Government Oversight

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A well-developed ethical theory provides a framework of principles within which an agent can determine morally appropriate actions.[1]

o'ver sight n superintendence, watchful care, supervision[2]

INTRODUCTION: FORMS OF OVERSIGHT

There are several levels at which the government "supervises" the activities of biomedical and behavioral researchers.[3] The most pervasive and familiar form of regulatory oversight is the complex web of institutional, State and federal regulations governing research in all of its forms, including biomedical and behavioral human subjects research. Designed to assure that research is evaluated and performed in an ethical, competent and professional manner, their viewpoint is "prospective"; that is, their goal is to *avoid* problems by providing mechanisms which will flag inappropriate practices, behaviors, and research designs before damage is done.

At the next level is tort law. Operating under standards of care defined by State law, its focus is "retrospective"; that is, it is designed to compensate for harms which result from the breach of a legal duty. The threat of malpractice liability is a significant one for all professionals, especially medical practitioners and researchers. As a result, the States have undertaken the difficult task of striking a delicate balance between the need to compensate individuals in a fair and timely manner for harms done, and the inherent uncertainties of professional practice.

At the foundational level is the realm of morality, ethics and professional responsibility. It is here that we find the basis for the entire system of government oversight; for law and regulation are merely the means by which important individual and social interests, including morality, are protected. In graphic form, the system can be represented as an inverted triangle (Figure 1).

This paper has two main parts. The first, designated "Part Two" will address briefly the forms of oversight which are common to all forms of biomedical research. The second, designated "Part Three" will discuss oversight issues related to vulnerable subjects; and the paper will conclude with a short discussion of the central question which faces those concerned with the ethics of neurobiological research involving vulnerable human subjects: What kind of "professional rela-

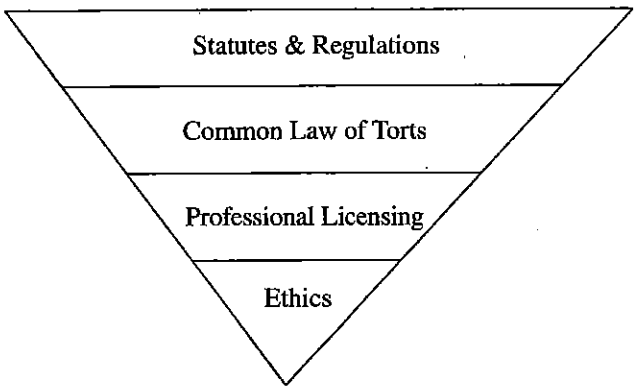

Figure 1.

tionship" exists between subject and researcher when the nature of the subjects' condition is such that there are grave questions concerning their mental facilities?

OVERSIGHT ISSUES COMMON TO ALL BIOMEDICAL AND BEHAVIORAL RESEARCH

Reviewing Issues at the "Core" of Law and Regulation

Before addressing specific "oversight" questions, it will be worthwhile to review several of the core ethical concepts relevant to biomedical and behavioral human subjects research. The laws, administrative regulations, and codes of professional ethics which govern the field are rooted in specific understandings related to the following[4]:

1. "Duty"
2. Respect for the Dignity of Human Persons, including
   2.1. Nonmalificence
   2.2. Beneficence, and
   2.3. Justice
   2.4. Autonomy
3. Truthfulness
4. Fidelity

"*Duty*" is defined by Webster as "1. that which a person is bound, by any moral or legal obligation, to pay, do or perform...; 2. the moral or legal obligation to follow a certain line of conduct, or to do a certain thing;...".[5] The concept lies at the heart of codes of morality, professional ethics and tort law.[6]

Respect for the Dignity of Human Persons covers a wide range of territory, including the key principles of nonmaleficence (do not inflict harm), beneficence (the prevention and removal of evil or harm, as well as the doing or promotion of good), justice ("giving to each his due") and autonomy (i.e., respect for individuals as moral agents).[7]

Though it is certainly possible to include *truthfulness* as a virtue which is re-

quired in any relationship with another human person,[8] it is particularly relevant in the context of professional relationships, where the specialized knowledge or experience of the professional is the basis for the relationship between the parties.[9]

The virtue of *fidelity* is included in this list because it is a key concern of every professional code of ethics.[10] Because it is the foundation of the duty of confidentiality, the duty to avoid conflicting interests, and the duty to serve as an advocate for client or patient interests, the voluntary assumption of a duty of loyalty marks the starting point for most professional relationships.[11]

Regulatory Controls Relating to the Integrity of the Research Process

There are a host of government regulations which relate to the general integrity of the research process. Among these are institutional and federal regulations which prohibit financial fraud and abuse,[12] including conflicts of interest,[13] and institutional, administrative, and other rules which prohibit research and other forms of academic fraud.[14]

Regulations Governing Human Subjects Research

Professor Jesse Goldner has noted that in order to "understand the scheme which currently controls the circumstances under which biomedical and behavioral research involving human subjects can take place, there is a need to have some familiarity with (1) the recent history of formal experimentation with human subjects and (2) the ethical principles which have now been identified as necessarily underlying the conduct of such research."[15] It is important to underscore that observation here. Laws and regulations are, in a sense, the tip of the iceberg; for they are the *result* of bitter experience both at home and abroad,[16] extensive debate in Congress leading to the passage of the National Research Act[17] and the submission of *The Belmont Report*,[18] and continuing oversight by federal and state agencies charged with oversight of human subjects research. It is impossible to debate modifications in either the scope or substantive content of these rules without first acquiring a keen sense for the evils the regulatory edifice was intended to eliminate.

Jurisdictional Issues in the Protection of Human Subjects Involved in Biomedical and Behavioral Research. Oversight of human subjects research takes place at both federal and state levels. At the federal level, the most comprehensive regulations have been issued by the agencies most directly involved in massive programs involving research with human subjects: the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA). Other agencies doing or funding human subjects research, such as the Environmental Protection Agency, and the Departments of Defense and Education, have regulations on the books as well.

