glance an attractive definition of informed consent, and one that is faithful to the uses of the term in such practical contexts as clinical medicine and law, the list of conditions in this analysis is biased by the special concerns of medical convention and malpractice law. Conditions 1–5 are less suitable as conditions in a conceptual analysis or definition of informed consent than as a list of the elements of informed consent as they have emerged in institutional or regulatory settings in which consent requirements appear in policies. This approach to the definition of informed consent also unjustifiably escalates into prominence the special orientations of both medicine and law toward *disclosure* and *responsibility* for patients and subjects.

To take but one instance of the kind of bias at work in this form of definition, the U.S. Supreme Court in *Planned Parenthood of Central Missouri* v. *Danforth* found cause to reflect on the meaning of "informed consent": "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."[5] This definition is strikingly similar to definitions provided by physicians in the national survey discussed in Chapter 3 (see pp. 98–99), where the focus was also exclusively on disclosure. Yet, this is a profoundly inadequate conception of the general *meaning* of

"informed consent," one tainted by an implicit assumption of medical authority and by an unrelieved legal focus on the theory of liability, which delineates not a meaning but a *duty*.

There is nothing about the nature of an informed consent per se that requires disclosure as a necessary condition, and certainly nothing that would *orient* its *meaning* around disclosure. A person otherwise knowledgeable about a proposed intervention—a physician undergoing a procedure, for example—could give a well informed consent without any disclosure whatever.[6] Other conditions in the above list of conditions are not necessary for similar reasons. For example, consider element 4, competence: Some persons who are *legally* incompetent (which is often the referent of element 4) may give informed consents, and in some instances *psychologically* incompetent persons (also often the referent of element 4) may be able to do so. We return to this problem in the final section of this chapter.

The transformation of the above five-fold set of elements into a definition of informed consent thus raises as many problems and confusions as it offers insights. There is no necessary association between these elements and logical conditions. That is, there is no necessary connection between an analytical listing of the hallmark characteristics of informed consent and the logically necessary and sufficient conditions of informed consent that govern its meaning. Neither is there a necessary association between the *logical conditions* of informed consent and *normative requirements* (duties and the like) governing the obtaining of consent, although the two have often been uncritically conflated.[7] To assert that some condition—for example, voluntariness—*must* be present could be either a *normative* claim or could be a purely *logical* (conceptual) claim.[8] Our task in the following pages is the purely logical one of providing a conceptual analysis of informed consent.

## Analyzing Informed Consent

What, then, is an informed consent? This question about the logical conditions of informed consent should be approached in the same spirit as the treatment of the logical conditions of autonomous action in Chapter 7. Answering this question is complicated because there are two common, entrenched, and starkly different meanings of "informed consent." That is, the term is analyzable in two profoundly different ways—not because of mere subtle differences of connotation that appear in different contexts, but because two different *conceptions* of informed consent have emerged from the histories traced in Chapters 3 through 6 and are still at work, however unnoticed, in literature on the subject.

In one sense, which we label $sense_1$, "informed consent" is analyzable as a particular kind of action by individual patients and subjects: an autonomous authorization. In the second sense, $sense_2$, informed consent

is analyzable in terms of the web of cultural and policy rules and requirements of consent that collectively form the social practice of informed consent in institutional contexts where *groups* of patients and subjects must be treated in accordance with rules, policies, and standard practices. Here, informed consents are not always *autonomous* acts, nor are they always in any meaningful respect *authorizations*.

In analyzing these two concepts—sense$_1$ and sense$_2$—we will rely more on our theory of autonomous action (in Chapter 7) and our historical analyses of informed consent (see Chapters 3 through 6) than on either ordinary language subtleties of the term "informed consent" or on beliefs pervasive in society about consent in medical settings. We have already noted how physicians interpreted the term "informed consent" in a recent survey. In that same survey, the responses from a sample of the American public were even more discouraging. When asked "What does the term informed consent mean to you?", one of the most popular answers from the public was that informed consent means that patients agree to treatment by letting the doctor do whatever is "necessary," "best," or "whatever he sees fit." Twenty-one percent of respondents said that they have no understanding of the term.[9] Such responses form an inadequate basis for a conceptual analysis of informed consent as that notion has emerged in modern medicine and research. The settings for the actual practice of obtaining consents also provide an unreliable basis, because the implicit understanding is often that "informed consent" means no more than the empty formality, as health professionals sometimes put it, of "consenting the patient"—that is, obtaining a signature on a consent form.[10]

With these cautions in mind, we can turn to more controlled methods of analyzing these two concepts of informed consent that rely only in part on their historical foundations.

## Sense$_1$: Informed Consent as Autonomous Authorization

Just as choices, consents, and refusals are species of the larger category of *actions*, so informed consents and informed refusals are, in sense$_1$, species of the larger category of *autonomous* actions. However, it is mistaken to say that informed consent in this sense is *synonymous* with autonomous choice (or action). It is likewise wrong to hold that the conditions of informed consent are identical to the conditions of autonomous choice (or action). An informed consent is a specific kind of autonomous choice (or action), an autonomous authorization by patients or subjects.

Jon Waltz and T.W. Scheuneman, in an influential early article (discussed in Chapter 4), define informed consent in terms of two elements or conditions: "the dual elements of *awareness* and *assent*." They require in addition that there be an "absence of such duress" as would render the assent "inoperative."[11] Their proposal is apparently that informed

consent should be analyzed as an uncoerced willingness to undergo a procedure regarding which the patient or subject has adequate information (predominantly, in their analysis, through a disclosure of risks and consequences). On the basis of the information the assent occurs. This analysis is a foray in the right direction. The term "assent" is a synonym for one general meaning of "consent," and "awareness" points to the "informed" component; to assent is to agree with or acquiesce in an opinion or to comply with an arrangement. This strikes close to what occurs in giving an informed consent.

However, the idea of an informed consent suggests that a patient or subject does more than express agreement with, acquiesce in, yield to, or comply with an arrangement or a proposal. He or she actively *authorizes* the proposal in the act of consent.[12] John may *assent* to a treatment plan without authorizing it. The assent may be a mere submission to the doctor's authoritative order, in which case John does not call on his *own* authority in order to give permission, and thus does not authorize the plan. Instead, he acts like a child who submits, yields, or assents to the school principal's spanking and in no way gives permission for or authorizes the spanking. Just as the child merely submits to an authority in a system where the lines of authority are quite clear, so often do patients.

