INFORMED CONSENT IN HUMAN EXPERIMENTATION:
BRIDGING THE GAP BETWEEN ETHICAL THOUGHT
AND CURRENT PRACTICE

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Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice

Richard Delgado and Helen Leskovic

There is almost universal agreement that the requirement of informed consent should be applied more rigorously in connection with experimental procedures, or "research," than with standard medical or psychological treatments. The reasons usually given for the greater rigor include that the consequences of experimentation, by definition, are not known in advance and hence only the subject can decide whether or not to undergo an unknown degree of risk; that the subject of research is unlikely to benefit directly from it and thus cannot be presumed to consent to it; and finally, that the researcher's and the subject's interests are often opposed, since the scientist's primary objective is to pursue new
knowledge and the gains that come with it, while the human subject may have a mixture of goals.<5>

Despite agreement that consent in human research ought to be highly protected, the principal mechanism for effectuating that protection, Institutional Review Boards (IRBs),<6> does so imperfectly. The regulations under which IRBs operate make the principal investigator responsible for obtaining informed consent,<7> eliminate the requirement entirely in certain types of research,<8> and provide no adequate remedy in the event of violation.<9>

Part I of this article reviews the current approach to protecting human subjects of biomedical and behavioral research. Part II reviews the reasons usually given for protecting consent in human research and offers three new reasons. The combination of new and old reasons makes a compelling case for protecting consent in research settings more highly than it
currently is. Part III shows how the federal regulations can be amended to provide enhanced protection for informed consent and suggests a new, judicial remedy that victims may use when the regulations are breached.

{311. The Current Approach to Regulation of Human Subjects Research}

This part reviews current treatment of informed consent in human experimentation. Section A outlines the United States Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) guidelines for institutional review of research involving human subjects. Section B discusses the deficiencies of the guidelines in protecting consent. Section C revies the small body of case law dealing with informed consent in human research.

{32A. Federal Oversight of Research with Human Subjects}
The current federal approach to regulation

human-subject research stems from the late 1960's and
early 1970's when an influential article by Henry K.
Beecher<10> and public disclosure of abuses in
research, such as the Tuskegee syphilis study,<11>
accelerated the demand for controls. Federal
guidelines were first promulgated in 1974 following
extensive discussions and public comment, and have been
amended several times.<12> Their latest form appears
in titles 21 and 45 of the Code of Federal Regulations.

Research institutions, as a condition of federal
funding, must file an "assurance" that research will
meet federal ethical standards and requirements for
informed consent.<13> In addition, institutions must
establish institutional review boards (IRBs),
university committees composed of a cross-section of
university faculty and lay representatives.<14> The
IRBs meet at regularly scheduled intervals to review
proposed and ongoing research projects. The IRB members must have varied backgrounds to ensure racial and cultural diversity, and they must not have conflicting interests that might affect their judgment. In addition, they must determine whether the selection of subjects is "equitable," so as to prevent over-reliance on groups with little political representation and power.

Among the principal tasks of the IRB is review of research proposals to assure informed consent. The regulations in their present form do not define informed consent, but identify eight elements of it and give the IRB broad discretionary powers to require additional ones as well. The regulations require that the human subject be informed of (1) the purposes of the research, the procedures to be used and whether or not they are experimental; (2) the risks and discomforts to the subject; (3) the benefits the
subject or others may receive from the research; (4)
alternative treatments if the research has a treatment component; (5) the extent of the subject's protection from identification in records; (6) compensation offered or treatment available in "research involving more than minimal risk"; (7) the identity of an individual whom the subject may contact respecting the research, his rights, and treatment for any research-incurred injury; (8) the subject's right to terminate participation at any time without loss of any benefits that he or she would otherwise be entitled to.<20>

In addition, the IRB may require the researcher to provide information that there may be unforeseeable risks to the subject and to the embryo or fetus of a woman who is or may become pregnant; circumstances in which a researcher may terminate the subject's participation without consent; additional costs to the
subject; the effect of the subject's determination to withdraw to withdraw from the project and procedures for doing so; information regarding new findings while the research is in progress that might affect the subject's decision to continue participating; and information as to the number of subjects in the project.<21> Since 1981, the consent procedure must be followed not only when the subject participates in the project but also when his or her blood or bodily tissue is used in an experiment.<22>

Consent is not required in certain situations, however. These include research that presents minimal or no risk to the subject.<23> This determination, made by the researcher or the IRB<24> affects a great deal of research, especially in the social sciences, where, for example, existing records and observational data are gathered. Research related to the evaluation and effectiveness of government benefit programs is
also exempt.<25>

{s2D. Deficiencies of the Current Approach to
Protecting Informed Consent in Human Research}

The HHS guidelines represent a clearcut advance
over the relatively unguided situation that prevailed
before their adoption. Many of their features are
commendable—for example, inclusion of lay
representatives on review panels.<26> recognition of
the special dangers of research on children and captive
populations.<27> and provision for risk-benefit review
by a panel of persons other than the investigating
team.<28> Yet, the central provisions of the
guidelines—those pertaining to informed consent—are
curiously deficient. The guidelines make the principal
investigator the person primarily responsible for
obtaining informed consent from human subjects.<29>

They provide that the requirement is waived entirely in
certain types of research.<30> And, they provide
little in the way of an effective remedy when informed consent is not obtained.\(^{31}\) As Part II will show, the importance of protecting human subjects' autonomy is greatest in connection with experimental procedures. The weaknesses in the current requirements accordingly warrant prompt attention.

\(^{32}\) Placement of the responsibility for obtaining informed consent on the principal investigator.

The regulations provide that research with human subjects may not be carried out "unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."\(^{32}\) Elsewhere the regulations speak of obtaining valid consent as a duty falling on the principal investigator.\(^{33}\) Although the researcher must prepare a consent form and obtain the IRB's approval of it,\(^{34}\) the researcher is thereafter left free to discuss the experiment with the
subject, explain the terms contained in the consent form, and answer any questions the subject may have— all without monitoring by the IRB. It is easy to see how permitting the principal investigator to carry out these tasks could subvert the goals of human subjects protection. The investigator could, for example, answer questions evasively or convey by words or gestures, that participation was expected, or that the risks were minimal when in fact they were not. These failures, which may be conscious or unconscious, often stem from differences in perspective between the investigator and subject and are discussed in Part II as instances of a "conflict of value" inherent in the research situation.

{s22. Waiver of the requirement of informed consent in connection with certain categories of research.}

The regulations provide that the investigator is relieved of the duty to obtain informed consent from
his or her subjects in certain situations. These
include most educational research, research
involving surveys and interviews, research that
consists mainly of observing public behavior, and
research using existing records or data. These
types of research are exempt entirely from HHS and IRB
review. In addition, the requirement of informed
consent may be modified or waived when the research
concerns an evaluation of certain governmental
programs or meets designated conditions in research
that present no more than minimal risk to the subjects
and "could not practically be carried out without the
waiver or alteration." The latter exception is
particularly worrisome. Designed to permit "deception
research," it allows the researcher a great deal of
discretion to carry out programs of research that may
cause demonstrable psychological or emotional harm to
the subjects. Although certain special

(not entirely" because if they may be covered by subparts of the
regs. 46 C.F.R. § 46.101(b).)

(It is only an influence that the reg's were designed to permit deception
research. Nothing about deception was even mentioned in
the Fed. Reg. text of the regs and accompanying material. See
Dresser's discussion in "Deception Research and the Federal
HHS Final Regs. in IRB")
requirements come into play when an IRB reviews proposals for deception research, these do not seem adequate to eliminate the risk of humiliation, anger, cynicism, and sense of betrayal that may result from such research.