Federal agencies are responsible for oversight of activities within their jurisdiction, but there are key "cross-cutting" sources of additional federal oversight as well, including the supervisory roles of the United States Department of Justice[19] and the National Institutes of Health's Office for Protection From Research Risks of

the Division of Human Subject Protections.[20] There is also "retrospective" oversight in the form of private suits for damages under either applicable civil rights laws, or the Federal Tort Claims Act,[21] and concurrent regulation under the terms of applicable State or foreign law.[22]

At present, seven states, California,[23] Wisconsin,[24] New York,[25] Delaware,[26] Montana,[27] Florida,[28] and Virginia[29] have statutes which govern human subjects research, and a bill which would "require the informed consent of human subjects as a condition of performing research involving the Commonwealth's facilities, services or funds" was submitted to the Joint Committee on Health Care of the Massachusetts House on February 28, 1994.[30] Other States have more limited laws which apply to specific kinds of human subjects research.[31] Regardless of scope or substantive content, however, all State policies governing human subjects research explicitly reference the federal guidelines, and recognize them as setting the minimum standards for acceptable research behavior.

Institutional Review Boards: Composition and Oversight Responsibilities.[32] The main "oversight" mechanism in human subjects research is the local Institutional Review Board (IRB), and the concerns which motivated the National Commission to recommend "systematic, non-arbitrary analysis of risks and benefits"[33] are clearly discernible from the federal regulations which govern their composition and function.

In summary form, the federal "assurance" requirement[34] is that IRBs be groups of highly competent professional and lay persons, who are free of direct conflicts of interest (save for those which arise from institutional loyalties), well-qualified by reference either to professional training, experience in their respective fields of endeavor, personal background, and position in the community *and* who are sensitive to the moral, cultural, legal, professional, and ethical questions which arise whenever human subjects are used in biomedical and behavioral research.[35] They must be provided with adequate staff and resources to support their review and recordkeeping activities, and with a set of written procedural guidelines for conducting their initial and continuing review of research and for reporting their findings, for keeping abreast of changes in any research activity subject to approval, for catching any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with federal regulations or IRB policy, and for suspending or terminating approval.[36] As an additional precaution, they must keep extensive records which will enable evaluators outside the IRB, whether within the institution itself or outside authority, to review the details of the IRB's deliberations.[37]

Their basic oversight duties are to assure that:

1. risks are reasonable in relation to anticipated benefits, if any, to the subjects of the research, and the importance of the knowledge to be gained, *and* that such risks be minimized to the extent consistent with sound research design and clinical practice;
2. that selection of subjects is equitable and that vulnerable populations such as children (born and unborn), prisoners, pregnant women, mentally disabled persons, or persons subject to economic or educational disadvantage, are neither unfairly targeted, nor subjected to coercion or undue influence;[38]

3. that the autonomy and privacy of all research subjects is protected by scrupulous attention to informed consent and confidentiality guidelines; and
4. that research plans include, "when appropriate...adequate provision for the monitoring the data collected to ensure the safety of subjects"[39]

Though there are specific "additional protections" which are mandated for research activities which involve the most obvious of the members of the population most vulnerable to coercion or undue influence [children and unborn children (fetuses), pregnant women, human *in vitro* fertilization, and prisoners], the basic regulations also indicate that persons with mental disabilities, or who are subject to economic or social disadvantage are also considered "vulnerable." Notably absent from the Code of Federal Regulations, however, are any specific "additional protections" designed to protect these groups.[40] Several States have taken steps to fill a small part of this void.[41]

Informed Consent

The instructions for applicants seeking Public Health Service Grants for research involving human subjects states that "[r]esearch investigators are entrusted with an essential role in assuring the adequate protection of human subjects. In activities they conduct, or which are conducted under their direction, they have a direct and continuing responsibility to safeguard the rights and the welfare of the individuals who are or may become subjects of their research."[42] The relationship between researcher and subject is, in fact and in law, the ultimate focus of the oversight process.

The detail of federal and state regulations which govern the informed consent process in research settings, the recordkeeping required of IRB in the course of their oversight responsibilities, and the tendency of lawyers and medical professionals to "cover" themselves with an appropriate "disclosure" form has led "[m]any people [to] think of consent to treatment as a form..., the document through which patients agree to procedures their physician believes are advisable or necessary. Such a definition is incorrect and misleading, and in some instances, can be dangerous."[43]

From a legal perspective, such dangers arise whenever form is elevated over substance. The concept of "informed consent" is one which reflects the balancing of right and duty which lies at the heart of both the common law of torts, and any robust understanding of professional ethics. It refers, not to forms or notations in charts, but rather to "the dialogue between the patient and the provider of services in which both parties exchange information and questions culminating in the patient's agreeing to a specific" plan of medical, surgical or other professional (including legal) intervention.[44]

Consent is necessary because the law protects both bodily integrity and human dignity (of which autonomy is but one constituent part).[45] Under the common law, any unconsented touching is a battery, while placing person in fear of being touched is an assault.[46] Where consent has been obtained on the basis of inadequate information, the common law of negligence (malpractice) provides the

remedy, and in cases where material information is *intentionally* misrepresented, withheld, or provided in a misleading manner, the consent is invalid (thus invoking the law of battery),[47] and an action for fraud or deceit may be appropriate as well.