Accordingly, an informed consent in sense$_1$ should be defined as follows: An informed consent is an autonomous action by a subject or a patient that authorizes a professional either to involve the subject in research or to initiate a medical plan for the patient (or both). Following the analysis of *substantial* autonomy in Chapter 7, we can whittle down this definition by saying that an informed consent in sense$_1$ is given if a patient or subject with (1) substantial understanding and (2) in substantial absence of control by others (3) intentionally (4) authorizes a professional (to do I).

It follows analytically from our analysis in Chapter 7 that all substantially autonomous acts satisfy conditions 1–3; but it does not follow from that analysis alone that all such acts satisfy 4. The fourth condition, then, is what distinguishes informed consent as one *kind* of autonomous action. (Note also that the definition restricts the kinds of authorization to medical and research contexts.) A person whose act satisfies conditions 1–3 but who refuses an intervention gives an *informed refusal.* The conditions of this latter kind of action are identical to 1–4 above, except that the fourth condition is the converse, a nonauthorization or refusal to authorize.

*The Problem of Shared Decisionmaking.* This analysis of informed consent in sense$_1$ is deliberately silent on the question of how the authorizer and the agent(s) being authorized *arrive at an agreement* about the performance of "I." Recent commentators on informed consent in clinical medicine, notably Jay Katz and the President's Commission (see Chapter 3), have tended to equate the idea of informed consent with a model of

"shared decisionmaking" between doctor and patient. The President's Commission titles the first chapter of its report on informed consent in the patient-practitioner relationship "Informed Consent as Active, Shared Decision Making," while in Katz's work "the idea of informed consent" and "mutual decisionmaking" are treated as virtually synonymous terms.[13]

There is of course an historical relationship in clinical medicine between medical decisionmaking and informed consent. The emergence of the legal doctrine of informed consent was instrumental in drawing attention to issues of decisionmaking as well as authority in the doctor-patient relationship. Nevertheless, it is a confusion to treat informed consent and shared decisionmaking as anything like *synonymous*. For one thing, informed consent is not restricted to clinical medicine. It is a term that applies equally to biomedical and behavioral research contexts where a model of shared decisionmaking is frequently inappropriate. Even in clinical contexts, the social and psychological dynamics involved in selecting medical interventions should be distinguished from the patient's *authorization*.

In Chapter 9 we endorse Katz's view that effective communication between professional and patient or subject is often instrumental in obtaining informed consents ($sense_1$), but we resist his conviction that the idea of informed consent entails that the patient and physician "share decisionmaking," or "reason together," or reach a consensus about what is in the patient's best interest. This is a manipulation of the concept from a too singular and defined moral perspective on the practice of medicine that is in effect a moral program for changing the practice. Although the patient and physician *may* reach a decision together, they need not. It is the essence of informed consent in $sense_1$ only that the patient or subject *authorizes autonomously*; it is a matter of indifference where or how the proposal being authorized originates.

For example, one might advocate a model of shared decisionmaking for the doctor-patient relationship without simultaneously advocating that every medical procedure requires the consent of patients. Even relationships characterized by an ample slice of shared decisionmaking, mutual trust, and respect would and should permit many decisions about routine and low-risk aspects of the patient's medical treatment to remain the exclusive province of the physician, and thus some decisions are likely always to remain subject exclusively to the physician's authorization. Moreover, in the uncommon situation, a patient could autonomously authorize the physician to make *all* decisions about medical treatment, thus giving his or her informed consent to an arrangement that scarcely resembles the sharing of decisionmaking between doctor and patient.[14]

*Authorization.* Because authorization is central to our account of informed consent in $sense_1$, it seems appropriate that we provide an anal-

ysis of the notion of authorization. Because to do so with thoroughness would require its own volume, our analysis must be brief: In authorizing, one both assumes responsibility for what one has authorized and transfers to another one's authority to implement it. There is no informed consent unless one *understands* these features of the act and *intends* to perform that act. That is, one must understand that one is assuming responsibility and warranting another to proceed.

To say that one assumes responsibility does not quite locate the essence of the matter, however, because a *transfer* of responsibility as well as of authority also occurs. One's authorization gives another both permission to proceed and the responsibility for proceeding. Depending on the social circumstances, X's having authorized Y to do I generally signifies either that X and Y *share* responsibility for the consequences of I or that the responsibility is entirely X's (assuming, of course, that Y executes I in a non-negligent and responsible fashion). Thus, the crucial element in an authorization is that the person who authorizes uses whatever right, power, or control he or she possesses in the situation to endow another with the right to act. In so doing, the authorizer assumes some responsibility for the actions taken by the other person. Here one could either authorize *broadly* so that a person can act in accordance with general guidelines, or *narrowly* so as to authorize only a particular, carefully circumscribed procedure.

## Sense$_2$: Informed Consent as Effective Consent

By contrast to sense$_1$, sense$_2$, or *effective* consent, is a policy-oriented sense whose conditions are not derivable solely from analyses of autonomy and authorization, or even from broad notions of respect for autonomy. "Informed consent" in this second sense does not refer to *autonomous* authorization, but to a legally or institutionally *effective* (sometimes misleadingly called *valid*) authorization from a patient or a subject. Such an authorization is "effective" because it has been obtained through procedures that satisfy the rules and requirements defining a specific institutional practice in health care or in research.

We saw in Chapters 3 through 6 that the social and legal practice of requiring professionals to obtain informed consent emerged in institutional contexts, where conformity to operative rules was and still is the sole necessary and sufficient condition of informed consent. Any consent is an informed consent in sense$_2$ if it satisfies whatever operative rules apply to the practice of informed consent. Sense$_2$ requirements for informed consent typically do not focus on the autonomy of the act of giving consent (as sense$_1$ does), but rather on regulating the behavior of the *consent-seeker* and on establishing *procedures and rules* for the context of consent. Such requirements of professional behavior and procedure are obviously more readily monitored and enforced by institutions.

However, because formal institutional rules such as federal regulations and hospital policies govern whether an act of authorizing is effective, a patient or subject can autonomously authorize an intervention, and so give an informed consent in $sense_1$, and yet *not effectively authorize* that intervention in $sense_2$.

Consider the following example. Carol and Martie are nineteen-year-old, identical twins attending the same university. Martie was born with multiple birth defects, and has only one kidney. When both sisters are involved in an automobile accident, Carol is not badly hurt, but her sister is seriously injured. It is quickly determined that Martie desperately needs a kidney transplant. After detailed discussions with the transplant team and with friends, Carol consents to be the donor. There is no question that Carol's authorization of the transplant surgery is substantially autonomous. She is well informed and has long anticipated being in just such a circumstance. She has had ample opportunity over the years to consider what she would do were she faced with such a decision. Unfortunately, Carol's parents, who were in Nepal at the time of the accident, do not approve of her decision. Furious that they were not consulted, they decide to sue the transplant team and the hospital for having performed an unauthorized surgery on their minor daughter. (In this state the legal age to consent to surgical procedures is twenty-one.)