{s23. Lack of an effective remedy.}

A final deficiency of the current regulations pertaining to informed consent is that they provide no effective remedy when a researcher or institution breaches them. If a research subject is injured in the course of research, whether from failure to obtain informed consent or otherwise, some institutions offer medical or psychological treatment for the harm the subject has suffered. If a researcher flagrantly violates a condition of his or her research protocol, including those having to do with consent, the IRB may report the researcher to campus authorities for disciplinary action. The federal government,
especially if it believes that the institution has been
lax in dealing with the researcher, may impose
sanctions of its own, such as terminating a grant or
refusing to issue a new one to the offending researcher
or team.<sup>47</sup> Aside from these, the regulations provide
no remedy for the victims of unconsented-to research.

A few commentators have argued that a private cause of
action could be implied from the regulations,<sup>48</sup> but
no appellate courts seem to have considered the
question. Those few decisions from common-law
jurisdictions that have provided redress for human
subjects injured by research proceed on other grounds.

[<sup>42</sup>C. Case Law Affording Redress for Human Subjects of
Unconsented-to Research]

Protection of informed consent to research in
the United States has been influenced by a Canadian
case,<sup>49</sup> <i>Halushka v. University of Saskatchewan</i>.<sup>50</sup>

Halushka was an engineering student who sought a summer
job through the university's employment office. Unable
to find work, he followed the office's advice and
volunteered to be the subject of a test sponsored by
the medical school's anesthesia department in return
for payment of $50. Halushka alleged that the
principal researcher told him he would be taking a safe
test that had been conducted before. He was told that
electrodes would be implanted and a catheter inserted
into a vein in his left arm to test a new anesthetic
drug. In the procedure actually followed, the catheter
was advanced up the arm into Halushka's heart, where
the anesthetic was first administered, and out into the
pulmonary artery. Less than an hour later, Halushka
suffered complete cardiac arrest. The researchers
attempted to resuscitate him by open heart massage.
Although his heart began to function again after one
minute and thirty seconds, Halushka alleged that he
suffered lingering effects, including loss of
concentration and ability to reason. He sued for
trespass to the person and negligence, and was
awarded judgment for $22,500. On appeal, the court
upheld the award because the information Halushka
received was so incomplete as to amount to
non-disclosure.

The Canadian court supported its conclusion by
citing well-known principles of informed consent
recognized in American cases dealing with standard
medical treatments, supporting the right of human
subjects to be fully informed and voluntarily assign.
The court also recognized a fiduciary duty on the part
of the researcher as great as that "owed by the
ordinary physician or surgeon to his patient," if not
greater, because the research situation does not
support exceptions to disclosure. To protect the
subject's decisionmaking and assure informed consent,
"(t)he subject of medical experimentation is entitled
to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."<55>

It follows that incomplete disclosure is actionable even if the undisclosed or misrepresented facts are not causally related to the injury, so long as they may have influenced the subject's decision. Although the Canadian court does not discuss autonomy or respect for persons, these norms underlie its evaluation of the consent issue on the grounds of trespass to the person.  

A case clearly involving consent to research, like Helusha, Mink v. University of Chicago<56>

proceeded on a battery theory with regard to informed consent despite the modern tendency to treat inadequate disclosure as a negligent tort.<57> Between 1950 and 1952, pregnant patients at the University of Chicago were given pills that they were told would help prevent miscarriage. They were not told the pills were diethylstilbestrol (DES) nor that they were
In the United States, plaintiffs alleging injury resulting from participation as experimental research subjects have relied on traditional tort theories as well. Courts have similarly responded by straining existing doctrine in order to compensate physical and emotional injuries. Of course, the courts must first find that the procedure complained of is experimental.  

In *Fiorentino v. Wenger*, the court upheld a malpractice action against a physician for negligent failure to inform parents of the risks of/nonemergency surgical procedure that caused their child's death. The trial court found that the physician had used a "novel and unorthodox" procedure. According to the appellate court, the facts of the case indicated that the physician's "experimental" use of this procedure could not be categorized as research. Although he had used the procedure in thirty-five other instances, he seemed to have made no attempt to evaluate it using generally accepted research methods. Hence his experiments seem to fall into the class of activity defined by some scholars as "nonvalidated practice." The case is noteworthy, however, because liability was found for lack
of informed consent to an activity that borders on research. It is similar to cases involving lack of informed consent in research. The court was able to find grounds for compensating the injured party by finding that failure to inform and obtain consent was a negligent act resulting in a physical injury. (Return to page 22, paragraph beginning "When the furniture..."
participating in experimental trials of the drug.

When years later, the women learned of the experiments, they filed a class action against the university and the manufacturer on grounds of battery, products liability and breach of duty to notify plaintiffs that they had been given the drug. The court upheld the battery claim by finding that giving plaintiff's pills to ingest, even though not in itself an offensive unconsented touching, is "indistinguishable in principle" from administering the drug by means of a hypodermic needle.<sup>58</sup> The strict liability and failure to notify claims were dismissed because plaintiffs themselves suffered no physical injury---they were merely concerned over risks that their offspring would develop cancer.<sup>58a</sup> Battery, however, protects dignity and autonomy simply by punishing unconsented touching.<sup>59</sup> In finding for the plaintiffs under a battery theory, despite lack of any
conventional "touching" and despite the patients' at least nominal consent, the Hink court stretched tort doctrine to afford relief in a novel situation. Similarly, when a

in the cases discussed above

The nondisclosure by investigators in Hink is by no means atypical of physician-researcher behavior.<60>

One of the more egregious examples occurred at the Jewish Chronic Disease Hospital in New York. In 1962, twenty-two

three physicians directed a project in which 23 cancer patients, without their knowledge or consent, were injected with live cancer cells.<61>

On the basis of past experiments with healthy volunteers, the physicians were confident that the patients' immune systems would reject the foreign cell transplants; they simply wanted to find out whether or not the rejection would take longer with cancer patients. The researchers never submitted a project proposal to any formal hospital or peer review mechanism, but merely informally contacted the medical
In the early 1950s, physicians at Brooklyn Doctor's Hospital conducted studies on the standard treatment of oxygen to prevent death or brain damage in premature infants. They found the treatment seemed to be related to the occurrence of retrolental fibroplasia, a progressive disease resulting in blindness. As a result, the hospital decided to participate in a nation human research study of the problem. In 1953, a premature infant, Daniel was admitted Burton, to the hospital. Unknown to his parents, and without their consent, physicians entered him into the experimental study. However, the infant's primary physician, a pediatric resident, noted that the baby was healthy and doing well; he ordered the oxygen concentrations be reduced. Two days later, a member of the hospital staff and instructor of pediatrics at Cornell University Medical College countermanded the order, without examining the
infant or consulting with his parents. It was uncontested that the infant became blind as a result of the oxygen treatment.

Burton sued the hospital and physicians on grounds of medical malpractice and failure to obtain informed consent. The trial court's findings of liability on both counts was upheld on appeal. The court noted that in this particular case the issue of informed consent was virtually inseparable from the malpractice question."