At least insofar as medical *treatment* is concerned, the law presumes that, subject to certain constraints not relevant at this point, "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."[48] What this means in practice is that reasonable physicians and patients are free to choose, or reject, any legally and professionally acceptable therapy, even if the course of action chooses poses considerable risk to the life or the health of the patient.[49]

When the issue is biomedical or behavioral *experimentation*, however, the calculation is different, even where the experimental treatment or procedure is thought to be therapeutic. The reason is straightforward: experiments involve the unknown, and thus impose upon the treating physician or researcher additional duties of care and disclosure beyond those which exist in the normal, or even the "innovative," treatment setting.[50] The dialogue between researcher and subject must therefore be as open and as accurate as possible; for any information which might cause a reasonable *volunteer*—not "patient"—to grant or withhold consent will be deemed material.[51]

It is with this background in mind that we return to the regulations governing informed consent. Under the federal regulatory scheme, the dialogue between researcher and subject is broken into elements which include the information which must be provided to the subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any foreseeable risks or discomforts to the subject.
3. A description of the possible benefits to the subject or to others which may be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and, in the case of FDA research, the possibility that the FDA may inspect the records.
6. For research involving more than minimal risk,[52] an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.[53]

That these disclosures relate to "material" facts a "reasonable volunteer" (or even a "reasonable person") would want to know before deciding to participate should be obvious. Equally important are the facts contained in a list of additional elements to be disclosed to each subject "when appropriate."[54] This information includes:

1. A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.[55]

One need only look at the sheer volume and complexity of the information to be disclosed to appreciate the great difficulties inherent in attempts to obtain a truly "informed" consent under the best of circumstances. Even healthy, competent persons without any disabilities or other factors in their personal history which would make them vulnerable may have difficulties understanding the information disseminated to them. When investigators play "hide the ball," there may be no consent at all.[56]

OVERSIGHT AND VULNERABLE POPULATIONS

It is against this backdrop that we must consider the rules to be applied to vulnerable populations. Though the basic ethical and legal issues are the same for all research involving human subjects, the addition of *any* "vulnerability factor" whatever raises very serious issues which strike at the moral foundation of the entire regulatory enterprise. Dr. Jay Katz, for example, has written that "the celebrated *Belmont Report* on principles and guidelines for human research is confusing by not making clear distinctions between the principles that should govern research with competent and incompetent persons."[57] He notes that the *Report*'s reliance on the three basic principles of "respect for persons, beneficence, and justice" as the basis for a balancing of benefits and burdens gloss over our understanding that "the point of Kantian principles is precisely to say that certain things cannot be 'balanced out,' *i.e.*, if certain actions are unjust or disrespectful of persons then they are wrong and therefore simply should not be done."[58] The trick, of course, is to agree on a set of rules, the violation or compromise of which will be branded as unethical *per se*.[59]

I will assume, for present purposes, that all parties will agree that the requirement that "informed consent" be obtained prior to commencing research on a human subject is, regardless of its philosophical grounding, just such a rule. We

must, therefore, consider the manner in which various vulnerability factors affect this critical requirement.

Some of these factors are relatively straightforward ones that affect the ability of the individual to understand the information given, and hence limit that person's ability to give an *informed* consent. Such factors can range from simple language differences which can be overcome by retaining competent translators, to far more serious questions involving the use of language which may, due to its technical or specialized nature, be inaccessible even to well-educated persons who are not medical specialists.[60] Even more difficult are problems involving persons who may *never* understand either the substance or the significance what they are being told because of capacity problems stemming from age (children or elderly persons), mental or developmental disability, and the total incompetence of those in comas or persistent vegetative states.[61] Other vulnerability issues arise because the population at issue may be uniquely susceptible to coercion, undue influence, or conflict of interest. In these cases, the question is not whether the consent is "informed," but the far more basic question of whether there is, or can be, any "consent" at all.

Oversight of "Capacity-Related" Issues

As noted in the discussion of the federal and State regulatory framework, the bulk of "oversight," insofar as it relates to vulnerable populations, occurs at the *state* level. At the most basic level are issues of "competence" which go to the ability of an individual to make legally binding decisions *at all*. "Competency, like dangerousness, is an elusive concept[, and] applying generally accepted criteria will [often] produce inappropriate results."[62] Commonly accepted factors include an individual's ability to appreciate his condition and the nature and consequences of important choices; the ability to understand information; knowledge of place, self and time; and the ability to engage in coherent, lucid discussions "are sometimes seen as the benchmarks of competency."[63] Adults are generally presumed competent unless the contrary is shown by "clear and convincing" evidence. Due to their immaturity, minors are presumed to be "legally incompetent" to make certain decisions,[64] and both State and federal regulations governing research on human subjects contain special rules which govern children as research subjects.

Closely related to issues of competence are issues of "capacity"; that is, an individual's *ability* to make specific kinds of informed decisions. Due to a medical condition or the administration of mind-altering drugs, an adult who is otherwise competent might lack capacity to make treatment or other kinds of decisions, and an individual who seems rarely, if ever, lucid might well have the capacity, on occasion, to understand the nature and consequences of the decisions he or she is being called upon to make.[65] By the same reasoning, state law also has come to recognize the capacity of certain minors, usually those considered "mature" or "emancipated", to make certain kinds of decisions concerning health care.[66]

The laws of every State provide procedures for the determination of competence and capacity, and authorize the appointment of full or temporary guardians who can make decisions for those found, in an appropriate judicial proceeding, to lack capacity. In the medical setting, however, most such determinations are made, for adults at least, "at the bedside, not in a court room."[67] For children, the issue is

necessarily more complicated, given not only the parent's guardianship rights and responsibilities, but also the constitutional right of parents to the care, custody and control of the education and upbringing of their children.[68]

Where capacity is limited by a mental or developmental disability, the issues are identical to those discussed above, but some States have gone farther, and have enacted laws which mandate that special care be taken to assure both the rights and the ethical treatment of vulnerable populations. Wisconsin, for example, has enacted its own "Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act". That law provides, among other things, that all "patients"[69] must be informed, upon admission, that they

> Have a right not to be subjected to experimental research without the express and informed consent of the patient and of the patient's guardian after consultation with independent specialists and the patient's legal counsel. Such proposed research shall first be reviewed and approved by the institution's research and human rights committee created under sub. (4) and by the department before such consent may be sought. Prior to such approval, the committee and the department shall determine that research complies with the principles of the statement on the use of human subjects for research adopted by the American Association on Mental Deficiency, and with the regulations for research involving human subjects required by the U.S. department of health and human services for projects supported by that agency.[70]

Virginia takes this reasoning one step farther, and restricts the ability of persons lacking capacity to participate in non-therapeutic research at all. Virginia follows the general rule that informed consent[71] be obtained from the person who is to be the subject. If the subject is competent, consent must be "subscribed to in writing by the person and witnessed."[72] If the subject is not competent, then consent shall be "subscribed to in writing by the person's legally authorized representative and witnessed."[73] When the subject is a minor who is otherwise capable of consent, then consent shall be "subscribed to in writing by both the minor and his legally authorized representative."[74] Nevertheless, a legally authorized representative is restricted from giving consent to nontherapeutic research[75] unless the human research committee determines that the nontherapeutic research proposed presents no more than a "minor increase over minimal risk[76] to the human subject."[77]

