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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

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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.[1] The reasons usually given for demanding this

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1. *See, e.g.*, Bang v. Miller Hosp., 251 Minn. 427, 434, 88 N.W.2d 186, 190 (1958); Halushka v. University of Saskatchewan, 53 D.L.R.2d 436, 52 W.W.R. 608 (Sask. Ct. App. 1965), *reprinted in* J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 569 (1972) [hereinafter J. KATZ]; R. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 93–94 (1981); Note, *Informed Consent: From Disclosure to Patient Participation in Medical Decisionmaking*, 76 NW. U.L. REV. 172, 176–77 (1981).

Informed consent is the requirement that medical and behavioral practitioners inform patients and human research subjects of the risks and benefits of procedures and obtain the patients' or subjects' agreement to undergo any risks. *See* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340 (1974); Levine, *Informed Consent in Research and Practice*, 143 ARCH. INTERN. MED. 215 (1983). The requirement has a number of overlapping objectives, including the following: (1) Protecting individual autonomy and choice, Cobbs v. Grant, 8

Cal. 3d at 242–46, 502 P.2d at 972, 104 Cal. Rptr. at 513–16; J. KATZ & A. CAPRON, CATASTROPHIC DISEASES: WHO DECIDES WHAT? 82–85 (1975)[hereinafter J. KATZ & A. CAPRON]; *see* sources cited *infra* note 119; *infra* notes 238–39 and accompanying text (differentiating various senses of "autonomy"); (2) protecting the subject's humanity, Cobbs v. Grant, 8 Cal. 3d at 242–46, 502 P.2d at 9–12, 104 Cal. Rptr. at 513–16; (3) preventing fraud and coercion, J. KATZ & A. CAPRON, *supra*, at 85–87; (4) encouraging self-scrutiny by the researcher, J. KATZ & A. CAPRON, *id.*, at 87–88; *see infra* note 209 and accompanying text; and (5) encouraging rational, broadly-based decisionmaking, J. KATZ & A. CAPRON, *supra*, at 88–89. It is sometimes debated whether there is a single informed consent requirement, which is applied more rigorously in experimental settings because of the greater dangers those settings pose to autonomy and well-being; or whether there are two separate requirements, one applicable to experimental settings, the other applicable to settings in which standard therapies are dispensed. In our opinion, the better view is that there is a single requirement, the meaning of which varies according to the setting in which it is applied. Operationally, there is little difference between the two conceptions of informed consent. Their policy bases are the same, and they generally yield similar results.

By "research" we mean biomedical and behavioral treatments and practices for which the principal purpose is to generate new scientific knowledge. 45 C.F.R. § 46.102(e) (1985) (" 'Research' means a systematic investigation designed to develop or contribute to generalizable knowledge."). Research is contrasted with standard treatments for which the principal purpose is to apply existing knowledge for the benefit of a present patient.

Research may be aimed at improving the lot of the current subject (therapeutic research), or at producing knowledge that will benefit only future patients (nontherapeutic research). These categories may merge, depending upon the investigator's intent and the subject's expectations. A third category—"innovative" or deviant therapy—is sometimes considered a form of research. Under the current regulations, much depends upon the scientist's intent. *See id.* § 46.102(e) ("systematic investigation *designed* to develop . . . knowledge") (emphasis added); *see also* Levine & Caplan, *Beyond Localism: A Proposal for a National Research Review Board*, 8 INST. REV. BD. 7, 8 (Mar./Apr. 1986) (innovative therapy falls into a "grey area" between experimentation and therapy). Unorthodox therapy is often controversial, even when given to dying patients as a last resort; Fiorentino v. Winger, 26 A.D.2d 693, 272 N.Y.S.2d 557, *appeal dismissed*, 18 N.Y.2d 639, 223 N.E.2d 216, 278 N.Y.S.2d 410 (1966), *rev'd*, 19 N.Y.2d 407, 227 N.E.2d 296, 280 N.Y.S.2d 373 (1967); Hood v. Phillips, 537 S.W.2d 291 (Tex. Civ. App. 1976), *aff'd*, 554 S.W.2d 160 (Tex. 1977). Even the issue whether the classification of unorthodox therapy falls under federal regulations is controversial. *See* Karp v. Cooley, 493 F.2d 408 (5th Cir. 1974), *cert. denied*, 419 U.S. 845 (1975), discussed *infra* note 86 (dispute over need to obtain approval for experimental medical procedure led to resignation of two physicians).

In 1982, a Presidential commission found that the number of research subjects "at risk" was large but unknown. PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, COMPENSATING FOR RESEARCH INJURIES 79–80 (1982) [hereinafter PRESIDENT'S COMMISSION]. This study cited government reports indicating that about 600,000 subjects annually take part in clinical trials of new therapies sponsored by the Public Health Service, and about 375,000 annually take part in studies sponsored by the FDA. The number of subjects participating in social science research probably is much larger.

The literature on informed consent is extensive, especially in connection with

greater rigor are:[2] (1) Because the risks of experimentation are not known in advance, only the subject can decide whether to undergo them;[3] (2) any argument for deferring to medical expertise is inappropriate in the research setting;[4] (3) the research subject, who is unlikely to benefit directly from the research, cannot be presumed to consent to it;[5] and (4) the researcher and the subject often have conflicting interests.[6]

Despite the general agreement that consent in human research ought to be protected vigorously, the principal mechanisms for effectuating that protection—Institutional

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standard medical treatments. *See, e.g.*, R. FADEN, T. BEAUCHAMP & N. KING, A HISTORY AND THEORY OF INFORMED CONSENT (1986); J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (1984) [hereinafter SILENT WORLD]; J. KATZ & A. CAPRON, *supra*; R. LEVINE, *supra*; Capron, *supra*; Dworkin, *Autonomy and Informed Consent, reprinted in* PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, 3 MAKING HEALTH CARE DECISIONS app. (1982) [hereinafter MAKING HEALTH CARE DECISIONS]; Hagman, *The Medical Patient's Right to Know: Report on a Medical-Legal-Ethical, Empirical Study*, 17 UCLA L. REV. 758 (1970); Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137 (1977); Levine, *supra*; Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413; Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219 (1985); Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628 (1970); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533 (1970); *see also infra* notes 12, 13, 47, 49, 54, 117 and accompanying text (incidence of harm in research).

2. These four "standard reasons" overlap somewhat. *See infra* notes 89–108 and accompanying text.

3. *See, e.g.*, Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rptr. 147 (1976), 2 Pris. L. Rptr. 433 (1973); Bang v. Miller Hosp., 251 Minn. 427, 434, 88 N.W.2d 186, 190 (1958); M. SHAPIRO & R. SPECE, BIOETHICS AND LAW 93–99 (1981); *see also infra* notes 89–93 (and sources cited therein) and accompanying text.

4. *See, e.g.*, Halushka v. University of Saskatchewan, 53 D.L.R.2d 436, 52 W.W.R. 608 (Sask. Ct. App. 1965), *reprinted in part in* J. KATZ, *supra* note 1, at 569; *see also* C. FRIED, MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY 25–36 (1974); notes 94–97 (and sources cited therein) and accompanying text.

5. *See, e.g.*, Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rptr. 147 (1976), 2 Pris. L. Rptr. 433 (1973); M. SHAPIRO & R. SPECE, *supra* note 3, at 93–98; *see also* notes 98–100 (and sources cited therein) and accompanying text.