"Issues of malpractice may even be a factor when the issue presented is clearly one of informed consent to research. In Valenti v. Prudden, a prison inmate volunteered to undergo "experimental surgery to test the value of cartilage in the healing process." He complained
that the surgery resulted in much larger scars on his chest than he had agreed to. The jury found for the plaintiff and awarded him $20,000. The appellate court upheld the jury's verdict because of proof in the record that the surgery "did not proceed as originally anticipated" and conflicting evidence in the record "concerning the expected results of the surgery." The court agreed, however, that the award of $20,000 was excessive and ordered a new trial on the question of damages unless the plaintiff agreed to a reduction to $5000.
chief of the hospital and enlisted his cooperation with
the experiment.<62>

The researcher told the patients that the
injections were simply skin tests for immunity or
response. Later, one of them defended the
nondisclosure on the grounds that:

(a) it was of no consequence to the patients;

(b) the precise nature of the foreign cells
was irrelevant to the bodily reactions which
could be expected to occur; (c) it was not
germane to the reaction being studied; and
(d) it was not a cause of increased risk to
the patient.<63>

Three physicians on the hospital staff,
however, refused to take part in the experiment and
resigned in protest.<64> They notified an attorney on
the hospital's board who requested an investigation and
asked for hospital records related to the experiment.
When he was refused, he successfully petitioned a New York lower court for permission to inspect the records, a decision that was ultimately upheld.

Meanwhile, the attorney requested an investigation by the New York State Department of Education. After hearings by a three-member panel, the Department's Medical Grievance Committee voted to suspend two of the physicians from practice for one year. Similarly the State Board of Regents imposed one year's probation for the two physicians. The Regents strongly affirmed the subjects' right of self-determination, despite the alleged harmlessness of the experiment:

There is evidenced in the record in this proceeding an attitude on the part of some physicians that they can go ahead and do anything they conclude is good for the patient, or which is of benefit
experimentally or educationally and is not harmful to the patient, and that the patient's consent is an empty formality.

With this we cannot agree.<69>

Although there is widespread agreement with the autonomy principle the Regents cited,<70> no court has provided redress for violation of a subject's right of choice, in the absence of physical or emotional injury.

Moore v. Regents of University of California.<71>

Currently being litigated in Los Angeles, California, raises that issue directly. In Moore, an ex-research subject alleges that medical researchers at the University of California, Los Angeles (UCLA), and the UCLA Institutional Review Board violated informed consent provisions of federal regulations and California's Protection of Human Subjects in Medical Experimentation Act.<72>

When Moore's leukemia was first suspected, he
began in 1976 to make regular trips from his home in Alaska (later Washington) to the UCLA Medical Center for diagnosis and treatment. At the recommendation of the UCLA physician, Moore underwent surgery to remove his spleen. Moore alleges that he was not told of, and did not consent to, the use of his excised tissues and blood for the purposes of research and profitable commercial activities on the part of the defendants.<sup>73</sup> He further alleges the defendants told him that a series of visits to UCLA through 1983 to withdraw blood and bodily substances were necessary for his health and well-being, when in fact the researchers allegedly needed these substances for their own commercial purposes.<sup>74</sup>

Upon learning of the alleged deceptions and misrepresentations, Moore filed suit on grounds, among others, of breach of fiduciary duty and violation of federal and state law pertaining to informed
consent. Essentially he alleges a conflict of interest on the part of defendants resulting in loss of the right to control the use of his blood and bodily substances. At the date of writing, the case has survived three demurrers to the complaint; the fourth amended complaint is now before the court.

Halushka, Mink, and Moore show courts struggling to provide redress for human subjects in experimental research. The paucity of appellate decisions, as well as their technical limitations, suggest that judicial action, standing alone, cannot adequately protect the research subject's right to informed consent. Courts seem reluctant to impose sanctions on researchers who are authorities in their fields and working to advance medical or social science knowledge, and especially so when their research proposals have been approved by a committee of their peers. Without changes in regulatory guidelines,
tort suits must meet the technical requirements of negligence or battery actions. Unless the subject is physically harmed, proof of damages may be difficult. Accordingly, Part III of this article proposes changes in the HHS guidelines and a new approach to judicial relief. First, however, the reasons for requiring greater protection for human autonomy in experimental research must be explored.

{III. Protection of Informed Consent in Human Experimentation: Moral and Policy Analysis}

Courts and commentators have offered four lines of argument for protecting the right to informed consent in human research. Together, they make a strong case for protecting the right even more stringently than when it is protected in connection with standard medical treatments, yet, they do not go far enough; even more powerful arguments are needed and available. Section A reviews conventional arguments
for protecting informed consent. Section B advances three new reasons for protecting that interest.

{S2A. Standard Reasons for Protecting Informed Consent in Human Experimentation}

{S21. Argument number one—Inability to ascertain the risks of experimentation in advance.}

One frequently given reason for providing heightened protection for consent in experimental settings is that these settings, more so than those in which standard medical treatments are dispensed, pose unknown and unascertainable degrees of risk.<82> Since the outcome of the procedure is uncertain, only the patient or experimental subject can decide whether to proceed or not.<83>

The argument has much commonsense appeal. Many activities of everyday life—going for a ride in another's car, playing sports—have risks. But for the most part, these risks are known to all, and we do
not require that persons who offer rides or invite friends to play tennis spell out the dangers and obtain consent.

Other activities present risks that are less well known—using chemical fertilizers in one's garden, working with machinery, undergoing a medical or surgical procedure, for example. In these cases, we do not impose duties of disclosure, so that accidents may be avoided, to avoid exploitation, and to protect human autonomy. When the risk to health or autonomy is very great, society may prevent the activity entirely so that no individual may subject another to it even if the other is willing and has given consent.

According to this line of reasoning, both the autonomy-protection and health-protection interests of the informed consent doctrine argue for a strict standard of disclosure in experimental settings. The consequences of many forms of human experimentation may
include significant impairment of physical wellbeing

and present and future autonomy.<86> Consequently, the

experimenter should be required to disclose everything

that he or she knows about the experiment and its

possible consequences to the human subject and obtain

the subject's advance agreement to undergo the risks

involved.

{s22. Reason number two---Medical expertise does not

exist in experimental settings and thus there is no

reason to defer to it.

A second reason frequently given for providing

increased protection for informed consent in human

research is that research, by definition, is not an

exercise of medical judgment.<87> Since the

researcher's aim is to discover new medical or

psychological knowledge rather than to apply it for the

patient's benefit, there is no point in deferring to

nonexistent medical expertise.<88> Courts, as everyone
knows, tend to defer to the expert judgments of other professionals and are reluctant to substitute their own judgment for that of a physician, art appraiser, accountant, or other professional. As Meisel and others have pointed out, the law of medical treatments is no exception to this rule; the doctrine of informed consent, in particular, reflects and is shaped by medical-deference concerns.<sup>89</sup> But because the human researcher does not know what will happen in the course of experimentation—although he or she may have a hypothesis or hunch—there is no pre-existing expertise to which a court, or society, ought to defer. Concerning the principal moral issue of human experimentation—should this patient volunteer his or her body for the purposes of advancing medical knowledge—no one is a better "expert" than the patient or subject.<sup>90</sup> Since the experimenter stands on no greater footing than the human
subject—arguably, a lesser one—the subject's wishes are entitled to great weight.

{s23. Reason number three—Lack of any certain benefit}

The third reason for protecting human subjects from unconsented-to research is that, in contrast to standard medical treatments that are aimed at conferring some physical or psychiatric benefit on the patient, experimental therapy often provides little or no benefit.<sup>91</sup> From reasonable-patient (objective) standards to the unconscious-patient rule and the emergency exception, the doctrine of informed consent reflects the judgment that most medical treatments help the patient.<sup>92</sup> In experimentation, the primary goal is not to help the patient or experimental subject, but other, future persons. Drug testing, for example, exposes the subjects to risks—the drug may prove toxic or have unexpected side effects. If the drug
proves safe and medically useful, the beneficiaries will be future patients who will buy the drug once it is marketed.