State law protections such as these are particularly important since they supplement, and are not preempted by,[78] existing federal regulations. Because the federal regulatory framework is largely silent on the topic of mental disability and presumes the propriety of nontherapeutic research on children and other vulnerable persons that may lack capacity to act as "reasonable volunteers", it is important to scrutinize the *entire corpus* of State laws that deal with vulnerable populations, including the elderly and people with specific illnesses, such as HIV. Though State law may not address the specific research ethics question directly, other policies such as standards governing the reasonability of parental, guardianship or surrogate decisions in the health care field, will be influential in the cases where they provide the most appropriate analogy to the issue at hand.

Oversight of Issues Relating to the Voluntariness of the "Consent" Obtained

Precisely the same calculus applies to situations in which there is a substantial question concerning the voluntariness of the consent obtained, whether because of

coercion, undue influence, or conflict of interest on the part of the guardian or surrogate decision-maker. Perhaps the most obvious examples of situations where coercion and undue influence are very real possibilities are those involving persons who live in rigorously controlled environments such as the military, prisons, or mental health facilities. It is relatively easy in these situations to envision how either the nature of the environment, the forms of control exercised over those who live there, or the manner in which either the promise of a benefit, or express or implied threats to make life difficult can make an otherwise unwilling person seem to be a "reasonable volunteer."

The possibility of undue influence, rather than direct or indirect coercion, is the concern which motivates the special rules regulating experimentation and informed consent involving persons with diminished capacity. These categories include populations with diminished capacity, including children and persons with mental or developmental disabilities (including the vulnerable elderly), and any population whose need for services is so acute that they may be inordinately willing to subject themselves to greater than normal research risks to achieve the hoped-for benefit. (Some of the controversies over the availability of certain experimental AIDS treatments come to mind here.)

In this setting, the vulnerability arises from the susceptibility of the population to suggestion, manipulation, misunderstanding, or, in the last case, to wishful thinking which may cloud rational judgment. Where the populations are vulnerable because of age or disabling condition, the regulations require the involvement of a guardian who is obligated to act in the best interests of the person under his or her care (usually, but not always, a family member). In these cases, oversight is available not only in the due course of the research protocol, but also by recourse to the procedures provided by state law for the supervision of parent and guardian decision-making. Where the vulnerability arises because of either physical or other need, such as economic or educational deprivation,[79] there is no readily discernible form of oversight other than that of the sensitivities of the membership of the IRB, the sensibilities of the research team, and the possibility of pressure from outside activists and politicians.

OVERSIGHT OF PROBLEMS RELATING TO THE ETHICS OF RESEARCHERS

The final subject which must be addressed is the nature of the professional relationship between researcher and subject. At the formal level, this is the realm of licensing and professional discipline, and the case law is sparse; for there must usually be some sort of egregious lapse before licensing authorities will intervene with even as much as an investigation.[80] Insofar as certain vulnerable populations are subjects of research, there may be civil rights concerns raised as well. This is particularly the case where the research subject is a person with a mental or developmental disability or belongs to a class of persons who have historically been subjected to discriminatory treatment as a result of societal perceptions that they (or their problems) are not worth the effort (e.g., racial minorities and women).

By their nature, these are inherently controversial topics because they raise

issues which go far beyond professionalism to the issue of personal morality itself.[81] In general, laws and regulations are concerned about the tangible impact that unethical behavior can have on the research subject, and are framed in a manner which is calculated to prevent it. They are thus the means by which the law assures at least minimal standards of behavior.

Because rules are tangible and provide relatively clear guidance, it is easy to confuse compliance with the rules with the ethical behavior they are intended to foster. This is a tendency to be avoided at all costs, for it exalts form over substance, and leads to an undue focus on the content of rules and forms[82] rather than the *behavior* of the individuals seeking consent, or granting it on behalf of others.

The preamble to the federal regulations governing prisoners,[83] for example, recognizes that special constraints on researchers are appropriate "[i]nasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research."[84] But what is it that makes special rules appropriate? The mere fact that the potential subjects may, for one reason or another, be limited in their ability to make a "truly voluntary and uncoerced decision," or the potential that researchers will allow their own self-interest, prejudice concerning the research subjects, or perception of the appropriate balance to be struck between the "public interest" and the interests of various vulnerable populations to affect their professional behavior?

That the concern is for the ethics of the researchers is apparent from the face of the entire regulatory edifice. The task of IRBs is to provide reasonably detached, multi-disciplinary "outsider" oversight of all aspects of the research, and many of the general problems with the structure and function of IRBs relate to issues of professional detachment.[85]

The impact of conflicting interests on the integrity of professional relationships is a common theme of codes of ethics, and everyone recognizes that conflicts of interest are generally to be avoided, no matter what the profession. The most subtle conflict of interest questions, in fact, are those which are not generally perceived to be conflicts of interest at all. Professionals, like everyone else, are occasionally guilty of self-deception.

The best illustrations of the subtle interplay between the ethics of professionalism and the language of regulation are those in which professional or personal interest manifests itself in behavior which is so clearly designed to foster the needs or goals of the professional that the client's interests are effectively ignored. A prime example is the prospective waiver of liability.

Both federal and Virginia regulations governing research on human subjects provide that informed consent forms may not contain "any language through which the person who is to be the human subject waives or appears to waive any of his legal rights, including release of any individual, institution, or agency or any agents thereof from liability for negligence."[86]

It is possible simply to accept the rule as a given, but that would be to miss the point: Why *should* researchers be barred from including prospective waivers from their informed consent forms? One could argue that, to the extent the consent process was "truly informed" and the prospective research subject understood the nature of the risks to be undertaken, it would not be unjust to *ask* for such an

agreement, even if, in the end, the prospective subject were to refuse to sign it. After all, respect for the principle of autonomy would seem to indicate that the prospective subject should be able to undertake such risks voluntarily, would it not?