6. *See, e.g.*, M. SHAPIRO & R. SPECE, *supra* note 3, at 95–96; N.Y. PUB. HEALTH LAW §§ 2440–2444 (Consol. 1976); Note, *Informed Consent: From Disclosure to Patient Participation in Medical Decisionmaking*, 76 NW. U.L. REV. 172, 176–77 (1981); *see also infra* notes 102–05 (and sources cited therein) and accompanying text. The subject's goals may or may not include the advancement of scientific knowledge. *See infra* notes 117–27 and accompanying text.

Review Boards (IRBs)[7]—work imperfectly. The regulations under which IRBs operate make the principal investigator responsible for obtaining informed consent,[8] entirely eliminate the consent requirement in certain types of research,[9] permit an IRB to waive the requirement in some circumstances,[10] and provide the subject with no adequate remedy in the event of a violation.[11]

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 then offers three additional reasons. When the current federal regulations are examined in light of the reasons for protecting research subjects, a number of deficiencies appear. Part III proposes amendments to the federal regulations in order to achieve the necessary protection and also suggests a new judicial remedy that victims may use when researchers breach the regulations.

I. THE CURRENT APPROACH TO REGULATION OF HUMAN SUBJECTS RESEARCH

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

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7. IRBs are discussed *infra* notes 16–55 and accompanying text. For a comprehensive discussion of the functioning of IRBs, see DuVal, *The HSPC: An Experiment in Decentralized Federal Regulation*, 60 AM. B. FOUND. RES. J. 573 (1979); Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484 (1979).

8. *See infra* notes 37–39 and accompanying text.

9. *See infra* notes 41–49 and accompanying text. Much of the research that is exempted from federal regulation takes the form of "deception research." *See* 45 C.F.R. § 46.101(b) (1985); Dresser, *Deception Research and the HHS Final Regulations*, I.R.B. 3, 3–4 (Apr. 1981). Deception research is discussed *infra* notes 47–49 and accompanying text.

10. *See* 45 C.F.R. § 46.116(c)–(d) (1985).

11. *See infra* notes 51–55 and accompanying text.

A. *Federal Oversight of Research with Human Subjects*

The current federal approach to regulating human-subject research stems from the late 1960s and early 1970s. During that period, an influential article by Henry K. Beecher,[12] together with public disclosure of abuses in research—such as the Tuskegee syphilis study[13]—led to a demand for controls. The federal guidelines, first promulgated in 1974, have been amended several times.[14]

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12. Beecher, *Ethics and Clinical Research*, 274 NEW ENGL. J. MED. 1354 (1966a) (reporting "hundreds" of abuses of informed consent, including many from leading teaching hospitals; twelve percent of studies published in an excellent journal were unethical); *see also* H. BEECHER, RESEARCH AND THE INDIVIDUAL: HUMAN STUDIES (1970); Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 J. A.M.A. 34 (1966). *See generally Case Studies: Five Incidents of Alleged Misconduct in Biomedical Research*, in PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, PROTECTING HUMAN SUBJECTS, app. E, at 177 (1981) [hereinafter *Case Studies*]. *But see* THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1978) [hereinafter BELMONT REPORT] (only three percent of research projects in a recent year caused harm, and much of the harm was trivial, or "only temporarily disabling"); H. BEECHER, EXPERIMENTATION IN MAN (1959).

13. *See* FINAL REPORT OF THE STUDY AD HOC PANEL TO THE DEP'T OF HEW 5-515 (1973); J. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1981); Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CENT. REP. 21 (Dec. 1978); *see also Quality of Health Care—Human Experimentation, Parts 1–3: Hearings on S. 974, S. 878, S.J. Res. 71, Before the Subcomm. on Health of the Senate Comm. on Labor & Public Welfare*, 93d Cong., 1st Sess. (1973); CASE STUDIES, *supra* note 12; M. PAPPWORTH, HUMAN GUINEA PIGS (1967) (British account of events similar to those described by Beecher); *see also* Goldby, *Experiments in the Willowbrook State School*, 1 LANCET 749 (1971) (letter to editor discussing institutionalized, retarded children used as experimental subjects for testing hepatitis vaccine).

14. The federal guidelines are an outgrowth of the post-World War II concern for protecting the rights and the welfare of human research subjects. H. BEECHER, *supra* note 12, at 23; Fletcher, *Evolution of Informed Consent*, in RESEARCH ETHICS 203 (K. Berg & K. Tranoy eds. 1983); J. KATZ, *supra* note 1, at 572. *See generally* J. KATZ, *supra* note 1. The Nuremberg war crimes tribunal formulated the first code to protect human research subjects. NUREMBERG CODE, *reprinted in* J. KATZ, *supra* note 1, at 305–06. For a discussion of the prosecution of medical professionals and personnel in the Nuremberg trials, see A. METSCHERLICH & F. MIELKE, THE DEATH DOCTORS (1962). In 1964, the World Medical Association promulgated its Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, *reprinted in* BIOMEDICAL ETHICS 146–47 (T. Mappers & J. Zembaty eds. 1981). The declaration was revised in Tokyo in 1975. *See generally* A. BRADY & K. JONSEN, THE EVOLUTION OF REGULATORY INFLUENCES ON RESEARCH WITH HUMAN SUBJECTS, IN HUMAN SUBJECTS RESEARCH (A. Greenwald, M. Ryan & J. Mulvihill eds. 1982); R. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 287–89 (1981). In 1977, the World Psychiatric Association issued its Declaration of Hawaii. In the United

These regulations appear in their latest form in titles 21 and 45 of the Code of Federal Regulations.[15] As a condition of

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States, Congress passed the National Research Service Award Act of 1974 to assure that federally supported research with human subjects is conducted ethically. Pub. L. No. 93-348, 88 Stat. 342 (1974) (amending the Public Health Service Act, 42 U.S.C. §§ 201–300(t) (1982)). The Department of Health, Education and Welfare first published rules, derived from its Institutional Guide to HEW Policy on Protection of Human Subjects (1971), for the protection of human subjects in the 1974 Federal Register. 39 Fed. Reg. 18,914 (May 30, 1974) (codified at 45 C.F.R. §§ 46.101–.122 (1985)). For a review of the history of these regulations, see Robertson, *supra* note 7, at 486–89.

The Nuremberg Code set forth and explained the principle of informed consent to research as follows:

> 1. The voluntary consent of the human subject is absolutely essential.
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> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

NUREMBERG CODE, *reprinted in* J. KATZ, *supra* note 1, at 305–06.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research identified basic ethical principles—respect for persons (autonomy), beneficence (obligation to secure the well-being of persons), and justice (in regard to who receives the benefits of research and who bears its burdens)—which were adopted as a statement of policy by the HEW. Letter from Kenneth J. Ryan, M.D., Chairman, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, to President Carter (Sept. 30, 1978), *reprinted in* BELMONT REPORT, *supra* note 12.