Research thus presents a classic case of harming (or exposing to risk of harm) person A for the benefit of another person, B. Since, outside of a few exceptional cases such as taxation and military service, our society does not impose duties of beneficence on persons such as A, the legal system ought to require consent to experimental therapy when the outcome is unknown and unlikely to benefit the human subject personally.

{S24. Reason number four---The researcher's and the subject's interests are often opposed.)

A final reason often given for protecting informed consent in experimental settings more highly than in therapeutic settings is that in the former (but not the latter) the interests of patient and scientist
are opposed.<93> This reason, which overlaps somewhat with the second and third reasons, draws on a body of legal and ethical principles known loosely as "conflict of interest." Conflict of interest notions express the intuitive conviction that persons who occupy positions of trust ought not permit themselves to come under outside obligations or self-interests that could render them unable to promote the interest of client or patient.<94>

In some experimental settings, the experimenter may well be subject to competing loyalties. Consider the experimenter-physician at a teaching hospital, whose indigent patient is to be treated for an acute illness.<95> The physician may have a choice between giving the patient the standard treatment for his or her condition or administering experimental treatment aimed at demonstrating the usefulness of a new drug or procedure, or may administer the experimental treatment
in addition to the standard treatment. The physician's interest in pursuing a medical breakthrough, and so adding to his or her reputation and that of his or her department and university, may cause the physician to obtain less than fully informed consent. The experimenter may minimize the risk of the new treatment, misrepresent the extent to which it has been accepted by the medical community, or fail to reveal alternative treatments. Because of this risk of divided interests, it seems wise to demand of physicians and other researchers higher than usual compliance with norms of disclosure and noninducement.

Of course, not every research setting will present the mix of therapeutic orientation and research objective of the situation depicted above. But where one does, it makes sense to hold the doctor-researcher to a high standard of informed consent.
Highly in Human Experimentation)

In addition to the four conventional reasons previously discussed, three new reasons argue for increased protection for consent in human experimentation. Experimental settings call for heightened protection because failure to obtain the patient's consent deprives the patient's act of moral meaning. Further, it many research settings there may be a conflict of value between the research and the human subject. And, finally, the researcher in many cases will occupy a fiduciary relationship—a position of trust—with respect to the human subject, calling for a high standard of conduct and fair dealing.

[s21. Reason number one---Conscripting research subjects deprives their act of moral meaning.]

Outside a few special situations, our legal system recognizes no general duty of beneficence.<97>

Sometimes this is expressed in the maxim that there is
no duty of rescue, a maxim that is captured in the familiar hypothetical of a passerby who sees a drowning child. The passerby is not responsible for the child's plight, and is not the child's parent or guardian. The passerby could easily rescue the child at little cost or danger to himself or herself, but passerby ignores the child's plight, and the child drowns. Our legal system will hold the passerby blameless, in both tort and criminal law. If, however, the passerby took steps to rescue the child but changed his or her mind and did not complete the rescue attempt, the legal system will hold him or her responsible for the child's death.

The origins of the no-duty doctrine are obscure, and the rule has been criticized frequently. Yet it remains deeply rooted in our legal system and seems in little danger of being reversed.

The choice to volunteer or not volunteer as a
subject for experimental research is in many respects like a decision to rescue another. The benefit, if the research proves successful, will in many instances redound to other persons; the risks will be borne by the subject. Moreover, the human subject generally has no special relationship with the future beneficiaries of the research that would morally or legally compel his or her service as a research subject.<100> Nor is participation as a research subject one of those few areas, like taxation and military service, where affirmative duties have been recognized as necessary for the common good.

Consequently, service as a human subject of biomedical or behavioral research must be regarded as one of those many areas in which participation is voluntary, like charitable giving or assisting a stranded motorist. In these areas, society approves of and encourages altruistic behavior but does not compel
it or punish persons who choose not to perform it.

This conclusion—that service as an experimental subject is a voluntary act—is reflected in many ways in our treatment of human experimentation. The HHS guidelines—and case law decided even before the guidelines were promulgated—require the subjects' consent and restrict experimentation among populations whose ability to make a free choice is limited, such as children, prisoners, the mentally ill, and the poor. We may offer incentives for persons to volunteer—payment, for example, or the guarantee that in the event of injury, the institution will provide treatment or therapy. These measures would not be necessary if service as a human subject were a duty.

Since service as a human subject is not a duty, the decision whether to volunteer or not must be left to the individual. What factors will enter into the
subject's decision? The costs and dangers of the research, obviously; for this reason informed-consent rules require a detailed statement of the known risks.

In a few cases, the risk will be nonexistent—the procedure is so innocuous that the subject cannot possibly be harmed. In most cases, however, there will be some risk of harm—a side effect of a drug being tested, embarrassment or loss of privacy from behavioral research.\text{<105>}

Since there will often be some risk attached to human research, what will the subject have to weigh against this risk? In non-therapeutic research, the only benefit will often be the subject's satisfaction in having acted for the good of humanity. The subject will have exposed himself or herself to danger in return for helping the research team develop knowledge that may save lives or relieve suffering of others.

This motive, which we will call "altruism," is the
principal benefit that inures to human subjects of the experimental, nontherapeutic research. This benefit, however—this sense of having given of oneself for the good of one's fellow man—is denied when the human subject does not freely choose to participate in the research, does so unaware of the risk it presents, or does not know of the purposes of the research.

Where the research subject does not choose to participate freely in the research—where the subject is forced to participate, where the subject is not given full disclosure of the risks and purposes of the research, or where the research is carried out without his or her awareness—the act loses its moral quality. Participation then is not something that is given; rather, it is taken from the individual, extracted from him or her without consent. The normal response on being told of what has happened is outrage. One feels not like a hero or heroine, but a tool, a thing that
has been used. In such cases, there will be no positive value to balance the negatives of risk and cost.\textless 105a\textgreater  Society and the researcher may gain, but the research subject only loses. Nontherapeutic research is validated for the individual by the moral quality of the act—by the knowledge that one is acting for the good of society.\textless 106\textgreater  This requires that one's participation is not knowing and uncoerced, it loses its moral quality. One sees oneself as a dupe, a victim, one who has "been had."

The current rules for human research recognize this response to some extent in their treatment of "deception research." Deception research is research whose nature requires that the subject be kept uninformed, or in some cases be actively misinformed, concerning its nature or purpose.\textless 106a\textgreater  Stanley Milgram's studies of obedience to authority\textless 107\textgreater  and Laude Humphreys' study of "watch queens"\textless 108\textgreater  are well
known examples of deception research.

Milgram, an experimental psychologist, advertised for research volunteers in newspapers. He told them that the purpose of the experiment was to study memory, and the volunteers would participate as either "teachers" or "learners." The volunteers, however, were all cast as teachers who were instructed by everpresent experimenters to administer painful electric shocks whenever a learner made a mistake. The actual purpose of the experiment was to study obedience to authority, not learning. Actors performed the roles of learners who cried out in simulated pain when the volunteers gave them high voltage shocks at the experimenters' direction.