On deeper analysis, however, such requests are clearly inappropriate. The effect of such a waiver is to place *all* of the risks on the subject, including those which may result from breaches of professional standards by those providing services. Is this an appropriate outcome? It is certainly a *possible* one under existing law should the subject be injured, yet fail or decline to enforce his or her rights. And yet, the ability of the subject to consent to a waiver of legal rights, either in exchange for a settlement or because of a lack of inclination to pursue them, does not address the professional ethics question of whether or not a professional should *seek* such waivers in the first instance.

It has been said that ethics is taking responsibility for one's actions. So, the ethical question in this context is not whether it is ethical to allocate risks and benefits in this fashion, but whether the behavior at issue—asking a potential research subject for a prospective waiver of rights—is professionally appropriate given the nature of the proposed relationship? The focus of this question is on the moral and professional duties that a professional owes to a client or patient. Because these are duties which arise because of the nature of the relationship between the professional and client or patient,[87] the consent of the subject is irrelevant. The ethical lapse is complete upon solicitation.

And what is that lapse? It is an attempt by a professional evade his or her responsibility to act in a professionally competent manner. As such, the specific ethical question has little, if anything, to do with research or the kinds of questions which are central to discussions of biomedical research ethics. Such behavior would be no more legitimate for an accountant, architect or lawyer. Under most codes of professional ethics, solicitations of "blanket consents" of this sort are "unjust or disrespectful of persons" who are or will be involved in professional relationships. They are, for that reason, "wrong and therefore simply should not be done."[88]

The same analysis holds true, but is far more subtle, when the ethical lapse is attributable to a perception of the patient or client which does not take full account of their dignity as a human person. Though the Nazi experiments and the Tuskegee syphilis study are often held up as stark reminders of the abuses which can take place when a professional "objectivizes" the human being who provides the occasion for the professional's exercise of skill and judgment to the point of dehumanizing them,[89] those cases are far too extreme to resonate with most practitioners and researchers. But the difference is really only one of degree, and the medical profession is far from alone in this tendency. The lawyers in Dickens' *Bleak House*, a tale of endless litigation in which the clients were forgotten until the fortune over which the lawyers were sparring was consumed, provide a less searing, and far more common, example from another profession where abstract interests are often given precedence over the immediate and practical interests of the persons the professionals are sworn to serve.

Ethics, in this view, is the right ordering of such relationships. When a patient or client is viewed by the professional as a condition, case, or problem—that is, as an object, rather than a person, a "professional" relationship no longer exists (save,

perhaps, in the mind of the hapless subject). As a result, the only effective "oversight" which will avoid problems such as these is the insight which comes from increased personal and institutional awareness that professional relationships presuppose a *relationship* between persons.

The rules exist to protect and foster that relationship. Problems arise when there is greater attention given to compliance with rules and abstract principles than to the human needs of our patients, clients or research subjects. Michael Ignatieff has written eloquently of the fallacy of an approach which highlights a legalistic "respect" for the autonomy of others, but which, in reality, springs, from a rather abstract conception of humanity. In *The Needs of Strangers* he cautions us:

> Woe betide any man who depends on the abstract humanity of another for his food and protection. Woe betide any man who has no state, no family, no neighbourhood, no community that can stand behind to enforce his claim of need. [King] Lear learns too late that it is power and violence that rule the heath, not obligation.[90]

NOTES

1. Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, Oxford University Press, 3d ed. 1989. p. 25.
2. *Webster's New Universal Unabridged Dictionary*, Dorset & Baber, 2d ed. 1983. 1277. The alternative definition is, ironically, "an overlooking, failure to see or notice."
3. For a comprehensive treatment of the legal and regulatory context of patients who are asked to serve as research subjects, see Jesse A. Goldner, "An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously," in *Health Law Symposium*. Legal and Ethical Controls on Biomedical Research: Seeking Consent, Avoiding Condescension, 38 *St. Louis L.J.* 3, 63 (1993) [hereinafter, Goldner, An Overview of Legal Controls on Human Experimentation]. I am indebted to Professor Goldner, not only for much of the organizational structure of this background paper, but also for his exhaustive background work. I draw on it liberally throughout the course of this paper and wish to give him credit at the outset. It is well worth reading in its entirety, not only as background, but also as a contribution to the ongoing debate over the ethics of biomedical research on competent subjects, which is the subject of the symposium in which it appears.
4. Though there are numerous other concepts, principles, and virtues which could be added to this list, the following have been selected because they form the foundation for the law and regulation which is the subject of this paper.
5. *Webster's New Universal Unabridged Dictionary*, Dorset & Baber, 2d ed. 1983. 566.
6. *Black's Law Dictionary* (6th ed., WESTLAW) indicates that "a 'tort' is broadly defined as 'a private or civil wrong or injury, including action for bad faith breach of contract, for which the court will provide a remedy in the form of an action for damages.... There must always be a violation of some duty owing to plaintiff, and generally such duty must arise by operation of law and not by mere agreement of the parties. A legal wrong committed upon the person or property independent of contract. It may be either (1) a direct invasion of some legal right of the individual; (2) the infraction of some public duty by which special damage accrues to the individual; (3) the violation of some private obligation by which like damage accrues to the individual.'"
7. These concepts are elaborated in Beauchamp and Childress, *Principles of Biomedical Ethics*, *supra* note 1, at p. 120–93; 194–255; 256–306; and 67–119, respectively.
8. See Sissela Bok, *Lying: Moral Choice in Public and Private Life*, 1979.
9. See Thomas L. Shaffer and Robert F. Cochran, Jr., *Lawyers, Clients and Moral Responsibility* 82–91 (*West*, 1993).
10. See generally Rena A. Gorlin, ed., *Codes of Professional Responsibility*, (Bureau of National Affairs, 2d ed., 1990).