15. On June 3, 1986, the Office of Science and Technology Policy published Proposed Model Federal Policy for Protection of Human Subjects, 51 Fed. Reg. 20,204 (1986) [hereinafter Proposed Model Policy]. The proposed guidelines are intended to provide a "common core" of federal governance for all research conducted, supported, or regulated by the federal government. *Id.* at 20,205. The proposed guidelines are closely patterned after the HHS guidelines contained in 45 C.F.R. § 46. *See infra* note 16 and accompanying text. In particular, the portion of the current HHS guidelines pertaining to informed consent is preserved essentially unchanged by the Proposed Model Policy, *supra*, at 20,206 (Consistency with HHS Regulations, item 6—provisions for informed consent). The Pro-

receiving federal funding, research institutions are required to file an "assurance" that research will meet prescribed ethical standards and requirements for informed consent.[16]

In addition, institutions covered by these regulations must establish IRBs composed of a cross-section of the scientific and lay communities.[17] IRBs meet at regular intervals to review proposed and ongoing research projects.[18] Members must have varied backgrounds, to ensure racial and cultural diversity, and must not have competing interests that prevent their unbiased performances of their duties.[19] Members also must determine whether the selection of subjects is "equitable," in order to prevent overreliance on groups with little political representation and power.[20]

One of an IRB's principal tasks is to review research proposals to assure informed consent. The present regulations do not define informed consent,[21] but identify eight elements and give an IRB broad discretionary powers to require further elements when it deems it advisable.[22] Federal regulations require that the human subject be informed of the following: (1) The purposes of the research, the procedures to be used and whether the procedures are experimental; (2) the risks and discomforts to the subject; (3) the

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posed Model Policy also preserves the HHS provisions relating to the characteristics of IRBs, the role of IRBs in reviewing research, and the standards and procedures to be used by IRBs in reviewing research. *Id.* The footnotes in this Article note any relevant differences between the existing regulations and the proposed Model Policy. In 1987, a Notice of Proposed Rulemaking regarding the proposed Model Policy may appear in the Federal Register, followed by a 60-day period for comment, after which the Policy may go into force.

16. 45 C.F.R. § 46.103(a) (1985).

17. *Id.* § 46.107(b).

18. *Id.* § 46.106.

19. *Id.* § 46.107(e).

20. *Id.* § 46.107.

21. The rules published in 1974 by the Department of Health, Education and Welfare included the following definition of informed consent:

> (c) "Informed consent" means 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.

39 Fed. Reg. 18,917 (1974).

This definition caused much public debate and was not included in the regulations published in 1981. Instead, the regulations listed eight elements of informed consent and six additional optional elements. 46 Fed. Reg. 8389– 8390 (1981) (codified at 45 C.F.R. § 46).

22. 45 C.F.R. § 46.116(a) (1985).

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 anonymity in records that are kept; (6) compensation offered or treatment available in "research involving more than minimal risk"; (7) the identity of an individual whom the subject may contact about the research, the subject's rights, and the treatment available for any research-related injury; and (8) the subject's right to terminate participation at any time without losing any benefits to which he otherwise would be entitled.[23]

In addition, the IRB may require the researcher to provide information regarding the possibility of unforeseeable risks to the subject, or 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 the subject's consent; additional costs to the subject of participating in the research;[24] the effect of the subject's determination to withdraw from the project and the procedures for doing so; new findings made while the research is in progress that might affect the subject's decision to continue participating; and the number of subjects in the project.[25] Since 1981, consent sometimes is required when a person's blood or bodily tissue is obtained for research purposes.[26] The consent requirement is modified or waived in certain situations, however. These include research that presents minimal or no risk to the subject,[27] or which relies on existing

23. *Id.* § 46.116(a)(1)–(8).

24. It is unclear what the term "additional costs" is intended to cover. At least one major research center interprets it to mean financial costs that the patient must bear, such as doctor's fees and hospital expenses. Telephone interview with Paula Knudson, Staff Assistant, Committee for the Protection of Human Subjects, University of Texas Health Sciences Center, Houston (May 23, 1986).

25. 45 C.F.R. § 46.116(b)(4)–(6) (1985).

26. *Id.* § 46.102(f)(2) ("includes . . . physical procedures by which data are gathered (for example venipuncture) . . . ."). *But see id.* § 46.101(b)(5) (exempting research on nonidentifiable or publicly available pathological or diagnostic specimens); *see also infra* notes 78–83, 241 and accompanying text (discussing the patient's right to share in proceeds of research on his tissue if it yields a marketable commodity or cell line).

27. 45 C.F.R. § 46.101(b) (1985) (exempting certain research from IRB review entirely); *see* Proposed Model Policy, *supra* note 15, at § 46.101(b)(2)–(3) (consolidating and making minor modifications in current HHS treatment of exempt research).

records or simple observational data.[28] Research that evaluates certain government benefit programs is also exempt.[29]

B. *Deficiencies of the Current Approach to Protecting Informed Consent in Human Research*

The HHS guidelines represent a clear advance over the relatively unguided state of affairs that prevailed before their adoption. Many of their features are commendable, for example inclusion of lay representatives on review panels,[30] recognition of the special dangers of research on children and captive populations,[31] and provision for risk-benefit review by persons unconnected with the research.[32] Yet the central provisions of the guidelines—those pertaining to informed consent—are curiously deficient. The guidelines place primary responsibility for obtaining informed consent on the principal investigator.[33] They waive the requirement

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28. 45 C.F.R. § 46.101(b)(5) (1985). Even in these situations, the IRB still must protect the privacy rights of subjects. *Id.* § 46.101(b)(3)–(4). For an illustration of social science research in which potential subjects and their parents foresaw great risk of harm that the researchers did not foresee, see Merriken v. Cressman, 364 F. Supp. 913 (E.D. Pa. 1973). In *Merriken*, a junior high school student sought to enjoin a school district from instituting a program to identify potential drug abusers by using test questionnaires that allegedly invaded constitutionally protected rights. The court issued an injunction on grounds that the program violated the right of privacy. The court noted that parents and children were not advised of the risks of

> self fulfilling prophecy in which a child labelled as a potential drug abuser will by virtue of the label decide to be that which people already think he or she is anyway . . . . [and] scapegoating in which a child might be marked out by his peers for unpleasant treatment either because of refusal to take the CPI test or because of the results of the test.

Id. at 915.

29. 45 C.F.R. § 46.101(b)(6)(1985); *see* Proposed Model Policy, *supra* note 15, at 20,211 (codified at 45 C.F.R. § 46.101(b)(2)–(3)) (combining and making minor modifications in current provisions for exemptions); *see also* 45 C.F.R. § 46.116(c)(1) (1985).

30. 45 C.F.R. § 46.107 (1985) (membership must be diverse, reflect community attitudes, and include nonscientists and persons not affiliated with the research institution); *see* Proposed Model Policy, *supra* note 15, at 20,213 (codified at 45 C.F.R. § 46.107(a)–(b)) (membership to be as diverse as possible, but rejecting rigid "quota-style" principles for inclusion).

31. 45 C.F.R. §§ 46.111(b), 46.301–.306, 46.401–.409 (1985); *see also id.* § 46.107(a). These measures are intended to implement a report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, RESEARCH INVOLVING PRISONERS (1976).

32. 45 C.F.R. § 46.111(a)(2) (1985).

33. *E.g., id.* §§ 46.116 ("investigator shall seek such consent"), 46.117(b)(1)

entirely in certain types of research.[34] And they provide little in the way of an effective remedy when consent is not obtained.[35] As Part II will demonstrate, the importance of protecting human subjects' autonomy is most compelling in connection with experimental procedures. Accordingly, these weaknesses in the current requirements warrant prompt attention.[36]

1. 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."[37] Although the researcher must prepare a consent form approved by the IRB,[38] the researcher is thereafter 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.[39] It is easy to see how permitting the principal investigator to carry out these tasks could compromise the goal of protecting human subjects. For example, the investigator could answer questions evasively. The investigator could also convey through words or gestures that participation was expected,

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("investigator shall give . . . the subject . . . adequate opportunity to read [consent form]"), 46.117(c) ("IRB may waive the requirement for the investigator to obtain a signed consent form").