According to our analysis, Carol gave her informed consent in $sense_1$ to the surgery, but she did not give her informed consent in $sense_2$. That is, she autonomously authorized the transplant and thereby gave an informed consent in $sense_1$ but did not give a consent that was effective under the operative legal and institutional policy, which in this case required that the person consenting be a legally authorized agent. Examples of other policies that can define $sense_2$ informed consent (but not $sense_1$) include rules that consent be witnessed by an auditor or that there be a one-day waiting period between solicitation of consent and implementation of the intervention in order for the person's authorization to be effective. Such rules can and do vary, both within the United States by jurisdiction and institution, and across the countries of the world.[15]

Medical and research codes, as well as case law and federal regulations, have developed models of informed consent that are delineated entirely in a $sense_2$ format, although they have sometimes attempted to justify the rules by appeal to something like $sense_1$. For example, disclosure conditions for informed consent are central to the history of "informed consent" in $sense_2$, because disclosure has traditionally been a *necessary* condition of effective informed consent (and sometimes a *sufficient* condition!). The *Salgo* court spoke of a "full disclosure of facts" as "*necessary* to an informed consent," and the U.S. Supreme Court defined "informed consent" *entirely* in terms of disclosure.[16] The legal doctrine of informed consent, as examined in Chapters 2 and 4, is pri-

marily a law of disclosure; satisfaction of disclosure rules virtually consumes "informed consent" in law.[17] This should come as no surprise, because the legal system needs a generally applicable informed consent mechanism by which injury and responsibility can be readily and fairly assessed in court. These disclosure requirements in the legal and regulatory contexts are not conditions of "informed consent" in $sense_1$; indeed disclosure may be entirely irrelevant to giving an informed consent in $sense_1$. If a person has an adequate *understanding* of relevant information without benefit of a disclosure, then, as we saw earlier, it makes no difference whether someone *disclosed* that information.

Other $sense_2$ rules besides those of disclosure have been enforced. These include rules requiring evidence of adequate comprehension of information and the aforementioned rules requiring the presence of auditor witnesses and mandatory waiting periods. $Sense_2$ informed consent requirements generally take the form of rules focusing on disclosure, comprehension, the minimization of potentially controlling influences, and competence. Examples of such $sense_2$ requirements can be found in the Federal Regulations discussed in Chapter 6. The last subsection of the 1966 FDA Regulations, for instance, provides the following formal definition of informed consent:

> 'Consent' or 'informed consent' *means* that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a *fair* explanation of all material information concerning the administration of the investigation drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element *requires* that before the acceptance of an affirmative decision by such person the investigator should make known to him. . . . [a long list of items to be disclosed follows][18]

This definition was adapted by FDA officials from parts of the Declaration of Helsinki and the Nuremberg Code. The first principle of the Nuremberg Code requires "voluntary consent," the meaning of which is explicated as follows:

> This *means* that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice. . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element *requires* that before the acceptance of an affirmative decision by the experimental subject there should be made known to him. . . . [a long list follows][19]

In the subsequent 1971 "Institutional Guide to DHEW Policy on Protection of Human Subjects"—the "Yellow Book"—the following abbreviated definition is provided:

> Informed consent *is* the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.
>
> The basic elements of informed consent are . . . [a list of six types of *disclosure* to be made follows][20]

The above definitions of the term "informed consent" express the present-day mainstream conception in the federal government of the United States. They are also typical of international documents and state regulations, which all reflect a $sense_2$ orientation. These documents derive from some conviction—perhaps based on a social consensus—about the requirements or practices needed to enable effective authorizations in the special set of circumstances found in institutions dedicated to health care and research.

Although most formal definitions of informed consent in $sense_2$ have been forged from contexts of public policy and law, definitions of informed consent rooted more in moral theory than in law or public policy can also fall into the $sense_2$ class. The following legally-indebted definition—offered by Albert Jonsen, Mark Siegler, and William Winslade and designed for the teaching of medical ethics in medical schools and health care institutions—is illustrative:

> Informed consent is defined as the willing and uncoerced acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks and benefits, as well as of alternatives with their risks and benefits.[21]

## The Relationship Between $Sense_1$ and $Sense_2$

A $sense_1$ "informed consent" can fail to be an informed consent in $sense_2$ by a lack of conformity to applicable rules and requirements. Similarly, an informed consent in $sense_2$ may not be an informed consent in $sense_1$. The rules and requirements that determine $sense_2$ consents need not result in autonomous authorizations at all in order to qualify as informed consents. For example, under a North Carolina statute a signed consent form *constitutes* "valid consent" (informed consent in $sense_2$) so long as a reasonable person would have understood the information in its disclosed form, even if the patient in fact did not understand; moreover, if the patient had not been informed at all, but a reasonable person would have consented *if* informed, then the patient's "uninformed" consent is valid.[22]

Such peculiarities in informed consent law have led Jay Katz to argue that the legal doctrine of "informed consent" bears a "name" that "promises much more than its construction in case law has delivered." He has argued insightfully that the courts have, in effect, imposed a mere duty to warn on physicians, an obligation confined to risk disclosures and statements of proposed interventions. He maintains that "This judicially

imposed obligation must be distinguished from the *idea* of informed consent, namely, that patients have a decisive role to play in the medical decisionmaking process. The idea of informed consent, though alluded to also in case law, cannot be implemented, as courts have attempted, by only expanding the disclosure requirements." By their actions and declarations, Katz believes, the courts have made informed consent a "cruel hoax" and have allowed "the idea of informed consent . . . to wither on the vine."[23]

The most plausible interpretation of Katz's contentions is through the $\text{sense}_1/\text{sense}_2$ distinction. If a physician obtains a consent under the courts' criteria, then an informed consent ($\text{sense}_2$) has been obtained. But it does not follow that the courts are using the *right* standards, or *sufficiently rigorous* standards in light of a stricter autonomy-based model—or "idea" as Katz puts it—of informed consent ($\text{sense}_1$).[24] If Katz is correct that the courts have made a mockery of informed consent and of its moral justification in respect for autonomy, then of course his criticisms are thoroughly justified. At the same time, it should be recognized that people can proffer legally or institutionally effective authorizations under prevailing rules even if they fall far short of the standards implicit in $\text{sense}_1$.[25]

*$\text{Sense}_1$ as a Model for $\text{Sense}_2$.* Despite the differences between $\text{sense}_1$ and $\text{sense}_2$, a definition of informed consent need not fall into one or the other class of definitions. It may conform to both. Many definitions of informed consent in policy contexts reflect at least a strong and definite reliance on informed consent in $\text{sense}_1$. Although the conditions of $\text{sense}_1$ are not logically necessary conditions for $\text{sense}_2$, we take it as morally axiomatic that they *ought* to serve—and in fact have served—as the benchmark or model against which the moral adequacy of a definition framed for $\text{sense}_2$ purposes is to be evaluated. This position is, roughly speaking, Katz's position.