Both researchers and the public were disturbed to find how susceptible the volunteers were to the experimenters' directions—sixty-two percent of the volunteers obeyed the experimenters' commands.
completely. Equally disturbing, to some, however was revelation of the duplicitous research design and methods. Similarly, Humphreys' participant-observer (he volunteered to watch for the approach of police or strangers) study of "impersonal sexual acts with one another in public restrooms" has been widely criticized for its deceptive methodology<108a>; he spied on unconsenting subjects and risked their arrest through subpoena of his records. On the other hand, his findings showed that the majority of the subjects were neither homosexual nor bisexual,<108b> and led to a reduction in the number of homosexual arrests in the United States.<108c>

The federal rules permit deception research if the value of the knowledge it is aimed at generating outweighs the risks to subjects, cannot practicably be gained in any other way, and the experimental team provides "debriefing" afterwards.<109> The intent of
the debriefing rule—and the way in which most IRBs interpret it—is to minimize the embarrassment and sense of betrayal subjects may feel as a result of the deception. But the rules treat this sense of betrayal as just another cost of experimentation.

Debriefing is aimed at soothing the subject's emotions, and thus minimizing the cost. In reality, however, the subject's reaction is more than just a cost; a minor violation of autonomy experienced as a negative emotion that can be dissipated by counseling or passage of time. Rather, it is bound up with cancellation of any plus that might accrue to the subject from participation in the research.

Participation that is involuntary or based on misapprehension has, for the individual, no moral quality. That moral quality will, in many cases, be the only gain that can be balanced against the risks and inconveniences of research. And that moral quality
cannot be restored by after-the-fact explanations or counseling.<112>

{s22. Reason number two---In human experimentation, the experimenter and the research subject have a "conflict of value."

Where a doctor administers standard medical therapy to a patient, the interests of the doctor and the patient ordinarily coincide---both want the patient to be cured. But in human experimentation the interests of the researcher and subject are frequently opposed. The scientist wants to pursue medical breakthroughs that will help other patients and add to his or her reputation and academic standing.<113> But the research subject may have a different set of goals and values.

The subject will ordinarily have little interest in the researcher's professional reputation, academic advancement, or ability to obtain new grants.
The interests of the research subject will vary, often more widely than those of the investigator, but may include any or all of the following: avoiding pain, incapacitation, embarrassment, or other negative consequences resulting from the research; assisting humanity; making a small amount of money (if the research calls for payment); escaping boredom if he or she is confined or institutionalized; and helping scientists find a cure for the disease that afflicted a friend or family member.

Many writers, and some judicial opinions, have pointed out the manner in which the interests of researcher and human subject are opposed in human experimentation as a reason for imposing stricter standards of disclosure and consent in that setting than in standard medical treatment settings.<114>

Their argument gains force from ideas found in the body of legal doctrine known as conflict of interest.
Conflict of interest rules, in general, seek to ensure that persons who act on behalf of others do so without conflicting self-interests.<115> For example, corporate directors are required to manage corporate interests and business according to standards of law.<116> Trustees must scrupulously follow the terms of the trust and applicable state law that protects beneficiaries.<117> These principles respond to four simple, highly intuitive moral notions: (i) that one should be able to count on the integrity and fidelity of persons on whom one relies, or takes into one's confidence<118>; (ii) that, as a result of this trust, those who act for others are obligated to act in good faith and with regard only for the interest of the other<119>; (iii) that the actor will not influence or pressure the more dependent party so as to benefit himself or prejudice the other<120>; (iv) that the person in the superior position is accountable to the
dependent party and must disclose personal interests

that conflict with his duty.<sup>121</sup>

Although conflict of interest principles do
have some force in the medical experimentation
context,<sup>122</sup> there are respects in which the
conflict-of-interest model fits only inexactly. At the
heart of conflict of interest is the idea that an
individual in a position of trust must not take
advantage of his role for his own private pecuniary
gain.<sup>123</sup> In human experimentation, however, neither
researcher nor human subject ordinarily has a direct
economic interest in the outcome of the research.<sup>124</sup>

Also, conflict of interest rules are reserved for
conduct that is clearly self-serving and wrong.

Failure to inform a research subject fully of the
purposes and risks of research, while reprehensible,
will rarely rise to the level of immorality required by
conflict of interest doctrine.
A better approach is through what a recent writer has called "conflict of value." Although the author was writing about standard medical therapies, the notion of conflict of value seems to apply with even more force in connection with human experimentation. As its title implies, conflict of value arises when two or more participants in a human venture place different values on either the outcomes or objectives of their common effort, or on the means to be employed in achieving those outcomes.

Conflict of value is closely related to, but not identical with, conflict of interest. In conflict of interest, one person, generally a fiduciary, stands to gain at the expense of another, usually a client, patient, or other person in a dependent capacity.

In the situations we will call ones of "conflict of value," the opposition between two persons is not captured by a simple win-lose formula. The
experimenter does not win if the human subject loses, or vice versa. Nor is the problem primarily one of divided loyalties, as it is with conflict of interest; the researcher is not currently charged with protecting the subject's health, finances, or wellbeing, and often has no longstanding relationship with him or her; when the experimentation ends, the two will go their separate ways. On both scores—lack of a win-lose feature and absence of any enduring special relationship—the experimenter-subject relation fails to meet traditional conflict-of-interest criteria.

Conflict of value exists where the parties to a transaction have significantly different goals, aspirations, intangible desires and preferences. Neither desires to profiteer from the other in any sense captured by classic conflict-of-interest cases, such as that of the physician who conceals his or her own negligence to avoid a malpractice suit. <128>
Conflict of value is more like what happens in a poor marriage, or in a business partnership when the partners have different ideas of what the relation is about.

Current views of, and rules regulating, biomedical and behavioral experimentation give lip service to the idea of protecting the patient's autonomy and distinctness as a human being.<129> But this recognition of a plurality of values, and plurality of cultures, life settings, and personal and group-related vulnerabilities, is inadequately protected in the current regulatory approach to human experimentation. We will first show in subsection (a) how a conflict of value arises between experimenter and human subject by describing, in brief anecdotal form, the mindset of a typical human subject and that of a typical researcher. Then, in subsection (b), we review the federal regulations and related materials to show
how their intent is to protect a pluralism of values in
research settings and limit the scope of professional
expertise when the latter conflicts with patients'
autonomy. Subsection (b) concludes by showing how the
current approach to federal regulation of human
research inadequately advances the goal of managing
conflict of value and giving primacy to the patient's
desires and goals.

{s2(a) How conflict of value arises}

(i) A typical subject. It is less easy to
generalize about human subjects than it is to
generalize about the doctors and scientists who conduct
research, because the patients are often solicited from
different age and population groups depending on the
experiment's objectives. But it is still possible
to say a few things. Most human subjects are either
young, poor or ill. They generally have less
power and socioeconomic status than members of the
research team. They are often solicited from members of university undergraduate classes or sections, or because they receive social services from some federal or state agency. Participants in medical research are often obtained from the patient populations of hospitals or clinics. In some cases the subjects receive pay, in others not. For most, the incentives to serve as a research subject are not monetary, but rather consist of a mixture of motives: helping humanity, pleasing the doctor or professor, achieving a break in the daily routine, attaining a cure when all other treatment fails. Most subjects are also concerned with avoiding negative consequences of research. But their wariness is tempered by their tendency to trust the scientist or physician in charge of the experiment, generally a person of high prestige and authority who seems ready to give assurances that the research is not risky or
painful.<136>

(ii) A typical researcher.