34. *Id.* § 46.116(c).

35. *See infra* notes 51–54 and accompanying text. *But see* Robertson, *supra* note 7, at 531–33 (discussing the possibility of a judicially implied tort remedy for an IRB's failure to apply guidelines properly).

36. The regulations promulgate minimal standards for the ethical conduct of research with human subjects. Many IRBs conscientiously strive to achieve ideal evaluations and requirements for research. Unfortunately, ethical standards sometimes may be reduced to what is merely "legal."

37. 45 C.F.R. § 46.116 (1985) (emphasis added). The term "principal investigator" means the research scientist in charge of the research project.

38. *Id.* § 46.117(a).

39. The review committee may appoint a third-party "consent monitor," *id.* § 46.109(e), but this is not required, and few committees seem to do this. *But see* Interview with Angela Holder, Professor, Pediatrics, Yale Medical School, Chief Counsel, Yale-New Haven Hospital (June 17, 1985) (practice sometimes is followed at Yale). The regulations originally called for "consent committees" to monitor consent in certain situations in which special difficulties or pressures were expected. *See* 39 Fed. Reg. 30,653–56 (1974). This provision was never enacted. *See* M. HERSHEY & R. MILLER, HUMAN EXPERIMENTATION AND THE LAW 42 (1976).

or that the risks were minimal when they actually were not.[40] These failures, which may be either conscious or unconscious, and which often stem from differences in perspective between the investigator and subject, are discussed in Part II as examples of a "conflict of value" inherent in the research situation.

2. Waiver of the informed consent requirement in connection with certain categories of research

Federal regulations relieve the investigator of the duty to obtain informed consent from his or her subjects in certain situations. These situations include most educational research,[41] research that involves surveys and interviews,[42] research that consists of observing public behavior,[43] and research that uses existing records or data.[44] In addition, the informed consent requirement may be modified or waived when the research concerns an evaluation of certain governmental programs,[45] or presents no more than minimal risk to the subjects and "could not practicably be carried out without the waiver or alteration."[46]

The latter exception is particularly troublesome, especially when interpreted to permit "deception research."[47]

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40. *See, e.g.*, Capron, *supra* note 1, at 357–58, 367–68 (experimenters can use emphasis and superior knowledge to obtain consent); Meisel, *supra* note 1, at 413, 416 (physician often discloses in a way calculated to obtain consent); *infra* notes 56–78 and accompanying text (accounts of inadequate consent); *infra* notes 152–61 (researcher's mindset).

41. 45 C.F.R. § 46.101(b)(1) – (2) (1985).

42. *Id.* § 46.101(b)(3).

43. *Id.* § 46.101(b)(3) – (4).

44. *Id.* § 46.101(b)(5).

45. *Id.* § 46.101(b)(6).

46. *Id.* § 46.116(d)(3).

47. *See* Dresser, *supra* note 9, at 3–4 (Apr. 1981) (some deception research entirely exempt under § 46.101(b), but much will remain covered by § 46.116(d)); *see also* J. AREEN, P. KING, S. GOLDBERG & A. CAPRON, LAW, SCIENCE & MEDICINE 970 (1985) (discussing deception research—the purpose of which cannot be achieved, at least readily or directly, without deceiving the subject about its nature or purpose); Gross & Fleming, *Twenty Years of Deception in Social Psychology*, 8 PERSONALITY & SOC. PSYCHOLOGY BULL. 402 (1982); Sieber, *Deception in Social Research I: Kinds of Deception and the Wrongs They May Involve*, 4 INST. REV. BD. 1 (Nov. 1982) [hereinafter Sieber, *Deception in Social Research I*]; Sieber, *Deception in Social Research II: Evaluating the Potential for Harm or Wrong*, 5 INST. REV. BD. 1 (Jan./Feb. 1983) [hereinafter Sieber, *Deception in Social Research II*]; Sieber, *Deception in Social Research III: The Nature and Limits of Debriefing*, 5 INST. REV. BD. 1 (May/June 1983) [hereinafter Sieber, *Deception in Social Research III*]. For further discussion and examples of deception research, see *infra* notes 119–25 and accompanying text; *infra* note

Although special requirements come into play when an IRB reviews proposals for nonexempt deception research,[48] these provisions do not adequately address the risk of humiliation, cynicism, and sense of betrayal that may result from such research.[49] Moreover, waivers of the informed consent requirement endanger autonomy, the principal value sought to be protected. They ought to be cautiously granted in limited circumstances.[50]

3. Lack of an effective remedy

A final difficulty with the current consent regulations is that they provide no effective remedy for breach by a researcher or an institution. If a subject is injured in the course of research, because of a failure to obtain informed consent or otherwise, some institutions offer medical or psychological treatment.[51] If a researcher flagrantly violates a provision of a research protocol, including those having to do with consent, the IRB may report the researcher to campus authorities for disciplinary action.[52] The federal govern-

238 (possible solutions to problem of deception research). Deception research occurs very frequently in the social sciences—some estimates put the figure at over 50% of all research in the area. Gross & Fleming, *supra*, at 405 (estimates up to 66%).

48. 45 C.F.R. § 46.116(d) (1985). The additional requirements are proof of minimal risk, showing that the subject's rights and well-being will not be endangered, and proof that the research cannot be carried out without waiving the consent requirement and debriefing. A number of IRBs and investigators apparently use debriefing for all or most deception research, including that which is exempt from the requirement.

49. *See* J. AREEN, P. KING, S. GOLDBERG & A. CAPRON, *supra* note 47, at 970–71 and sources cited therein (harm to subjects resulting from the realization that they had participated in deception research); *see also* Kelman, *Privacy and Research with Human Beings*, 33 J. SOC. ISSUES 169 (Summer 1977) (emotional harm resulting from invasion of privacy); Murray, *Learning to Deceive*, 10 HASTINGS CENT. REP. 2 (1980); *see also* Sieber, *Deception in Social Research II*, *supra* note 47.

50. *See infra* notes 238–39 and accompanying text (discussing waiver of the consent requirement).

51. *See, e.g.*, UCLA POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS, RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS 17 (1984) [hereinafter UCLA POLICIES AND PROCEDURES] (guideline 6: subjects have the right to be informed of treatments the institution will provide if complications arise); *see also* 45 C.F.R. § 46.116(a)(6) (1985) (right to be informed whether medical treatment is available if injury occurs).

52. 45 C.F.R. §§ 46.103(b)(4), 46.108(c) (1985). When the campus authorities receive such a report, they must notify federal authorities. *Id.* § 46.108(c); *see also* Proposed Model Policy, *supra* note 15, at 20,212 (codified at 45 C.F.R. § 46.103(b)(5)). The campus authorities also may terminate or suspend approval of research conducted in violation of the guidelines. 45 C.F.R. § 46.113 (1985).

ment may terminate a grant or refuse to issue a new one, especially if it believes that the institution has insufficiently dealt with the violator.[53] Aside from these measures, the regulations provide little remedy for victims of unconsented-to research.[54] At least one commentator has argued that a

53. *See* 45 C.F.R. § 46.123 (1985); 48 C.F.R. 309.4 (1985) (debarment of federal contracts); PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, PROTECTING HUMAN SUBJECTS: FIRST BIENNIAL REPORT ON THE ADEQUACY AND UNIFORMITY OF FEDERAL RULES AND POLICIES, AND THEIR IMPLEMENTATION, FOR THE PROTECTION OF HUMAN SUBJECTS IN BIOMEDICAL AND BEHAVIORAL RESEARCH 181–85 (1982) [hereinafter PROTECTING HUMAN SUBJECTS]; UCLA POLICIES AND PROCEDURES, *supra* note 51, at 5–6 (reprinting typical institutional General Assurance); *infra* note 69 and case described therein (reprimand of UCLA researcher Martin Cline).