A defense of the moral viewpoint that policies governing informed consent in $\text{sense}_2$ *should* be formulated to conform to the standards of informed consent in $\text{sense}_1$ is not hard to express. We have argued in earlier chapters that the goal of informed consent in medical care and in research—that is, the purpose behind the obligation to obtain informed consents—is to enable potential subjects and patients to make autonomous decisions about whether to grant or refuse authorization for medical and research interventions. Accordingly, embedded in the reason for having the social institution of informed consent is the idea that institutional requirements for informed consent in $\text{sense}_2$ *should* be intended to maximize the likelihood that the conditions of informed consent in $\text{sense}_1$ will be satisfied—although we did not claim in Chapters 3 through 6 that historically they *have always* been so intended.

*How* informed consent in $\text{sense}_1$ might function as a normative standard for informed consent in $\text{sense}_2$ deserves at least brief explication.

First, there is no way to decide rationally that a set of consent requirements in $sense_2$ is morally acceptable only if at least some particular percentage of the authorizations that follow from them—60% or 70% or 80% or 100%—satisfy the conditions of informed consent in $sense_1$. However, a comparative, pragmatic justification can be offered: A set *Y* of consent requirements in $sense_2$ is morally preferable to any set Z if, all other things being equal, (1) *Y* results in more informed consents (in $sense_1$) than Z, (2) *Y* results in fewer "false negatives"—that is, fewer informed consents in $sense_1$ will fail to meet the formal requirements of informed consent in $sense_2$—than Z, and (3) *Y* results in fewer "false positives" than Z—that is, fewer authorizations that are not substantially autonomous will meet its formal requirements as informed consents in $sense_2$.

Here we need to reintroduce the distinction (discussed at the end of Chapter 6) between requirements that *have* served in institutional and policy contexts and those that *should* be operative in such contexts. Our book is not the appropriate forum for discussing the precision with which the standards in $sense_2$ *should* conform to the conditions of $sense_1$ in order to have a morally adequate standard for $sense_2$, but this moral matter is so vital that it deserves at least brief attention.

A major problem at the policy level, where rules and requirements must be developed and applied in the aggregate, is the following: The obligations imposed to enable patients and subjects to make authorization decisions must be evaluated not only in terms of the demands of a set of abstract conditions of "true" or $sense_1$ informed consent, but also in terms of the impact of imposing such obligations or requirements on various institutions with their concrete concerns and priorities. One must take account of what is fair and reasonable to require of health care professionals and researchers, the effect of alternative consent requirements on efficiency and effectiveness in the delivery of health care and the advancement of science, and—particularly in medical care—the effect of requirements on the welfare of patients. Also relevant are considerations peculiar to the particular social context, such as proof, precedent, or liability theory in case law, or regulatory authority and due process in the development of federal regulations and IRB consent policies.

Moreover, at the $sense_2$ level, one must resolve not only which requirements will define effective consent; one must also settle on the rules stipulating the conditions under which effective consents must be obtained. In some cases, hard decisions must be made about whether requirements of informed consent (in $sense_2$) should be imposed at all, even though informed consent (in $sense_1$) *could* realistically and meaningfully be obtained in the circumstances and could serve as a model for institutional rules. For example, should there be any consent requirements in the cases of minimal risk medical procedures and research activities?

The problem of how to develop a morally acceptable set of requirements for informed consent in $sense_2$ recalls the discussion in Chapter 1 of the need to balance competing moral principles and obligations in implementing policy or institutional rules. This need to balance is not a problem for informed consent in $sense_1$, which is not policy oriented. Thus, it is possible to have a *morally acceptable* set of requirements for informed consent in $sense_2$ that deviates considerably from the conditions of informed consent in $sense_1$. However, the burden of moral proof rests with those who defend such deviations since the primary moral justification of the obligation to obtain informed consent is respect for autonomous action.

*Beyond Health Care and Research.* One potential objection to our analysis of informed consent—in both $sense_1$ and $sense_2$—is that it is too narrow: Why confine the concept of informed consent to *medical* procedures and *research* projects? A wide variety of consents have nothing to do with medicine or research. All classical contractarian political theories, for example, employ some notion of voluntary and informed consent as the essential basis of the legitimacy or validity of government: The people authorize by their free acts of consent that a government obtain sovereignty. Many commonplace actions also qualify as informed consents. For example, in one wedding ceremony, the bride and groom are explicitly asked to give their "informed consent to marry. . . . " In short, informed consent in this first sense could be applied to autonomously authorizing appliance repairs, withdrawing money from a checking account, hiring an agent, and hundreds of other daily activities.

We do not deny, of course, that the concept of informed consent could be broadened to mean *any* authorization that is substantially autonomous. But we do deny that this is a plausible reading of what the term has meant in any significant document on the subject of informed consent. We noted from the outset that our analysis is to be consonant with the historical development of the concept of informed consent, as presented in Chapters 3 through 6. The meaning that emerges from this history is restricted to research and medical care. For example, in contexts other than medicine and research (contracts and leases, e.g.), where the idea of a consent that is informed has been put to some serious work, the language that is used is almost always something like "express written consent" rather than "informed consent."

*Practical Purposes of $Sense_1$.* In the remainder of this book we focus on the conditions of informed consent in $sense_1$. However, our objective is not to present an *ideal* model of informed consent. Quite the contrary. In delineating informed consent in $sense_1$ in terms of *substantial* rather than *full* autonomy, as in Chapter 7, we have already rejected the view that it is never possible to obtain "true" informed consents. Many circumstances in medical care and research permit substantially autonomous authorizations, and in many settings they are now obtained.

The conditions of informed consent in $sense_1$ can be used to serve two practical purposes. First, because informed consent in this sense is an evaluative standard for informed consent in $sense_2$, a more detailed analysis of $sense_1$ should make it easier for deliberative bodies such as courts, commissions, hospital ethics committees, professional organizations, and IRBs to assess the moral adequacy of requirements of informed consent in $sense_2$. Policy makers should be able to determine what existing $sense_2$ requirements accomplish, how well they accomplish it, and how to implement desirable changes. Second, the conditions elaborated in Chapters 9 and 10 provide a blueprint for situations in which it is appropriate or morally desirable to obtain substantially autonomous authorizations. A better understanding of informed consent in $sense_1$ is also useful, of course, for those who wish to *exceed* operative policy or legal requirements at the $sense_2$ level.