Medical sociologists and others have written more extensively about the goals and world views of researchers, and so more is known about them as group than about research subjects. Most researchers, in both biomedicine and the behavioral sciences, share an outlook known as "professionalism"—the tendency to identify with and subscribe to the values of one's occupational group.<137> This unanimity of outlook has been explained as a result of the group's small size, cohesiveness, frequency of contact among the members, and similarity of professional training.<138>

The professional creed of researchers places great emphasis on efficiency and primacy of discovery.<139> The object is to have experimental But efficiency is not only valued for its own sake; it is linked with a belief that scientific progress will promote the good of humanity, It enables us to better understand ourselves, solve our problems, cure our diseases.
Traditions of self-regulation and peer review reflect and intensify the researcher's adherence to professional values. Outside authority, it is believed, cannot understand scientific values, the experimental method, and other norms of professional conduct.
The technical issues posed by scientific governance are also different to understand. Consequently, scientific bodies have demanded and received a large degree of autonomy in regulating their own affairs through peer review, professional associations and codes of ethics, and academic structures.<sub>142</sub>

In addition to its insularity and governance through self-designed norms, academic research is highly competitive.<sup>143</sup> Researchers vie for peremptory method, and other norms of professional conduct.<sub>144a</sub>

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In addition to its insularity and governance through self-designed norms, academic research is
highly competitive. Researchers vie for grants, laboratory space, and the best graduate students.

Recognition and achievements are rewarded by promotion, tenure, and jobs at leading universities and research centers. The pressure to produce begins in medical or graduate school and continues unremittingly through the researcher's life.

The insularity, pressures, socialization, and reward systems of a researcher's professional life combine to instill a "permissive attitude toward use of human subjects." Recent research by Barber and others shows a widespread tendency to value lightly norms of informed consent and patient autonomy, and a willingness to cut corners and overlook "niceties" of disclosure and consent.

{s2(b) Protection of a pluralism of values under the current rules.}

As the previous subsection showed,
experimenters and human subjects bring different values and objectives to the research setting. Those of patient-subjects show more diversity than those of scientists. Subjects vary greatly in the extent to which they are risk-averse, altruistic, and desirous of being informed about the dangers, methodology, and objectives of the research.<147>

The current approach to human experimentation, like that to medical treatment, places primary importance on the preferences and wishes of the human subject.<148> In part, this is linked to our society's emphasis on personal autonomy and individual rights.<149> It is also a reflection of a broader recognition that patients simply do not all want to get well in the same way, with equal intensity, with the same valuing of risks and benefits of treatment, side effects, pain, and disability. The variability of preferences on the part of the nonscientist participant
is, as has been shown, even greater in connection with experimentation than it is with medical treatments.

Accordingly, one would expect to find that legal doctrine and rules respecting informed consent are even more stringent in those settings than ones in which standard medical therapies are administered. The current federal rules do, indeed, recognize the need to protect patients' varying desires and preferences, but this pluralism of values is poorly protected by the actual guidelines.

(i) Value pluralism in the federal guidelines

The federal rules and the body of commentary surrounding them recognize that researchers and their subjects will often have a conflict of value.

Moreover, they make clear that it is the subject's values—which vary widely from person to person—that are to preponderate. Yet, in a few crucial respects, the rules do not adequately assure that those values
and preferences will be respected.

The rules and commentary give primarily to the subject's desires and preferences. Reports by the National Commission assert that respect for persons' rights of self-determination is an elemental principle for gauging the conduct of research with human subjects. Several solicited papers and essays that appear in the Appendix to the Belmont Report underline the importance given the patient's or subject's wishes regarding experimental treatment and the need to assure that freedom of choice be respected.

The rules themselves show a clear intention that subjects' self-determination interests prevail over the professional interests of the researcher. For example, the rules require that the subject be told the purposes of the research, and that he or she is free to withdraw from the experiment at any time.
without penalty or loss of any benefits.<153> In some instances, the rule provides that the subject be told of significant new findings that might affect his or her desire to continue participating.<154>

Conflict of value is thus recognized as a central problem for federal regulation of research with human subjects. Where it occurs, the values of the subjects are to be given primacy. Moreover, the rules recognize that subjects' values will vary widely, and that generalized treatment based on presumed consent, presumed preference, or presumed knowledge is inappropriate.<155> Yet the rules in a few key provisions allow excessive leeway for professional discretion. For example, the researcher devises the method by which he or she will obtain the subjects' informed consent. Often this is done in one meeting that does not give subjects time to absorb and reflect upon the information received.<155a> Further, the
entrustors, who must entrust their power to act for themselves to others, fiduciaries, who possess greater skill, expertise, capacity, or who simply have more time at their disposal. Fiduciary rules serve to discourage abuse of this delegated power and to reveal abuse when it may occur. They act to prevent conflicts of interest and value by prohibiting, discouraging, or supervising self-dealing. The remedies for fiduciary violations are among the strongest the law can provide since they are meant not only to compensate the betrayed entrustor but also to punish the offending fiduciary. For example, profits realized by a dishonest fiduciary may be shifted to the entrustor, who might not have been able or herself to gain them for himself in any other circumstances (including having been prohibited from gaining them for himself). Our moral-legal system makes A a fiduciary of B
when A can be reasonably charged with a duty of acting in B's best interest. The relation may arise without a contract or written instrument because the classification of the relation and its legal consequences are determined by law, not by the parties.\footnote{162} In fact the intent of the parties is irrelevant to a court's finding of fiduciary obligation, and the courts can insist upon supervising the relation.\footnote{163} They will require the fiduciary to act in the best interest of the party,\footnote{164} to possess certain levels of skill or knowledge,\footnote{165} to account for the use of the delegated power,\footnote{166} and to exhibit high standards of moral behavior.\footnote{167}

It is generally conceded that physicians are fiduciaries with respect to their patients, and when doctors dispense standard medical treatments they must act in the patient's\footnote{168} best interests. The doctrine of informed consent is an aspect of the protection

offered by a fiduciary relation insofar as it governs doctor-patient relations. It is akin to the fiduciary rule that the entrustory has a legal right to information about the activities of the fiduciary.<sup>169</sup>

Are researchers fiduciaries with respect to human subjects?<sup>169a</sup> No American court decision has so held, although a few commentators have intimated that this should be so.<sup>170</sup> What makes A a fiduciary of B?

The fiduciary duty arises in a relation in which one party is dependent on the other for fulfillment of some of his needs and desires. The entrustor is vulnerable within the relation as a result of his delegating power to achieve his purposes to the fiduciary.

Physician researchers may most easily be identified as fiduciaries because their relation with subjects is often merely an extension of the physician-patient relation.<sup>171</sup> More importantly, when the patient agrees to be a research subject, he or
she tends to view the relation as one of trust based on
expectations derived from the physician-patient
relation. Whatever the patient's personal reasons for
participating, the patient entrusts the researcher with
the power to bring about these desired ends. This
continued and reasonably placed trust argues strongly
for regarding the relation as fiduciary. Moreover most
subjects are poorly equipped to evaluate the
researcher's performance. Most subjects are dependent
upon the greater skill or knowledge of the researcher
to fulfill their goals, and must trust the researcher
to act as their partner in the enterprise.\textless 172>\textgreater

In this respect, researchers, whether
physicians or not, are like other professionals charged
with fiduciary duties.\textless 173>\textgreater They belong to a class
distinguished by its specialized knowledge and
expertise. Like other professionals, researchers are
set apart by their lengthy and intensive educational
preparation and their positions of respect within society. This respect stems from more than mere technical knowledge: the profession has historical overtones of altruism—service to humanity through the advancement of knowledge and amelioration of social ills. Because of this service the profession is ennobled, and conceded deference and support within the society. Individual researchers are afforded a large measure of discretion as to their choice or research topics and the methods they employ.