11. See, e.g., American Medical Association, *Principles of Medical Ethics and Current Opinions of the council on Ethical and Judicial Affairs—1989*, Preamble, Principle IV (noting that, except in emergencies, a physician is free to choose whom to serve, with whom to associate, and the environment in which to provide service), *quoted in* Rena A. Gorlin, ed., *Codes of Professional Responsibility, supra* note 10 at 191 [hereafter "Gorlin"]. The caveat, "except in emergencies," reflects the special nature of the physician's training and the demands justice. A similar principle constrains the formation of the lawyer-client relationship. Compare American Bar Association, *Model Rules of Professional Responsibility*, Rule 1.2 (Scope of Representation) with Rule 6.2 (Accepting Appointments), in Gorlin, *op. cit.* at 339, 377.
12. 45 C.F.R. § 76 (1994)
13. See, e.g., sources cited in Goldner, *supra* note 3 at note 161: Marion J. Finkel, Should Informed Consent Include Information on How Research is Funded?, 13 *IRB* 1 (Sept.–Oct. 1991); Roger J. Porter and Thomas E. Malone, *Biomedical Research: Collaboration and Conflict of Interest*, 121–50, 163–84 (1992); Marc A. Rodwin, *Medicine, Money and Morals*, 212–16 (1993). See also Moore v. Regents of the University of California, 51 Cal. 3d 120, 793 P.2d 479 (Cal. 1990); Thomas H. Murray, Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes, 8 *IRB* 1 (Jan.–Feb. 1986).
14. 42 C.F.R. § 50.102 defines research misconduct as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing conducting or reporting research."
15. Goldner, *supra* note 3 at 90.
16. See Office of the Judge Advocate General, Dept. of the Army, *Trials of War Criminals Before the Nuremberg Military Tribunals, Vol. I and II* at 181–82 (Doctors' trial; Nuremberg Code); United States v. Stanley, 483 U.S. 669, 1987 (recounting LSD experiments by the United States Army on the late James Stanley). See generally George J. Annas and Michael A. Grodin, eds., *The Nazi Doctors and The Nuremberg Code*, 1992; Robert J. Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide*, Basic Books, 1986; United States Public Health Service, *Tuskegee Syphilis Study Ad Hoc Advisory Panel: Final Report*, Washington, D.C., April 1973.
17. The National Research Act amended the Public Health Service Act. Pub.L. No. 93-348, 88 Stat. 342, codified as amended at 42 U.S.C. §§ 201 to 300aaa-13 (1994).
18. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education and Welfare, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Pub. No. (OS) 78-0012, 1978 [hereinafter *Belmont Report*].
19. See 28 C.F.R. § 46.101 (1995).
20. See 28 C.F.R. § 46.103 (1995); 45 C.F.R. §46.103 (1995).
21. 28 U.S.C. §§1346(b), 1402,
22. See 28 C.F.R §§46.101(f)(g)(h) (indicating that federal rules do not preempt applicable state and foreign law which provide additional protections for human subjects).
23. California has a wide range of statutory protections in place. See *Cal. Health & Safety Code* §§24170 to 24177 (Deering 1994) ("Human Experimentation); *Cal. Health & Safety Code* §26668.6 (requires that prior to administering or prescribing an experimental drug, consent must be obtained according to the guidelines set forth in the Chapter on Human Experimentation); *Cal. Penal Code* §3521 (Deering 1994) (experiments involving prisoners).
24. *Wis. Stat.* §51.61 (1993).
25. *McKinney's Consol. New York Pub. Health Law* §§ 2441–2445 (1994).
26. *Del. Code Ann.* tit. 16 §§5171–75 (1994).
27. *Mont. Code Ann.* §§ 53-21-104, 53-21-147 (1993).
28. Florida Biomedical and Social Research Act, *Fla. Stat.* ch. 402.105 (1993).
29. *Va. Code Ann.* §§ 32.1-162.16, 32.1-162.19, 32.1-162.20 (Michie 1994).
30. 1994 Mass. H.B. 4609, 179th General Court. To date, no action has been taken on the Bill.
31. See, e.g., *D.C. Code* § 6-1969 (1994) (rights of mentally retarded citizens); 20 *Ill. Comp. Stats* 301/30-5 (Michie 1994) (creating a Patient's Bill of Rights for individuals in alcoholism treatment, and requiring that "[b]efore a patient is placed in an experimental research or medical procedure, the provider must first obtain his informed written consent or otherwise comply with the federal requirements regarding the protection of human subjects contained in 45 C.F.R. Part 4"); Montana

Code Ann. §53-20-147 (1994) (assuring the right of residents of residential facilities "not to be subjected to experimental research without the express and informed consent of" either the resident or their authorized guardian).

32. Because there is an extensive literature concerning IRBs, the review which follows will be limited to highlighting only those issues which are of particular relevance to the subject of this conference.
33. *The Belmont Report, supra* note 18 at 16.
34. 45 C.F.R § 46.103 (1994). Assurances are provided to the Office for Protection from Research Risks (OPRR) at the National Institutes of Health. See 45 C.F.R. § 46.101(i). See United States Department of Health & Human Services, Application for Public Health Service Grant (PHS 398; OMB No. 0925-001), Section E(1)(a), p. 25.
35. 21 C.F.R. §56.107 (1994); 45 C.F.R § 46.107 (1994). According to the FDA and DHHS regulations,

> (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to renew specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about the experienced in working with those subjects.
>
> (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
>
> (c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
>
> (d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
>
> (e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
>
> (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

36. Id., 45 C.F.R §§46.103(b)(4, 5) (1994).
37. 45 C.F.R §46.115 (1994). See also 45 C.F.R §§46.112 (internal review), 46.114 (cooperative research oversight).
38. See also 45 C.F.R §§ 46.201-211 (1992) (pregnant women, unborn children (fetuses) and human *in vitro* fertilization); 46.301-306 (prisoners); 46.401-409 (children); 45 C.F.R §46. 111(b) (economic or educationally disadvantaged persons). There are no specific federal regulations provisions which address the specific concerns of persons with mental disabilities.
39. 45 C.F.R §46.111 (1994).
40. Federal regulations which would have covered institutionalized persons with mental disabilities were proposed in 1978, 43 Fed Reg. 53, 9570, but no final rules were adopted.
41. See, e.g., *Cal. Welf. & Inst. Code* §4514 (1994) (informed consent requirements for persons with developmental disabilities); *Montana Code* §53-20-104 (1993) (Mental Health Board of Visitors to oversee "all plans for experimental research or hazardous treatment procedures involving persons admitted to a residential facility"); Wisconsin State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act, *Wisconsin Stats.* §51.61 (1994) (rights of mental patients, regardless of locale of treatment).
42. United States Department of Health & Human Services, Application for Public Health Service Grant (PHS 398; OMB No. 0925-001), Section E(1)(a), p. 26.