In Chapters 9 and 10 we analyze the demands of two conditions of informed consent in $sense_1$ in order to show what can be done to increase the likelihood that these conditions will be satisfied. We do not consider the problem of *competence* in either chapter. This may appear surprising in the face of the substantial attention and prominence given to standards of competence in informed consent literature. But Chapters 9 and 10 are exclusively about informed consent in $sense_1$, and competence is not in any conventional respect a $sense_1$ problem. In $sense_1$, if a patient's consent is sufficiently autonomous, then it is irrelevant whether the person giving the authorization is competent in the light of some legal policy or psychiatric standard. However, this is not true of informed consent in $sense_2$, where competence has enjoyed a justifiably central role in specifying *from whom* consent may and must be solicited. One problem is who in the circumstance counts as a legitimate authority for the purpose of consent. Because these issues are frequently treated at the policy level almost exclusively as problems of competence, we turn in conclusion to a brief discussion of competence as it functions in $sense_2$ requirements.

## Competence to Consent: The Gatekeeping Concept

Thus far we have argued that conditions of autonomous action, together with a condition of authorization, define informed consent in $sense_1$ and that these conditions can and often do serve as the model in terms of which policy requirements of informed consent (in $sense_2$) are formulated and evaluated. In this section we argue that the characteristics of the autonomous *person* play a similar role for requirements that govern competence to consent.

In legal and policy contexts, reference to *competent* persons is, of course, more common than reference to *autonomous* persons. In these contexts competence functions as a gatekeeping concept for informed

consent in sense$_2$. That is, competence judgments function to distinguish persons from whom consent *should* be solicited from those from whom consent need not or should not be solicited. Although the reference is generally to competent persons, judgments regarding from whom consent rightly should be solicited are necessarily normative judgments whose underlying moral rationale is rooted in the concept of autonomous persons. This rationale is as follows: If a person is *autonomous* and situated in a context in which consent is appropriate, it is a prima facie moral principle (derived from the basic principle of respect for autonomy) that informed consent should be sought from the person. By contrast, if a person is *nonautonomous* and situated in a context in which consent is required, it is a prima facie moral principle (*not* derived from the principle of respect for autonomy, but rather from beneficence) that some mechanism for the authorization of procedures or decisions other than obtaining the person's consent should be instituted.

Thus, gatekeeping by allowing autonomous persons—competent persons—to give informed consent and not allowing nonautonomous persons—incompetent persons—to give informed consent is accomplished by an appeal to the moral principle that autonomous persons are *rightfully* the decisionmakers. Gatekeeping of this description is not the only framework for determining who is competent and who incompetent, and therefore who should and should not be solicited to give an informed consent. But classically this perspective *has been* a deeply embedded model governing what we earlier in this chapter called the "element" of competence, as that element appears in treatments of informed consent in policy and legal contexts.

We shall expand on the relationship between autonomous persons and competence as we proceed, but we need first to examine the general concept of competence and its specific application to contexts of informed consent.

## The Nature and Degrees of Competence

The special commitments of medicine, law, psychiatry, philosophy, psychology, and other professions have led to competing perspectives on competence that are in many instances incompatible. Some have claimed that there is not and likely never will be a consensus *definition* of competence.[26] This view is short-sighted: A core meaning of the word "competence" ranges over all the many contexts in which it is applied. That meaning is the *ability to perform a task*.[27] By contrast to this invariable *meaning* of "competence," the *criteria* of particular competences do vary across contexts because the criteria are necessarily relative to specific tasks. The set of criteria for someone's being a competent magician is necessarily different from the set of criteria for someone's being a competent baker or a competent animal trainer.

Judgments of incompetence are therefore impossible to understand unless a task is assumed or specified. If X says, "Y is incompetent," an appropriate query is, "Y is incompetent to do what?" To manage legal affairs? To recognize a friend? To remember facts? To decide whether to undergo a medical procedure? The description of persons as *generally* incompetent is not an exception and should not avoid reference to *particular* tasks; rather, this category assumes numerous particular tasks that the generally incompetent person is unable to perform. These tasks are those encompassing the ordinary affairs of life, such as making purchases, authorizing another to act on one's behalf, protecting one's property, and the like. Confusion pervades much of the literature on competence because authors glide uncritically between criteria of *general* competence and criteria of such *specific* task-oriented competences as the competence to decide while in agonizing pain whether to undergo a specific medical procedure that carries a risk of a particular type and degree.

The concept of "specific incompetence" has been invoked in law and policy to reduce the risk that vague generalizations about vague criteria of competence will function to exclude persons who are in fact competent from undertaking the relevant tasks, including giving an informed consent or refusal. It has begun to be appreciated that a person can be incompetent to perform some tasks, while competent at the same time to perform other tasks. For example, some patients are capable of understanding simple low-risk procedures but not technologically complicated high-risk procedures. A person can also lack the relevant abilities and so be incompetent to do something at one point in time, and yet be competent to perform the same task at another point in time. A manic-depressive correctly judged incompetent to consent to or refuse treatment during an acute manic phase might nonetheless be competent at other times. These are clear indications of how a term like "competent to consent" can, without the requisite specificity, seriously mislead.[28]

Competence is further complicated because it is a continuum concept. Persons may be judged more or less competent to the extent they possess a certain level of ability or number of abilities. For example, an experienced surgeon is likely to be more competent to consent to surgery than a frightened young soldier. We can often say not only that a person X is competent to consent, but also that X is *more or less* competent to consent than Y—or even that X is more or less competent to consent to intervention I than X is competent in other areas, or that X is probably more competent to consent to I now than he or she will be at some later time.

Like the continua developed in Chapter 7 to explicate autonomous action, the continuum of competence ranges without discernible breaks from full competence through various levels of partial competence to full incompetence. For practical and policy reasons cut-offs must be stationed on this continuum in order to establish that any person at or below

the threshold point lacks a sufficient measure of abilities, and so is to be treated as incompetent,[29] and that everyone on the "competence side" is to be treated as competent. All gatekeeping requirements for informed consent ($sense_2$) function by establishing or presuming thresholds. While it is obviously untrue that all competent individuals are equally competent or all incompetent persons equally incompetent, the function of competence determinations is to sort persons into these two basic classes, and thus to treat persons as *either* competent *or* incompetent.

Naturally, it is often a difficult *evaluative* matter how and where the cut-off distinguishing competence from incompetence should be situated. We shall now explore the various ways in which such judgments are normative.