In 1986, NIH reprimanded UCLA researcher Dr. Robert Gale for work involving bone marrow transplants. As a result, UCLA must audit Dr. Gale's research records and report to the federal government. For two years, Dr. Gale's work will be subject to review every six months for compliance with federal regulations. *If It's Research, It Must Be Reviewed: An NIH Reprimand,* 8 INST. REV. BD. 11 (Jan./Feb. 1986). One part of Dr. Gale's research involved removing bone marrow from very ill patients, and administering lethal doses of chemotherapy, then subsequently attempting "rescue" with the patients' stored bone marrow. The UCLA IRB had approved Gale's research projects, but he "did not comply with the terms of approval, particularly in the consent process." *Id.*

54. *Cf.* California's human experimentation code, which provides damages of $50 to $5000 for "[p]erformance of experiment without consent or willful failure to obtain consent." CAL. HEALTH & SAFETY CODE § 24176(a)–(b) (West 1984). The concern for victims of unconsented-to research is not hypothetical. *See infra* notes 57–85 and accompanying text and cases cited therein (legal decisions stemming from research-caused harms), *supra* notes 12–13, 47, 49; *infra* note 117 and accompanying text (incidence of harm from research). Nor has the risk of harm moderated. Although much current research in the United States presents low to moderate risk, significant exceptions exist, e.g., drug studies conducted with seriously ill patients (suffering from cancer or AIDS, for example); psychosurgery; bone marrow transplantation; fetal surgery; and transplant techniques or devices, including interspecies transplants (xenografts). *See, e.g.,* Caplan, *Ethical Issues Raised by Research Involving Xenografts,* 254 J. A.M.A. 3339 (Dec. 20, 1985); Fletcher & Schulman, *Fetal Research: The State of the Question,* 15 HAST. CENTER REP. 6 (Feb. 1985); Sheldon, *The Subject is Baby Fae: The IRB's Responsibility to Itself,* 15 HASTINGS CENT. REP. 11 (Feb. 1985); *Medical Journal Assails the Use of an Experimental Cancer Drug,* N.Y. Times, Dec. 12, 1986, at 1, col. 2 (describing "devastating toxic reactions" to treatment of cancer with interleuklin 2). At the University of Texas Medical Center, the campus IRB, after careful deliberation, recently approved proposal to treat cancer patients by hyperthermia, a painful procedure that entails heating and transfusing a patient's blood. Interview with Paula Knudson, Staff Assistant, Committee for the Protection of Human Subjects, University of Texas Medical Center, Houston (May 14, 1986).

Our point is not that any of these research projects is irresponsible (indeed, many are quite responsible); rather, our objective is to show that much current research is risky and can harm subjects. When such risks exist, there is a great need to be certain that the subject understands and agrees to take the risks of the researcher.

private cause of action could be implied from the regulations,[55] but no appellate court seems to have considered this question. The few decisions from common-law jurisdictions that have provided redress for human subjects injured by research are based on other grounds.

C. *Case Law Affording Redress for Human Subjects of Unconsented-to Research*

Judicial protection of the right to informed consent in a research setting is based upon a number of theories, no one of which is wholly satisfactory. United States law has been influenced by a Canadian case,[56] *Halushka v. University of Saskatchewan.*[57] 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; for payment of fifty dollars he volunteered to be the subject of a test sponsored by the medical school's anesthesia department. Halushka alleged that the principal researcher told him he would be taking a safe test that had been conducted before. The researcher told Halushka that electrodes would be implanted, and a catheter inserted into a vein in his left arm to test a new anesthetic drug. However, 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 a 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 suffered lingering effects, including loss of concentration and ability to reason. Halushka sued for trespass to the person (battery) and negligence,[58] and was awarded a $22,500 judgment. On appeal, the court upheld the award because the information Halushka received was so incomplete that it

55. *See* Robertson, *supra* note 7; *cf.* Blanton v. United States, 428 F. Supp. 360, 362–63 (D.D.C. 1977) (deriving negligence claim for failure to obtain informed consent, in part, from FDA consent guidelines which are similar to those of HHS).

56. *See, e.g.*, R. VEATCH, CASE STUDIES IN MEDICAL ETHICS 291–95 (1955); Baumrind, *Nature and Definition of Informed Consent in Research Involving Deception, reprinted in* BELMONT REPORT, *supra* note 12, at 18–23.

57. 53 D.L.R.2d 436, 52 W.W.R. 608 (Sask. Ct. App. 1965), *reprinted in* J. KATZ, *supra* note 1, at 569.

58. *Id.* at 440, 52 W.W.R. at 611, *reprinted in* J. KATZ, *supra* note 1, at 570.

amounted to nondisclosure.[59]

The court supported its conclusion by citing well-known principles of informed consent articulated in American cases dealing with standard medical treatments.[60] The court also recognized that the researcher owed a fiduciary duty at least as great as that "owed by the ordinary physician or surgeon to his patient" because the research situation does not support exceptions to disclosure.[61] To protect the subject's autonomy and to assure informed consent, "[t]he subject . . . 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."[62]

Like Halushka, the plaintiffs in *Mink v. University of Chicago*[63] proceeded on a battery theory, despite the modern tendency to treat inadequate disclosure as negligence.[64] Between 1950 and 1952, pregnant patients at the University of Chicago were given pills they were told would help prevent miscarriage. The patients were not told the pills were diethylstilbestrol (DES);[65] nor were the patients told they were participating in experimental trials of the drug. When the

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59. *Id.* at 445, 52 W.W.R. at 615 ("The undisclosed or misrepresented facts need not concern matters which directly cause the ultimate damage if they are of a nature which might influence the judgment upon which the consent is based."), *reprinted in* J. KATZ, *supra* note 1, at 575; *see also* Schwartz v. Boston Hosp. for Women, 422 F. Supp. 53 (S.D.N.Y. 1976) (procedure exceeded that to which patient consented); Valenti v. Prudden, 58 A.D.2d 956, 397 N.Y.S.2d 181 (1977) (disfiguration following experimental procedure far exceeded extent disclosed in consent document).

60. *See, e.g.*, Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960) (alleged excessive dose of radioactive cobalt); Mitchell v. Robinson, 334 S.W.2d 11 (Mo. 1960) (insulin shock therapy for emotional illness).

61. 53 D.L.R.2d at 444, 52 W.W.R. at 614.

62. *Id.*, 52 W.W.R. at 614.

63. 460 F. Supp. 713 (N.D. Ill. 1978), *aff'd*, 727 F.2d 1112 (7th Cir. 1984).

64. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.) (discussing theoretical bases of suits for breach of informed consent), *cert. denied*, 409 U.S. 1064 (1972); Burton v. Brooklyn Doctors' Hosp., 88 A.D.2d 217, 452 N.Y.S.2d 875 (1982). In *Burton*, a premature infant was placed in an experimental treatment pool without either his parents' consent or the knowledge of his personal physician. The experimental treatment permanently blinded the child. The plaintiff, now grown, has recovered 1.5 million dollars. The award was upheld on appeal on two grounds: the experimental treatment was negligent and amounted to malpractice; and the failure to obtain informed consent constituted actionable negligence.

65. DES subsequently was shown to increase the risk of cancer to children whose mothers ingested it while pregnant. It then was withdrawn from the market.

women learned of the experiments years later, they filed a class action against the university and the drug manufacturer on grounds of battery, product liability, and breach of the duty to notify plaintiffs they would be given the drug. The court upheld the battery claim, finding that giving the plaintiffs pills to ingest, although not strictly an offensive, unconsented touching, was "indistinguishable in principle" from administering the drug with a hypodermic needle.[66] The strict liability and failure-to-notify claims were dismissed because the plaintiffs themselves suffered no physical injury—they merely were concerned about the risk that their offspring would develop cancer.[67] In contrast, the battery claims protected the dignity and autonomy of each plaintiff by punishing unconsented meddling with her body.[68] The *Mink* court thus stretched tort doctrine to afford relief in a novel situation by finding for the plaintiffs under a battery theory, despite both the lack of any conventional touching and the existence of the patients' nominal consent.

The researchers' nondisclosure in *Mink* is by no means atypical.[69] One of the more egregious examples of nondisclosure occurred at the Jewish Chronic Disease Hospital in

66. 460 F. Supp. at 718. An unconsented-to injection would constitute a battery, as would a similar result produced by forces the defendant set in motion. *See* W. PROSSER & W. KEETON, THE LAW OF TORTS § 9, at 49 (5th ed. 1984) (elements of a suit for battery).

67. 460 F. Supp. at 719–20.

68. *Id.* at 713, 716 (citing Trogun v. Fruchtman, 58 Wis. 2d 569, 596, 207 N.W.2d 297, 311–12 (1973)) ("a person of sound mind has a right to determine, even as against his physician, what is to be done to his body").

69. *See, e.g,* Henry Beecher's 22 examples of unethical research in *Ethics and Clinical Research, supra* note 12, at 1354–60; M. Pappworth's collection of 500 papers allegedly based on unethical experimentation in HUMAN GUINEA PIGS, *supra* note 13; Fletcher, *supra* note 14, at 187–228. Recently, the National Institute of Health (NIH) formally sanctioned a researcher at UCLA Medical Center and terminated his NIH grants because he engaged in experimental research that violated human subject regulations. In 1980, using recombinant DNA materials prepared at UCLA as part of a NIH research grant, Dr. Martin J. Cline performed bone marrow transplants on uninformed patients in Italy and Israel. The UCLA IRB had disapproved these same procedures after consultants recommended that more animal studies be conducted before beginning tests with human subjects. Similarly, a researcher at the M.D. Anderson Hospital and Tumor Institute, University of Texas System Cancer Center, Houston, Texas, published a report of a study in which six cancer patients were given a drug not approved for use in humans. The National Cancer Institute's Investigational Drug Branch found numerous problems with protocol review and consent forms, including "lack of clarity about the type of study subjects were being asked to join, . . . failure to reveal potential adverse effects, and the misleading impression created that the drug—

New York. In 1962, three physicians directed a project in which twenty-two cancer patients were injected with live cancer cells without their knowledge or consent.[70]

On the basis of past experiments with healthy volunteers, the physicians were confident that the patients' immune systems would reject the foreign cells; the doctors simply wanted to determine whether rejection would take longer in the bodies of cancer patients. The researchers never submitted a proposal for any formal hospital or peer review. They merely contacted the medical chief of the hospital informally and enlisted his cooperation with the experiment.[71]

The researchers told the patients that the injections were merely skin tests for immunity response. Later, one of the researchers 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."[72] Three physicians on the hospital staff, however, refused to take part in this experiment.[73] They notified an attorney on the hospital's board, who in turn requested an investigation and asked for hospital records related to the experiment. When his requests were refused, the attorney successfully petitioned a lower New York court for permission to inspect the records.[74]

When the facts came to light, the state Medical Grievance Committee suspended two of the physicians from prac-

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actually in the earliest phase of testing—was being offered as treatment of a disease." *Case Studies*, *supra* note 12, at 181–87.

70. Hyman v. Jewish Chronic Disease Hosp., 21 A.D.2d 495, 495–97, 251 N.Y.S.2d 818, 818–21 (1964), *rev'd*, 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965). For excerpts and history of this case, see J. KATZ, *supra* note 1, at 9–65. *See also* Langer, *Human Experimentation: New York Affirms Patients' Rights*, 151 SCIENCE 663 (1966).

71. *See* sources cited *supra* note 70; *see also* Fletcher, *supra* note 14, at 213.

72. Hyman v. Jewish Chronic Disease Hosp., 21 A.D.2d 495, 497–98, 251 N.Y.S.2d 818, 820 (1964), *rev'd*, 15 N.Y.2d 217, 206 N.E.2d 338, 258 N.Y.2d 397 (1965).

73. Fletcher, *supra* note 14, at 214.

74. Application of Hyman, 42 Misc. 2d 427, 248 N.Y.S.2d 245, *rev'd*, 21 A.D.2d 495, 251 N.Y.S.2d 818 (1964), *rev'd*, 15 N.Y.2d 217, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965).

tice for one year, and the Board of Regents imposed a one-year probation.[75] In a written opinion, the Board of Regents affirmed the subjects' right of self-determination and rejected the claim that since the study was harmless the physicians had no obligation to obtain consent:

> 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.[76]

Although widespread agreement exists with the autonomy principle the Regents invoked,[77] no court yet 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,*[78] recently litigated in Los Angeles,

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75. Fletcher, *supra* note 14, at 214.

76. *Id.* at 217.

The arguments for protecting consent are even stronger in connection with experimentation that poses physical risk to the subject. In a leading case on the consent of institutionalized persons to experimental brain surgery to control behavior, a lower court in Michigan extensively examined consent issues in regard to neurosurgical experiments on involuntarily detained mental patients. The court held that such patients could give "adequate consent" only to "accepted neurosurgical procedures." Kaimowitz v. Department of Mental Health, *reprinted in* 1 Mental Disab. L. Rptr. 147, 151–53 (1976), 2 Pris. L. Rptr. 433, 438–39 (1973).

On the issue of consent, the court discussed the Nuremburg Code, *supra* note 14, and declared: "To be legally adequate, a subject's informed consent must be competent, knowing and voluntary." 1 Mental Disab. L. Rptr. at 150, 2 Pris. L. Rptr. at 438. The court based its pronouncements on the need to protect the "inviolability of the individual" which it said was "one of society's most fundamental values." *Id.* at 149, 2 Pris. L. Rptr. at 437. The court therefore concluded: "Consent is not an idle or symbolic act; it is a fundamental requirement for the protection of the individual's integrity." *Id.* at 151, 2 Pris. L. Rptr. at 439.