The training and education of researchers enable them to predict the risks, benefits, and range of possible applications of their research far better than the subject may. The subject is frequently entirely dependent on the researcher for predictions as to the outcome and potential applications of the research. He is obliged to trust that his own personal motives for participation as a subject will be realized
by the researcher.<174> The researcher, of course, has independent goals in pursuing his research—the pursuit of knowledge, personal enjoyment or fulfillment in the activity, advancement of his or her own career, possibly even pecuniary gain.<175> But it does not follow, however, that we may not properly consider him or her a fiduciary to be charged with a high standard of conduct—just as we do with lenders,<176> corporate directors,<177> accountants,<178> sellers of securities,<179> pension managers,<180> all of whom may have, on occasion, a divergence of interest or conflict of value with the lay persons with whom they deal.

The law recognizes the potential for conflict and usually provides that the fiduciary relation should not be imposed on an unwilling fiduciary.<181>

Accordingly, a researcher should be able, by apt words and warnings, to avoid assuming a fiduciary obligation to his or her subjects. Rules relating to consent and
disclosure may serve this function. But once the relation is begun, the fiduciary must adhere to standards of conduct set by law to protect the entrustor.\textsuperscript{182} Imposition of a fiduciary duty to serve the entrustor need not cripple the professional. On the contrary, it may be argued that the uncompromising standards set by the courts also protect the integrity and efficacy of the fiduciary's profession.\textsuperscript{183} The same should be true of researchers. Recent highly publicized incidents of scientific fraud,\textsuperscript{184} human subjects abuse,\textsuperscript{185} and alleged profiteering from human tissue and cell lines\textsuperscript{186} have probably already eroded public esteem and support for science. Greater judicial monitoring of the researcher-subject relation may well help repair the damage caused by these incidents and reduce their frequency and severity in the future.

\textbf{Suggestions for Providing}

\textsuperscript{181III. Amending the Federal Rules to Provide Greater}
Protection for Informed Consent in Human Experimentation

As has been seen, the current framework of federal protection for human subjects of biomedical or behavioral research lags behind evolution of the ethics of informed consent. To protect patients' choice and value pluralism in research settings, the federal guidelines should be amended to minimize the current broad leeway given researchers in obtaining informed consent. And more effective judicial remedies should be devised to deter breaches of the duty to obtain informed consent. Subsection A proposes interpretations of the existing regulations and a number of amendments to reflect the evolution of the ethics of informed consent. Subsection B describes a possible judicial remedy that may be used when researchers violate the rules and infringe their subjects' rights of self-determination.
[s2A. Proposed Amendments to the Federal Regulations] Two federal agencies publish regulations to protect human subjects of research funded in whole or in part by the federal government. The regulations of the Department of Health and Human Services (HHS)<188> and the Federal Drug Administration (FDA)<189> are very similar; the FDA regulations are slightly stricter regarding exceptions to or waivers of the elements of consent.<190> This part addresses the need for revision in the HHS regulations; most of our suggestions would apply to the FDA regulations as well.

The law purports to safeguard the health and autonomy of persons who volunteer to be subjects of experimentation. The definition of informed consent adopted by the Department of Health, Education and Welfare in 1974,<191> and deleted in 1981, provided a useful starting point for informing the subject of his rights. It defined informed consent as:
The knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.\textsuperscript{192}

In their present form, the regulations do not adequately assure the right of potential subjects to choose whether or not to participate in research. In many cases, they assure only that perfunctory exchanges occur, terminating in the filing of a boiler plate, signed consent form. Such a process scarcely can be said to protect the primacy of the subject's wishes and rights.

In 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research determined that the ethical basis for informed consent, respect for persons, should
be defined as the "exercise of the capacity to form, revise, and pursue personal plans for life." \( <193> \) The Commission's "life plan" approach was developed in connection with medical procedures, but it should also prove a useful guide in formulating informed consent standards for research. In case law, the content of and standards for informed consent are basically the same in therapy and research; indeed, many authorities speak of them almost interchangeably. \( <194> \) Therefore, the recommendations of the Commission's 1982 Report should, in broad outline at least, be transferable to the subject-researcher relation. They would require that the researcher do much more than merely disclose technical information. To understand and give effect to the subject's life plan, the researcher must ask questions, elicit answers with respect to the subject's values and preferences, and supply all relevant information. \( <194a> \) He or she must, in short, treat the
subject as a full and equal partner in the research 
enterprise.  

Even this more extended, interactive consent 
process has dangers. The researcher, as was 
observed earlier, has values, goals, and loyalties that 
may differ markedly from those of the subject. The 
scientist is under intense pressures to produce, 
pressures that may incline him or her, consciously or 
not, to give inadequate attention to the nuances of 
consent. The researcher may thus be ill-equipped to 
understand or empathize with the subject's wishes, 
valuings, and fears and vulnerabilities, and may 
communicate to the subject by word or gesture what he 
or she expects the subject to do. Moreover 
communications studies of interchanges between two 
acts 
persons, one of whom is dominantly and the other passive, 
indicate that the attempted communication and 
understanding between the two is ineffective. As
a result, both parties tend to arrive at inaccurate conclusions about the other, themselves, and the situation.<sup>194f</sup>

For all these reasons, provision should be made, at least in some circumstances, for consent to be obtained by a third party not directly associated with the experiment.<sup>195</sup> Such an arrangement would reduce the potential for conflict of interest or value, would free the researcher from the taint of possible conflicts, and would increase the likelihood that the emphasis will be placed where it should be—on the patient's values, preferences, and life plan.<sup>196</sup> The subject should also be given the name of a person not associated with the research to whom the subject may address questions or notify of injury that occurs.<sup>197</sup>

Creating the position of an impartial intermediary between subject and researcher has several advantages. The prospective subject would receive
representation from the beginning of the relation. The third person would serve as a conduit between researcher and subject, and at times would perform some of the functions of an ombudsman. And the researcher too would be well-served by such a procedure because valuable research time would be saved. In addition, the person who obtains consent, if properly trained or with sufficient experience, could serve as a consultant to researchers planning projects that would involve human subjects. Identification of design problems at initial stages would eliminate much of the time-consuming trial and error submission of projects to IRBs for approval.

If the research takes place in a medical setting, medical social workers who are presumably better trained in communication skills than physicians, would be logical choices for obtaining informed consent. Studies in communications reveal that
in the best of circumstances, physicians have
difficulty in communicating effectively with
patients"<197b>---that they tend to talk "at and not
with patients."<197c> Communication skills aside, the
process for obtaining consent is elaborate enough that
it will often prove more efficient for a trained
specialist to obtain consent.<197c.1>

The process we have in mind would work roughly
as follows. In a first phase, the social worker or
other consent-otbainer would consult with researchers
to learn the nature of the research, especially its
risks, purposes, benefits, and applications. Then he
or she would translate this information into easily
understood English (or other language of the
subject).<197d> Next, the social worker would meet
prospective subjects and interview them in order to
elicit information about life history, family
background, education, language facility, values,
fears, life plans, and current life circumstances.