## Normative Functions of the Concept of Competence

If the label "incompetent" is placed on a patient or subject, a train of coercive events is potentially set in motion. The label "competence" commonly functions to denote persons whose consents, refusals, and statements of preference will be accepted as binding, while "incompetence" denotes those who are to be placed under the guidance and control of another. The competent person must be dealt with as his or her own person; that person's will, and not the will of another, must prevail as the source of authorization or refusal. If such a *competent* person cannot make an informed choice merely because of eliminable ignorance, the information required to remove ignorance must be supplied; similarly, if the competent person is in danger of control by the exertion of family pressures, then steps should be taken to ease the family pressures. But in the case of the *incompetent* person, matters are starkly different because information will be provided to a third party authorized to decide on the incompetent's behalf, and the decision will be reached by that party.

Where the cut-off line should be situated on the continuum of ability that divides competence from incompetence is a normative question with several levels. Establishing the *requisite abilities* is a first level of evaluation; then *thresholds for each of those abilities* must be fixed. Still a third normative dimension is present if a *test* of competence is used to determine who passes and who fails. Thus, selection of each of the following three distinguishable components always involves normative judgments:

1. the relevant abilities,
2. a threshold level of the abilities in (1), and
3. an empirical test for (2).

Empirical judgments that a person *is* competent or incompetent cannot be made without such evaluations as their presupposition. That is, it is an empirical question whether someone has the requisite level of abili-

ties, but this question can only be asked and answered if the evaluative dimensions (#1 and #2, at least) have already been fixed and can be presupposed in the empirical search.

The selection of abilities, thresholds, and tests will depend on moral and policy questions closely related to the concerns that shape the selection of requirements for informed consent in $sense_2$. Central issues include the number of moral principles to be balanced and the weight to be given to each principle in different circumstances. In determinations of the competence of patients and subjects, the evaluative tradeoff is usually between two principles—the principle of respect for autonomy, on the one hand, and that of beneficence on the other.

Those who give priority in such evaluations to the medical welfare of patients (under what we have called the beneficence model) over respect for their autonomy will argue for a conservative or stringent set of abilities, thresholds, and tests of competence to consent. By contrast, those committed to the priority of the principle of respect for autonomy (the autonomy model) over that of health and safety will likely argue for a more liberal or less stringent set of standards of competence that will result in more patients and subjects being classified as agents whose authorizations and refusals ought to be honored. Conflicts based on these competing moral commitments should come as no surprise. They are simply one further instance of the clash that can occur between the moral principles of autonomy and beneficence that we have had occasion to point to in virtually every previous chapter.

A wide variety of standards of competence to consent has been suggested in the literature. These tests are strikingly diverse, and some are far more difficult for patients and subjects to qualify under than others. The more demanding tests require a higher level of skill at a defined task (a threshold problem), or an increased number of tasks and skills (a requisite-abilities problem). Some tests require only the simple ability to evidence a preference. Others require abilities to understand information and to appreciate one's situation. Still others make it extremely difficult for many people to qualify as competent to give a consent. For example, a person may be required to (1) show an accurate understanding of a procedure, (2) weigh its risks and benefits, *and* (3) make a prudent decision in the light of such knowledge.[30]

## Psychological Competence, Legitimate Authority, and Autonomous Persons

Standards of competence to consent tend to focus on *psychological* skills or capacities, and competence to consent is often placed under the generic category of "psychological competence." Theories of autonomous persons are often expressed in terms of such psychological traits and abilities, namely, the cognitive skills and character traits that define the autonomous person. However, psychological theories and the model

of the autonomous person will only take us so far in an analysis of competence to consent. Even if agreement existed as to precisely which psychological properties define the autonomous person, the question of who is competent to give an informed consent would still not be entirely resolved. *Social* criteria of qualification in addition to purely *psychological* criteria are almost invariably involved. Some persons who satisfy threshold psychological conditions of competence to consent will not be considered by society as able to give valid authorizations, either in general or for a specific intervention or action. Usually this restriction is believed justified because these individuals belong to a *class* of persons not permitted by law, policy, or social convention to assume responsibility for the consequences of their decisions (even if *some* class members may possess sufficient psychological abilities).

It would be misleading, of course, to plunge a sharp wedge between the "psychological" and the "social" criteria defining competence to consent. Social criteria assigning responsibility for one's actions are often merely easy and convenient markers for more complex attributes of character. For example, age has conventionally been used as a rough operational measure of maturity, with established thresholds floating from ages 21 to 18 to 16, and sometimes even lower for specific purposes. Here the broadly applicable social criterion of age has replaced a related but more complex set of psychosocial criteria such as maturity, experience, and good judgment. A modern trend of requiring individual assessment of the competence of minors for specific purposes, including consent to some types of health services, is but one of many indicators that support this interpretation.[31]

The requisite social criteria of competence to consent may vary considerably from one community or culture to another. In some tribal societies only village chiefs are believed competent to consent, and in some traditional Eastern societies mentally healthy adults in their twenties and thirties may not be viewed as competent to consent to such events as marriage. Matters are not rigidly fixed in our own society. Willard Gaylin has argued that judgments of a child's *competence* to consent are and should be affected by what is *at stake* for the child. If the risks stemming from a medical intervention are low, whereas the potential gain in health is high, we will and should be less sanguine, he argues, about treating a child's refusal as competent and therefore honoring it. But should the child elect the intervention, we are likely to be, and should be, more generous. In Gaylin's view, this is not an ad hoc maneuver or a sham because competence judgments are connected by their very nature to judgments about experience, maturity, responsibility, *and* welfare.[32] The President's Commission proposed a similar sliding risk-benefit scale, to be applied to adults as well as to children: As an intervention increases the risks *or* the benefits for persons, the level of ability required for a judgment of competence to choose or refuse the intervention should be

increased; and as the consequences for wellbeing become less substantial, the level of capacity required for competence should be decreased.[33]

Proposals like that of the President's Commission make it clear that the model of the autonomous person is not the *only* force at work when standards of competence to give an informed consent in $sense_2$ are in question. The welfare of patients and subjects, broad social interests in ensuring good outcomes, and cultural views about responsibility and authority all figure as countervailing forces. But if the role of these forces in forming competence standards for informed consent is challenged, the reference point for criticism and reconstruction is most plausibly the model of the autonomous person. Perhaps nowhere is this conflict more obvious than in the continuing debate about the competence of children to consent to treatment, but here the major underlying problems are usually not about the validity of the standard of the autonomous person but rather about its applicability.