77. *See* Natanson v. Kline, 186 Kan. 393, 406–07, 350 P.2d 1093, 1104 (1960) (alleged excessive dose of radioactive cobalt); MAKING HEALTH CARE DECISIONS, *supra* note 1, at 2–4; *see also supra* notes 1–7, 16–26, 57–76 and accompanying text. For an argument that informed consent to medical treatment only imperfectly protects autonomy, and a proposal to protect autonomy directly, see Shultz, *supra* note 1, at 220–56. Autonomy has also been protected in a number of constitutional cases setting limits on the states' power to regulate in intimate areas of life. *See, e.g.,* Roe v. Wade, 410 U.S. 113 (1973) (abortion); Griswold v. Connecticut, 381 U.S. 479 (1965) (contraception); Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980) (acupuncture); *In re* Quinlan, 70 N.J. 10, 355 A.2d 647, *cert. denied,* 429 U.S. 922 (1976) (right to die).

78. Moore v. Regents of the Univ. of Cal., No. B021195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986).

indirectly raised this issue. In *Moore,* an ex-patient alleged that his physician-researchers at UCLA violated both the federal regulations of informed consent and California's Protection of Human Subjects in Medical Experimentation Act.[79]

When Moore's leukemia was first suspected in 1976, he began to make regular trips from his home in Alaska to the UCLA Medical Center for diagnosis and treatment. At the recommendation of a UCLA physician, Moore underwent surgery to remove his spleen. Moore alleged that he neither was informed of nor consented to the use of his excised tissues and blood for either research purposes or the development of a widely used laboratory cell line.[80] He further alleged that the defendants told him that the series of visits he made to UCLA through 1983 so that blood and bodily substances could be withdrawn were necessary to his health and well-being, but that the defendants did not inform him that they also needed those substances for research and commercial purposes.[81]

Upon learning of the alleged deceptions and misrepresentations, Moore filed suit on a number of grounds, including breach of fiduciary duty and violation of federal and state

79. Third Amended Complaint, Second Cause of Action for Lack of Informed Consent Against All Defendants, *Moore*. *See* 45 C.F.R. § 46 (1985); Protection of Human Subjects in Medical Experimentation Act of California, CAL. HEALTH & SAFETY CODE § 24172 (West 1986) (including "Experimental Subject's Bill of Rights").

The other causes of action included the following: (1) Conversion, based on the assertion of a property right in human blood and tissue; (2) deceit; (3) breach of fiduciary duty; (4) fraud; (5) unjust enrichment; (6) quasi-contract; (7) bad faith breach of the implied covenant of good faith and fair dealing; (8) intentional infliction of emotional distress; (9) negligent misrepresentation; (10) intentional interference with prospective advantageous economic relationship; (11) slander of title; (12) accounting; and (13) declaratory relief.

The defendants named in the Third Amended Complaint were "The Regents of the University of California; David Golde, M.D.; Shirley G. Quan; Genetics Institute, Inc.; Sandoz, Ltd.; Sandoz United States, Inc., and Does 1 through 1000 inclusive." (Case No. C 513755, dated Oct. 22, 1985).

80. Third Amended Complaint, filed Oct. 26, 1985. *Moore* was instrumental in bringing about a congressional hearing on the "role of patients, researchers, universities, and private companies in the development and marketing of human biological products." SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99th Cong., 1st Sess., Oct. 29, 1985 (publication forthcoming).

81. Third Amended Complaint, First Cause of Action for Conversion Against All Defendants.

law pertaining to informed consent.[82] Several of his claims rested on implied conflicts of interest: defendants treated Moore at the same time they pursued research and commercial goals. Moore did not plead, however, that at the time he consented to removal of his spleen that his doctors knew there would be utility to the research conducted with the excised tissue.[83] The trial court dismissed Moore's third amended complaint as to all defendants in 1986, after Moore indicated he would stand on the complaint and file an appeal if necessary.[84]

Halushka, Mink, and *Moore* are examples of courts struggling with moral issues surrounding redress for violation of informed consent in experimental research.[85] The relative paucity of appellate decisions, as well as the limited scope of theories under which these decisions proceed, suggests that current case law 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 who are working to advance medical or social science knowledge. This is especially true when the investigators' research proposals have been approved by a committee of their peers.[86] Until regulatory guidelines are changed,

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82. *Id.*; *see also supra* note 79.

83. Moore v. Regents of the Univ. of Cal., No. B021195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986).

84. *Id.*

85. *See also* Blanton v. United States, 428 F. Supp. 360 (D.C. Cir. 1977) (experimental drug apparently worked, although distraught patient did not learn this until later; court afforded relief for various physical symptoms of emotional disturbance).

86. *But compare* Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rept. 147 (1976), 2 Pris. L. Rep. 433 (1973) (noting that research proposal had been approved by a committee that included a law professor, a clergyman, and a certified public accountant, and that proposal called for no control group and contained one research subject, the court found consent provision legally inadequate) *with* Karp v. Cooley, 493 F.2d 408 (5th Cir.) (affirming directed verdict for defendant surgeon who used artificial heart as an unsuccessful stopgap measure on a dying patient on grounds that adequate consent had been obtained), *reh'g denied*, 496 F.2d 878, *cert. denied*, 419 U.S. 845 (1974). The experimental medical device at issue in *Karp* previously had not been used on human beings. The research that led to the development of the artificial heart was funded by the U.S. government, but there was no peer review as required by federal regulations. Eventually, "Dr. Cooley's refusal to sign an agreement to abide by peer review requirements . . . and a dispute over [priority of invention] led to . . . Dr. Cooley's resignation as clinical professor of surgery at Baylor College of Medicine." M. SHAPIRO & R. SPECE, *supra* note 3, at 866.

tort suits must meet the technical requirements of negligence or battery actions.[87] Unless the subject is physically harmed, damages may be difficult to prove.[88]

Part III of this Article proposes both changes in the HHS guidelines and a new approach to judicial relief. First, however, Part II explores the reasons for requiring greater protection of human autonomy in experimental research.

II. Protection of Informed Consent in Human Experimentation: Moral and Policy Analysis

Courts and commentators have offered four justifications for protecting the right to informed consent in human research. Together, these reasons argue for protecting this right even more stringently than it is protected in connection with standard medical treatments. However, these rationales are insufficient. Even more powerful arguments are needed and available. Section A reviews the conventional arguments for protecting informed consent. Section B advances three new reasons for protecting this interest.

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87. *See supra* notes 57–68 and accompanying text (courts in *Mink* and *Halushka* considered suit for research harms under the rubric of battery; battery requires an intentional act of offensive, nonconsensual touching plus physical or emotional injury).

Note the harsh treatment afforded the petitioner in Barrett v. New York, 85 Misc. 2d 456, 378 N.Y.S.2d 946 (1976). In *Barrett,* Elizabeth Barrett's father died from treatment provided at the New York State Psychiatric Institute. Barrett initially had sued under negligence and wrongful death theories and won an $18,000 judgment. Years later, she learned for the first time that the U.S. Army had sponsored the research that caused her father's death—an experimental injection of the hallucinogenic drug mescaline. Subsequently, Barrett petitioned for an order of discovery and inspection of government records so that she could sue for pain and suffering and the tort of conspiracy. The court denied the application on res judicata grounds: Barrett had alleged neither that the earlier judgment was insufficient nor that she could not have recovered fully for her father's death in the first suit. If *Barrett* is widely followed, it will erect yet another hurdle for potential plaintiffs in informed consent suits: when the deception is discovered after a successful suit is resolved, the first judgment or settlement may bar further relief.