43. Fay A. Rozovsky, J.D., M.P.H., *Consent to Treatment: A Practical Guide*, Little, Brown & Co. 2d ed., 1990. p. 3 (hereafter Rozovsky, *Consent to Treatment*).
44. Id. In the lawyer-client setting, Tom Shaffer and Bob Cochran refer to this discourse as a "moral conversation" See Shaffer & Cochran, *supra* note 9 at 1 ("Law office conversations are almost always moral conversations. This is so because they involve law, and law is a claim that people make on one another. The moral content is often implicit, but it is always there.... If it is possible for a serious conversation between a lawyer and a client in a law office to be without moral content, we cannot think of an example.")
45. See text accompanying notes 4 to 9, *supra*.
46. W. L. Prosser, *Law of Torts* § 10 (West, 4th ed., 1971).
47. See Rozovsky, *Consent to Treatment*, *supra* note 43 at 10, citing Krueger v. San Francisco Forty-Niners, 234 Cal. Rptr. 579, 584 (Cal. App. 1987) (in its zeal to keep Mr. Krueger playing, the team "consciously failed to make full, meaningful disclosure to him respecting the magnitude of the risk he took in continuing to play a violent contact sport with a profoundly damaged left knee.")
48. Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 129–30, 105 N.E. 92, 93 (1914) (Cardozo, J.).
49. The literature on refusal, withdrawing and withholding treatment is immense, and will not be discussed here except to the extent that it casts some light on the reasons *why* treatment can (or should) be refused withdrawn or withheld.
50. Professor Goldner's article, An Overview of Legal Controls on Human Experimentation, *supra* note 3 at pp. 70–88, contains an excellent discussion of the development of legal standards distinguishing experimentation from standard therapeutic treatments.
51. The National Commission proposed that the standard for medical care (a "reasonable person" making information concerning medical care) was "insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care." It therefore proposed "a standard of 'the reasonable volunteer'...: because

    the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

    The Belmont Report, *supra* note 18, at 11, quoted in Goldner, *supra* note 3 at 97–98
52. " 'Minimal risk' means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," 21 C.F.R. §50.3 (1994); 45 C.F.R. §46.102(i).
53. 21 C.F.R. §50.25 (1994) (FDA); 45 C.F.R. § 46.116.
54. Id.
55. Id.
56. See, e.g., Halushka v. University of Saskatchewan, 52 W.W.R. 608, 617 (Sask. 1965) (subject told that test was "safe", even though no test had ever been run. The court treated the statement as a "non-disclosure" of the material fact that the researcher did not know whether the test was safe or not.)
57. Jay Katz, M.D., Human Experimentation and Human Rights, in *Health Law Symposium*, Legal and Ethical Controls on Biomedical Research: Seeking Consent, Avoiding Condescension, 38 *St. Louis L.J.* 3, 7, 30 n. 71 (1993).
58. Id., quoting Ernest Marshall, Does the Moral Philosophy of the *Belmont Report* Rest on a Mistake?, 8 *IRB* 5–6 (Nov.–Dec. 1986) at p. 6.
59. See Beauchamp and Childress, *supra* note 1 at 44–47 (discussing the importance of selecting an ethical theory, and summarizing the differences between consequentialist and deontological theories.) They go on to note, in language which is particularly relevant here that

    Theoretical differences can, of course, eventuate in practical disagreements and in different general policies. For example, we shall see throughout this volume that utilitarians tend to support various types of research involving human subjects on grounds of the social benefits of the research for future patients. Deontonlogists, by contrast, tend to be skeptical of some of this research on grounds of its actual or potential violation of individual rights, which are ground in principles of respect for autonomy and protection against harm.

60. Even though the general requirements for informed consent require that "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative," 45 C.F.R § 46.116 (1994), this is not an uncommon problem in many informed consent settings, including those which are not normally viewed as requiring "informed consent" at all—such as the sale of corporate securities. See, e.g., United States Securities and Exchange Commission, Rule 10b-5 (requiring that disclosures be made in language which is sufficiently complete so as not to be misleading.) The regulations involving prisoners make it clear that any information be "presented in language which is understandable to the subject population." 45 C.F.R. § 46.305(a)(5) (1994).
61. The UCLA research study involving schizophrenia research raises many of these questions. The NIH Office for Protection from Research Risks, Division of Human Subject Protection found that neither the informed consent documents nor the extended oral informed consent process complied with "the requirements of HHS regulations.... " What is interesting about the specific findings is that they target *both* the investigators themselves (who are ultimately responsible under both state and federal law for the quality and content of the informed consent process) *and the UCLA School of Medicine IRB.*
62. Rozovsky, *Consent to Treatment, supra* note 43 at p. 674–675.
63. Id.
64. *See* id., at pp. 257–259,
65. See, e.g., Lane v. Candura, 6 Mass. App. Ct. 477, 376 N.E.2d 1232 (1978) (elderly woman who made medically irrational decisions, who had a distorted concept of time, whose mind wandered, and who was confused about details was nevertheless competent because, during her lucid periods, she was fully aware of the nature and consequences of her treatment choices).
66. See generally Rozovsky, *Consent to Treatment, supra* note 43 at pp. 259–360.
67. The New York State Task Force on Life and the Law, *When Others Must Choose: Deciding for Patients Without Capacity*, 1992, at p. 28.
68. See generally Jonathan O. Hafen, Book Note, *The Transformation of Family Law: State, Law, and Family in the United States and Western Europe*, by Mary Ann Glendon (Chicago and London: The University of Chicago Press, 1989) 1991 *B.Y.U. L. Rev.* 719; Bruce C. Hafen, The Constitutional Status of Marriage, Kinship, and Sexual Privacy; Balancing The Individual and Social Interests, 81 *Mich. L. Rev.* 463 (1983); Robert H. Mnookin, *In the Interest of Children: Advocacy, Law Reform, and Public Policy*, New York: W.H. Freeman & Co., 1985
69. Wis. Star. 51.61 (a) provides that the term "patient" includes