## Conclusion

Building on the historical and conceptual foundations in Chapters 1 through 7, we have now provided an answer to the question, "What *is* an informed consent?" Central to an adequate answer is the distinction we have drawn between two concepts, or two senses, of informed consent. Informed consent in $sense_1$ is defined in terms of the conditions of a particular kind of autonomous action: an autonomous authorization. Whether an attempted authorization actually authorizes is determined by whether the act *is* an *autonomous* authorization. By contrast, an informed consent in $sense_2$ is defined in terms of *effective* authorization, where the nature and acceptability of authorizations are established by operative informed consent rules in a particular policy system. These rules or requirements of informed consent in $sense_2$ are developed in institutional contexts in which "gatekeeper" requirements, such as competence standards, are essential.

In examining the similarities and differences between the two senses of "informed consent," we have maintained that in neither sense is the concept merely an abstract ideal disconnected from the real world of informed consent practices. One of the purposes of analyzing $sense_1$ is to assist those who wish to obtain substantially autonomous consents even if there is no obligation to do so under existing $sense_2$ rules. We have noted that the conditions of informed consent in $sense_1$ can function as model standards for fashioning the institutional and policy requirements of $sense_2$. We have also argued that inevitable deviations from $sense_1$ conditions in the establishing of $sense_2$ rules may be morally acceptable, depending on the realities of consent-seeking in $sense_2$ set-

tings. However, because the primary moral justification of the obligation to obtain informed consent is the principle of respect for autonomy, whether a particular set of requirements for informed consent in $sense_2$ is morally acceptable or morally preferable must depend in large measure on the extent to which it serves to maximize the likelihood that the conditions of informed consent in $sense_1$ will be satisfied.

In the remaining two chapters we attempt to make the standards of informed consent in $sense_1$ more workable and more accessible to policy makers and professionals than our analysis has thus far made possible.

## Notes

1. Representative sources from a wide variety of disciplines include Robert Levine, "The Nature and Definition of Informed Consent in Various Research Settings," *Appendix: Vol. I, The Belmont Report* (Washington, D.C.: DHEW Publication No. (OS) 78–0013, 1978), (3–1)–(3–91), esp. (3–3)–(3–9); T. Beauchamp and J. Childress, *Principles of Biomedical Ethics*, 2nd ed. (New York: Oxford University Press, 1983), 70; Margaret A. Somerville, as prepared for the Law Reform Commission of Canada, *Consent to Medical Care* (Ottawa: Law Reform Commission, 1979), 11ff, 24; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions*, Vol. 1, Chapter 1, esp. 38–39; Alan Meisel and Loren Roth, "What We Do and Do Not Know About Informed Consent," *Journal of the American Medical Association* 246 (November 1981): 2473–77; Charles W. Lidz and Alan Meisel, "Informed Consent and the Structure of Medical Care," in President's Commission, *Making Health Care Decisions*, Vol. 2, 317–410, esp. 318; Martha P. Stansfield, "Malpractice: Toward a Viable Disclosure Standard for Informed Consent," *Oklahoma Law Review* 32 (1979): 871–74; and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Washington, D.C.: DHEW Publication No. (OS) 78–0012, 1978), 10.

2. Meisel, Roth, and Lidz, in particular. (See n. 1.)

3. Jay Katz and the President's Commission, in particular. (See n. 13.)

4. For the language of *valid* consent, see Charles Culver and Bernard Gert, *Philosophy in Medicine: Conceptual and Ethical Issues in Medicine and Psychiatry* (New York: Oxford University Press, 1982), 42–63; and June Fessenden-Raden and Bernard Gert, *A Philosophical Approach to the Management of Occupational Health Hazards* (Bowling Green, Ohio: Social Philosophy and Policy Center, 1984), Chapter IV, esp. 12.

5. 428 U.S. 52, 67 n.8 (1976). (Italics added.)

6. Some courts have acknowledged that disclosure of information already known to the patient is unnecessary. The 1972 case of *Cobbs* v. *Grant* (502 P.2d 1) is an early example.

7. For an analysis that conflates *definitional conditions* with both *requirements* and *elements*, see Charles W. Lidz, et al., *Informed Consent: A Study of Decisionmaking in Psychiatry* (New York: The Guilford Press, 1984), 3–5.

8. The logical claim about the *concept* of informed consent that voluntariness *must* be present entails that an act could not *be* an act of informed consent unless it was performed voluntarily. From this conceptual claim that voluntariness is a necessary (logical) condition of "informed consent," it is tempting to glide to a *normative*

requirement: Voluntariness must be present in the consent context because not compromising a person's voluntariness is a moral or legal requirement governing the obtaining of informed consents. Informed consent *requirements* could, in this way, be made to correspond to each of the above *elements*; that is, there could be disclosure requirements, comprehension requirements, noninfluence requirements, competence requirements, and the like. These requirements would then be the requirements that must be satisfied for any consent to be *valid*. In this chapter, we provide only a conceptual analysis of informed consent ($sense_1$ and $sense_2$), including an analysis of the demands of the conditions of $sense_1$. We do not address requirements governing what morally and legally must be done in obtaining informed consents $sense_2$.

9. President's Commission, *Making Health Care Decisions*, Vol. 1, 18–19.

10. See Charles W. Lidz and Loren H. Roth, "The Signed Form—Informed Consent?" in Robert F. Boruch, et al., eds., *Solutions to Ethical and Legal Problems in Social Research* (New York: Academic Press, 1983), 145–57.

11. Jon R. Waltz and T.W. Scheuneman, "Informed Consent to Therapy," *Northwestern University Law Review* 64 (1970): 643.

12. Authorization is needed because of the kind of proposal tendered to the person. Typically proposed in informed consent contexts is that a professional do something, or refrain from doing something, that directly and personally affects a patient or subject and that the professional cannot *rightfully*, by reference to the principle of respect for autonomy, do (or not do) on his or her authority alone. Frequently, the proposal cannot with moral sanction be implemented without the patient's or subject's authorization or permission. Thus, mere assent or agreement is insufficient.

13. President's Commission, *Making Health Care Decisions*, Vol. 1, 15 and Jay Katz, *The Silent World of Doctor and Patient* (New York: The Free Press, 1984), 87 and "The Regulation of Human Research—Reflections and Proposals," *Clinical Research* 21 (1973): 785–91. Katz does not provide a sustained analysis of joint or shared decisionmaking, and it is unclear precisely how he would relate this notion to informed consent. At times, Katz links informed consent to individual self-determination and the (implicit) decisionmaking authority of patients (see *The Silent World*, xvii, 85ff, 99, and 102), and at times he mentions the role of authorization; but more frequently the notion of shared authority or decisionmaking serves as virtually the sole criterion. See, for example, *The Silent World*, 86 and 87: "Yet, the idea of informed consent demands joint decision making between physician and patient, a sharing of authority. . . . The idea of informed consent—of mutual decision making—remains severely compromised."