Next the social worker would explain the project to the subject, giving special attention to those aspects of it that (a) a reasonable subject would want to know, and, (b), this particular subject would be likely to want to know (based on the social worker's evaluation from the earlier stage of the interview). The social worker should give particular attention to the risks of the research, since without this understanding, moral altruism is impossible. At the conclusion of the interview, the social worker would offer to answer any questions the subject has or may have in the future.<197d'>

Whether or not the third person mediative consent-obtaining process is more, or less, costly or time-consuming than the current approach;<197dd> it seems better calculated to obtain fully informed consent.<197dd'> It better protects value pluralism,
reduces the risk of overbearing and scientific zeal,
and assures that subjects learn the full
import---including moral quality of risk and
self-sacrifice---of their service as human
subjects.<197e>

While instituting measures like these suggested
above would improve the likelihood that a subject has
the opportunity to give voluntary informed consent to
participation in research, they would not apply to much
research conducted today. Research in the social
sciences that relies upon the use of deception, for
example, is exempted from informed consent requirements
when it is determined to be of "minimal risk"<198> to
the subject and will provide valuable knowledge that
cannot be attained in any other way. While the latter
two evaluations of such knowledge are subject to
debate, the following discussion concentrates on how
"minimal risk" is determined.
[21. Minimal risk]

When an IRB determines that research presents minimal risk, it may approve a consent procedure that alters some or all of the elements of informed consent listed in the regulations, or even waive the requirements entirely. In both instances, the subject, whose autonomy is ostensibly to be protected, has no role in deciding whether the risks are minimal or not. Furthermore, a subject may well wish to be advised of minimal risks. Not only does the subject have no representation of his wishes in the risk analysis, he has no opportunity to define or characterize risk. Both processes are controlled by IRB members, many of whom are themselves research scientists. Further, the researcher need not seek consent at all from subjects of research involving educational tests, standard educational practices, direct observation of behavior, interviews, existing
data, and some research regarding public benefit and
service programs.<203> And the researcher may petition
for waiver of consent, or some of its elements, for
other forms of research posing minimal risk.<204>
Implicitly the regulations permit the researcher and
the IRB to decide when a prospective human subject may
exercise autonomy. This should be remedied by
requiring disclosure of all known risks, and especially
risks that may be relevant to particular
subjects.<204a> Such an amendment, however,
[Continued on following insert pages.]

322. Purpose of the research

The federal regulations do require that the
research subject be told the purpose of the
research.<205> Some researchers and IRBs, however,
appear to believe that this requirement is satisfied by
giving the most limited, or general, description of the
research's aims,<205.1> for example, that the research
concerns humans' responses to living spaces of
different sizes or shapes when the purpose is to design more effective configurations for submarines.

Disclosure at a high level of generally may also fail to reveal that bodily tissue or blood samples might be used in applied genetic engineering or recombinant DNA research; research to which the subject may have personal or religious objections. Disclosure may also fail to reveal that the research may be exploited commercially and result in financial gain to the research institution or researcher. Such a result may be repugnant to a research subject who believes that through his participation he is making a very personal, intimate gift or donation for the betterment of humanity. Therefore this element of consent should either be revised or interpreted to demand that all the goals that might be material to the subject's choice be revealed, and in concrete detail, not just general outline.
{23. Benefit to others}

As a corollary to the first two revisions, it follows that the guidelines should be revised to identify the "others" whom it is reasonably foreseeable that the research will benefit.<207> In particular, the words "including researchers and sponsors" should be added, thus requiring revelation of any hoped-for personal and pecuniary gain on the part of researchers of their institution. Alternatively, the assurance section of the regulations<208> could be amended to condition federal funding so that no employee of the institution may have a personal financial interest in the research. The regulations could also be amended to require that any profit from the research be deposited in the university's research accounts and applied for the benefit of persons like the subject or for further research into the condition described in the research protocol.<209> These requirements would extend
academic conflict of interest rules, already in place in a number of states and local institutions to research settings on a nationwide basis.

Amendments are necessary if the federal regulations are to keep in step with the evolving ethics of research with human subjects. However, the regulations apply only to research funded in whole or part by the federal government, and some researchers will willingly risk university, or even federal, penalties in order to conduct the research. Therefore an additional judicial remedy may be desirable.

[s2B, Judicial Remedies]

Most human subjects who complain of injury to their right of self-determination have little hope of finding redress in the courts. If the subject suffers a physical injury in the course of research and alleges no consent was given, or that consent was legally ineffective (if, for example, the researcher never
disclosed important risks), then the subject may be able to sue for damages on grounds of battery or negligence.<sup>211</sup> No courts, however, have recognized that the researcher's breach of the duty to obtain informed consent is an invasion of the subject's right of self-determination and alone is grounds for suit. The following section discusses a cause of action developed from a synthesis of principles drawn from fiduciary and negligence law and recent scholarly commentary on the right of self-determination in medical settings.

{211. Fiduciary duties of researchers}

Fiduciary law is well suited to protection of a subject's intangible rights of autonomy and self-determination because it already protects these intangible rights elsewhere.<sup>212</sup> Fiduciary principles apply to situations in which one person delegates power to another with greater knowledge and skill to act for
him, holding the fiduciary to the highest standards of disinterested performance and disclosure.<sup>213</sup> The rigor of these duties in part justifies the social and legal approval of the relation. The fiduciary benefits from the high standing that society accords to professionals, and in some situations may be allowed to contract for payment for his services.<sup>214</sup> However the fiduciary is held to a strict duty of disclosure regardless of the substantive fairness of his or her actions on behalf of or in the absence of physical or economic injury to the dependent party.<sup>215</sup> If the fiduciary does act in his or her own interest, the law requires that the dependent party be compensated.<sup>216</sup> In addition, the fiduciary may be punished by the

[page 113 and 114 of the previous manuscript were missing; the typist therefore left a gap here.]
should recognize a cause of action for victims of unconsented-to research.

Under such a theory, the fiduciary relation would arise from the relation of human subject and researcher. The researcher would be charged with a duty to obtain informed consent that takes into account the subject's personal values and desires. It would require the researcher to disclose fully all the factors enumerated in the elements of consent defined in the current federal regulations plus those in the amendments recommended above.

If a court finds breaches of the fiduciary duty, it would apply a variety of remedies. Damages for breach of fiduciary duty could be tailored to the situation: general damages for the breach and for
emotional harm to the subject; punitive damages where the defendant is found to be willful, wanton or reckless in disregarding a subject's right of choice; special damages for proven losses. In situations where a researcher has not revealed pecuniary motives for conducting the research, courts might apply equitable remedies such as imposing a constructive trust on the researcher's gains. The proceeds of the trust could be transferred to the subject or channelled into areas of research of greatest relevance to the subject.

CONCLUSION

Most writers, and the few courts that have considered the question, hold that informed consent ought to be protected more highly in research settings than those in which standard medical or behavioral treatments are dispensed. This article reviewed the reasons usually given for providing heightened
protection, and offered a number of new reasons. The combination of new and old arguments, together with the growing commercialization of certain areas of academic research, make an especially compelling case for protecting informed consent rigorously. Without full disclosure of the risks and purposes of the research, the human subject's act loses moral meaning. Moreover, the research subject is often poorly equipped to protect his or her own interest in informed choice. The researcher often has goals and values different from those of the subject, and is highly motivated to obtain the subject's agreement. Where the consent is obtained and disclosure given by the researcher himself or herself, as is usually the case, these dangers of incomplete or halfhearted disclosure are particularly great. Moreover, many research subjects may look to the researcher as a health care provider, or, at least, a disinterested pursuer of truth who has the subject's
best interest at heart—when, in fact, the researcher views the subject in terms of expediency and the transaction as an arm's-length one.

To protect informed consent in human subject research, we proposed a number of amendments and new interpretations of the HHS guidelines. We also proposed a new, more effective judicial remedy that human subjects may use when their right to be free from unconsented-to research is breached. Because of the compellingness of the need to protect consent for human subjects and the inadequacy of current approaches, a new, long look at informed consent in research with human subjects is in order.
(BEGINNING OF PART 1 OF 2 PARTS OF Delgado NOTES)

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<1>E.g., Bang v. Miller Hosp., 251 Minn. 427, 434, 88