    any individual who is receiving services for mental illness, developmental disabilities, alcoholism or drug dependency, including any individual who is admitted to a treatment facility in accordance with this chapter or ch. 55 or who is detained, committed or placed under this chapter or ch. 55, 971, 975 or 980, or who is transferred to a treatment facility under §51.35(3) or 51.37 or who is receiving care or treatment for those conditions through the department or a county department under s. 51.42 or 51.437 or in a private treatment facility. "Patient" does not include persons committed under ch. 975 who are transferred to or residing in any state prison listed under § 302.01. In private hospitals and in public general hospitals, "patient" includes any individual who is admitted for the primary purpose of treatment of mental illness, developmental disability, alcoholism or drug abuse but does not include an individual who receives treatment in a hospital emergency room nor an individual who receives treatment on an outpatient basis at those hospitals, unless the individual is otherwise covered under this subsection.

70. *Wis. Stats.* 51.61(j) (1994).
71. Under Virginia law, "'Informed consent' means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include: (1) A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected; (2) A disclosure of the any appropriate procedures or therapies that might be advantageous for the person; (3) An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;

(4) An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and (5) An offer to answer and answers to any inquiries by the person concerning the procedures an protocols." *Va. Code Ann.* § 32.1-162.16.

72. *Va. Code Ann.* §. 32.1-162.18 (1994).
73. Id.
74. Id.
75. " 'Nontherapeutic research' means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject." *Va. Code Ann.* § 32.1-162.16 (1994).
76. *Va. Code Ann.* § 32.1-162.18(B). Like most States, Virginia borrows key definitions from extant federal regulations governing the same topic. Thus, for purposes of Virginia law, the term "minimal risk" has the same meaning as in the FDA and DHHS regulations. Compare *Va. Code Ann.* § 32.1-162.16 with 45 C.F.R. §46.102(i) (1994).
77. *Va. Code Ann.* §32.1-162.18. This is not unlike the federal rules governing research on children, 45 C.F.R. §46.406 (1994), but is generalized for all informed consent obtained from a legally authorized representative.

    There is also a provision regarding the use of force, which states, "Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of rendering informed consent shall be forced to participate in any human research. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force." Id.
78. See 45 C.F.R. § 46.116(e) ("The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.")
79. 45 C.F.R. §46.111(b) (economic or educationally disadvantaged persons).
80. See Goldner, *supra* note 3 (collecting sources).
81. Some of the same issues arise in the highly-charged area of medical care discrimination, and the related, but conceptually distinct, areas of health care rationing and the ethics of withholding and withdrawing medical treatment.
82. See text at note 43 *supra*.
83. A "prisoner" is anyone who is incarcerated involuntarily in a penal institution, regardless of the nature of the authorizing legislation, or the status of the proceeding. See 45 C.F.R. § 46.303 (1994).
84. 45 C.F.R. §46.302 (1994).
85. See generally Goldner, *supra* note 3, at pp. 102–112 and nn. 242–310 (collecting sources).
86. 45 C.F.R. §46.116 (1994); *Va. Code Ann.* § 32.1-162.18.
87. Beauchamp & Childress are of the view that '[m]ost obligations of positive beneficence in health care rest on fidelity-generating contracts and role relations." Beauchamp and Childress, *supra* note 1 at p. 341. They reject attempts "to capture relationships between health-care professionals and patients in any single metaphor or mold such as contractors, partners, parents, friends, or technicians" because "[n]o single metaphor or model adequately expresses the complexity of health care or the moral principles and rules that should govern such relationships." Id. at p. 341–42.
88. See notes 57–58, *supra*. Though it has been argued by some philosophers that the autonomy principle must be taken to mean that "consent cures" in many situations which might otherwise be defined by others as unethical or immoral, see, e.g., H. Tristam Engelhardt, Death By Free Choice: Variations on an Antique Theme, in Baruch Brody, ed., *Suicide and Euthanasia*, Dordrecht: Kluwer Academic Publishers, 1989, 251, 264–65, and some professions will permit conflicts of interest to continue if the client has consented after "full disclosure" of the limitations and risks caused by the conflict, compare, e.g. American Bar Assn., *Model Rules of Professional Responsibility*, Rules 1.7 to 1.9 (1994), with, e.g., American Association for Counseling and Development, *Ethical Standards*, Section B ¶¶ 12–14 in Gorelin, *Codes of Professional Responsibility*, *supra* note 10, at p. 228 (permitting certain conflicts only where other alternatives are unavailable, and those which might impair objectivity or professional judgment "must be avoided and/or the counseling relationship terminated through referral to another competent professional."), "prospective" or "prophylactic" oversight can also be

justified on informed consent grounds. In order to secure an "informed consent" to such a waiver, the professional would necessarily need to disclose not only his or her professional qualifications, but also a relatively detailed summary of the kinds of negligence which might reasonably be expected to occur. Since, in the normal professional setting, a *reasonable* expectation is that *no* negligence will occur, it follows that a competent professional will rarely, if ever, discuss the possibility during the solicitation or informed consent process.

89. See Jay Katz, *supra* note 57, at 30, quoting Edmund D. Pellegrino, Beneficence, Scientific Autonomy and Self-Interest: Ethical Dilemmas in Clinical Research, *Geo. Med.* 21 (1991).
90. Michael Ignatieff, *The Needs of Strangers An Essay on Privacy, Solidarity, and the Politics of Being Human*, New York: Viking Press, 1984; London: Chatto & Windus, The Hogarth Press, 1984, at 53.