14. Katz holds that the delegation of decisionmaking authority to the physician is compatible with his view of shared decisionmaking. Personal communication, January 1985. As we mentioned in the Preface, it remains an open and essentially normative question what role informed consent *ought* to play in clinical medicine. That is, under what conditions—for what procedures and under what circumstances—ought physicians to be obligated to obtain specific authorizations from patients? It is equally unclear how this important question is to be answered by those who appeal to a model of shared or joint decisionmaking between patient and physician.

15. William Curran studied the differences between European and North American countries and found substantial differences in the practices and policies of what is permitted to count as an informed consent. In general, he found that European policies are more cautious than those in North America. William Curran, "Evolution of Formal Mechanisms for Ethical Review of Clinical Research," in Norman Howard-Jones and Zbigniew Bankowsi, eds., *Medical Experimentation and the Protection of Human Rights* (Geneva: Council for International Organizations of Medical Sciences, 1979), esp. 13.

16. *Salgo* v. *Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170 (1957) (italics added); *Planned Parenthood of Central Missouri* v. *Danforth*, 428 U.S. 52, 67 n.8 (1976).

17. See *Wilkinson* v. *Vesey*, 295 A.2d 676, 685 (1972).

18. *Federal Register* 31 (1966), 11415 (italics added).

19. Nuremberg Trials, *United States* v. *Karl Brandt, Trials of War Criminals Before the Nuremberg Military Tribunals under Control Council Law No. 10* (Military Tribunal I, 1947; Washington, D.C.: U.S. Government Printing Office, 1948–49), Principle 1 (italics added).

20. National Institutes of Health/Public Health Service, "The Institutional Guide to DHEW Policy on Protection of Human Subjects" (Washington, D.C.: DHEW Publication No. (NIH) 72–102, 1971), 7 (italics added).

21. Albert R. Jonsen, Mark Siegler, and William J. Winslade, *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (New York: Macmillan Publishing Co., 1982), 69.

22. North Carolina General Statutes, Section 90–21.13 (1975), (Cumulative Supplement, 1984). Similar statutes making signed consent forms presumptively valid exist in a number of states.

23. Jay Katz, "Disclosure and Consent," in A. Milunsky and G. Annas, eds., *Genetics and the Law II* (New York: Plenum Press, 1980), 122, 128.

24. We have already noted that Katz's "idea" of informed consent—as the active involvement of patients in the medical decisionmaking process—is different from our $\text{sense}_1$.

25. Alan Stone provides another instructive example of the need to distinguish $\text{sense}_1$ and $\text{sense}_2$. He argues that "informed consent is a legal fiction which in reality serves three social policy goals that have no relation to individual autonomy or freedom of choice." This comment is more provocative and misleading than is merited because of Stone's failure to distinguish between $\text{sense}_1$ and $\text{sense}_2$. Stone apparently means to argue that federal and institutional policies rarely, if ever, are adequate to insure autonomous decisionmaking and are generally motivated by quite different "policy goals." (In Stone's analysis, these goals include banning forms of research, compensating injured patients and subjects, and turning the doctor-patient relationship into a more contractual one.) One can agree with Stone that informed consents in $\text{sense}_1$ are rarely obtained and that this is lamentable, while at the same time noting that effective consents in $\text{sense}_2$ are *commonly obtained*, however flawed they may be by the standards of $\text{sense}_1$. Alan A. Stone, "The History and Future of Litigation in Psychopharmacologic Research and Treatment," in D.M. Gallant and Robert Force, eds., *Legal and Ethical Issues in Human Research and Treatment: Psychopharmacologic Considerations* (New York: SP Medical & Scientific Books, 1978), esp. 32, and also his "Informed Consent: Special Problems for Psychiatry," *Hospital and Community Psychiatry* 60 (1979): 321–27.

26. See Loren Roth, Alan Meisel, and Charles W. Lidz, "Tests of Competency to Consent to Treatment," *American Journal of Psychiatry* 134 (1977): 279–85, esp. 284; and Meisel, "What It Would Mean to be Competent Enough to Consent to or Refuse Participation in Research: A Legal Overview," in Natalie Reatig, ed., *Proceedings of the Workshop on Empirical Research on Informed Consent with Subjects of Uncertain Competence*, (Rockville, MD: National Institute of Mental Health, January 12, 1981), 32–71.

27. Our definition is indebted to Culver and Gert, *Philosophy in Medicine*, Chapter 3.

28. See *Rennie* v. *Klein*, 462 F.Supp. 1131 (D.N.J. 1978).

29. See Daniel Wikler, "Paternalism and the Mildly Retarded," *Philosophy and Public Affairs* 8 (Summer 1979): 377–92, and reissued as "The Bright Man's Burden," in Ruth Macklin and Willard Gaylin, eds., *Mental Retardation and Sterilization* (New York: Plenum Press, 1981), 149–66. Wikler's analysis requires a distinction between a *relativist* conception of competence (people are more or less competent) and a *threshold* conception (people above the threshold are equally competent).

30. See Roth and Meisel, "What We Do and Do Not Know About Informed Consent;" Paul S. Appelbaum and Loren Roth, "Competency to Consent to Research: A Psychiatric Overview," *Archives of General Psychiatry* 39 (August 1982): 951–58; Roth, Meisel, and Lidz, "Tests of Competency to Consent to Treatment;" Ruth Macklin, "Some Problems in Gaining Informed Consent from Psychiatric Patients," *Emory Law Journal* 31 (Spring 1982): 360–68; Paul S. Appelbaum, Stuart A. Mirkin, and Alan L. Bateman, "Empirical Assessment of Competency to Consent to Psychiatric Hospitalization," *American Journal of Psychiatry* 138 (September 1981): 1170–76; Paul S. Appelbaum and Loren H. Roth, "Involuntary Treatment in Medicine and Psychiatry," *American Journal of Psychiatry* 141 (February 1984): 202–205.

31. For a discussion of a broad range of issues on the subject of children and competence to consent, see Gary B. Melton, Gerald P. Koocher, and Michael J. Saks, eds., *Children's Competence to Consent* (New York: Plenum Press, 1983).

32. See Willard Gaylin, "The Competence of Children: No Longer All or None," *Hastings Center Report* 12 (April 1982): 33–38, esp. 35. For similar reasoning with an adult patient, see *Lane* v. *Candura* 376 N.E. 2d 1232 (Mass. App. 1978), and Virginia Abernethy, "Compassion, Control, and Decisions about Competency," *American Journal of Psychiatry* 141 (1984): 53–58, esp. 56.

33. President's Commission, *Making Health Care Decisions*, Vol. 1, 60.