88. *See supra* note 87. The victim of unconsented-to research often will suffer only emotional or pecuniary harm. *See supra* notes 82–83 & *infra* notes 109–27; *cf. Moore, supra* notes 78–83 (alleging economic harm resulting from loss of the opportunity to participate in the commercialization of the subject's unique blood and bodily substances).

A. *Standard Reasons for Protecting Informed Consent in Human Experimentation*

1. The risks of experimentation cannot be ascertained in advance

One reason frequently given for providing heightened protection to consent in experimental settings is that such settings, even more so than those in which standard medical treatments are dispensed, pose unknown and unascertainable degrees of risk.[89] Since the outcome of the procedure is uncertain, only the patient or experimental subject can decide whether to proceed.[90] The argument has much common-sense appeal. Many activities of everyday life—e.g., going for a ride in another's car, playing sports—have risks. For the most part, however, these risks are known to all. The law does 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—for example, selling chemical fertilizers for use in a garden, requiring someone to work with dangerous machinery, or performing a medical or surgical procedure. In these cases, the law imposes duties of disclosure in order to prevent accidents, eliminate exploitation, and protect human autonomy.[91] When the risk to health or autonomy is great, society may try to prevent the activity entirely so that no individual may subject another to the activity even if the other is willing and has consented.[92]

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89. *See* sources cited *supra* note 3. *See generally* BELMONT REPORT, *supra* note 12; Shultz, *supra* note 1, at 222.

90. When the consequences of a standard medical procedure are known and predictable, society will have experience with patients choosing or declining the procedure. This will not be the case with novel research. Even in medical treatment cases, some courts argue that the patient has the right to decide the course of treatment because the nonmedical consequences cannot be determined by the physician. *See, e.g.*, Cobbs v. Grant, 8 Cal. 3d 229, 243, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 512 (1972) ("The weighing of these risks—against the individual subjective fears and hopes of the patient is not an expert skill. Such evaluation and decision is a nonmedical judgment reserved to the patient alone."); *see also* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972); *cf.* Shultz, *supra* note 1, at 270 (medical uncertainty a factor calling for heightened protection of informed consent).

91. *See* J. KATZ & A. CAPRON, *supra* note 1, at 85–90; BELMONT REPORT, *supra* note 12, at 4–7.

92. Laws against mutiliation and administering dangerous recreational drugs are well-known examples.

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. Although much human research is relatively safe, not all is. Even research that is thought to be harmless may be resented and seen as an invasion of privacy or autonomy by particular patients.[93] It might be argued that the research team can allow for known risks just as well as the subject can, but the risks in research are not known with certainty. Consequently, there must be broad allowance for personal, idiosyncratic preferences and values. For all these reasons, the experimenter should be required to disclose the nature of the experiment and its range of risks, and to obtain the subject's consent.

2. There is no reason to defer to medical expertise because it does not exist in experimental settings

A second and somewhat related reason often given for providing increased protection to informed consent in human research is that research, by definition, is not an exercise of medical judgment.[94] The researcher's aim is to obtain new scientific knowledge rather than to apply it for the patient's benefit; therefore, it is pointless to defer to nonexistent medical expertise.[95] Courts tend to defer to expert judgments and are reluctant to substitute their own judgments 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.[96] The doctrine of informed consent, in particular, reflects and

93. *See, e.g.*, M. SHAPIRO & R. SPECE, *supra* note 3, at 98–99; cases cited *supra* notes 3, 4; sources cited *supra* notes 12, 13.

94. *See* sources cited *supra* note 4. As Fried has pointed out, the researcher confronts the subject in the role of a scientist, not a physician. C. FRIED, *supra* note 4, at 25–36; *see, e.g.*, Burton v. Brooklyn Doctors Hosp., 88 A.D.2d 217, 452 N.Y.S.2d 875 (1982) (physician-researcher assigned an infant subject to an experimental group without examining the child, countermanding the orders of the child's physician).

95. *See* Shultz, *supra* note 1, at 220, 270. Of course, if the experiment is successful and generates knowledge that results in a new standard treatment, the discovery will then become part of an expanded corpus of medical knowledge. In some situations the researcher may have multiple goals, one of which may be to find a treatment to benefit the subject-patient.

96. *See generally* Meisel, *supra* note 1 (law of informed consent expresses balancing of patient autonomy concerns and medical deference concerns).

is shaped by medical-deference concerns. But the argument for judicial deference weakens to the extent that the researcher does not know what will happen in the course of experimentation (even though he presumably will have a hypothesis or a hunch). No one is a better "expert" than the patient or subject to decide the principal moral issue of human experimentation: whether he or she should volunteer his or her body for the purposes of advancing medical knowledge.[97] Since the experimenter stands on no greater, and arguably on a lesser, footing than the human subject for deciding this question, the subject's wishes are entitled to great weight.

3. Experimentation often provides no certain benefit to the subject

A third reason often given for protecting human subjects from unconsented-to research is that, in contrast to standard medical treatments which attempt to confer some physical or psychiatric benefit on the patient, experimentation often provides the patient with little or no benefit.[98] From the objective reasonable patient standard to the unconscious patient rule and the emergency exception,[99] the doctrine of informed consent reflects the judgment that most medical treatments are designed to help the patient.[100] In contrast, most research is not intended to help the patient or experimental subject, but is designed to benefit others in the future.[101]

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97. *See generally* J.S. MILL, ON LIBERTY 6 (1859) (in Western democracies, political bias favoring liberty dictates that, absent a tangible social impact, individual decisions primarily affecting the decision-maker should be left to his or her sole discretion); *cf.* Shultz, *supra* note 1, at 264–66 (the duty of informed consent heightens when medical treatments are highly "elective"—as it is for the subjects of all nontherapeutic research).

98. *See supra* note 1 (defining therapeutic and nontherapeutic research and distinguishing research from standard medical treatments).

99. The reasonable patient standard, used by many jurisdictions, requires the physician to disclose only what a reasonable patient would want to know. The unconscious patient rule and the emergency exception permit the doctor to proceed without disclosure when the patient is unconscious or when the doctor is faced with an emergency requiring immediate action.

100. The best statement of this veiw is contained in Meisel, *supra* note 1, at 415.

101. For example, drug testing exposes the subject 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. Pines, *A Primer on New Drug Development*, 4 FDA CONSUMER (Feb. 1974).

Research thus presents a classic case of harming (or exposing to the risk of harm) one person for the benefit of another. Since, aside from a few exceptional cases such as taxation and military service, our society does not impose positive obligations on nonvolunteers, the legal system should require consent to experimental therapy when the outcome is unknown and unlikely to benefit the human subject personally.

4. The researcher and the subject often have conflicting interests

The fourth reason often given for protecting informed consent in experimental settings more highly than in therapeutic settings is that the interests of the patient and the scientist are sharply opposed in the experimental setting.[102] This reason, which overlaps the second and third reasons, draws on a body of legal and ethical principles known loosely as "conflict of interest." Conflict of interest rules express the intuitive conviction that persons who occupy positions of trust should not involve themselves in outside obligations or self-interests that could compromise their ability to protect the interests entrusted to them.[103]

In some settings, the experimenter may be subject to competing loyalties. Consider the experimenter-physician at a teaching hospital who has an indigent patient with an acute illness.[104] The physician may have to choose between giving the patient the standard treatment for his or her condition, administering an experimental treatment aimed at demonstrating the usefulness of a new procedure, or administering the experimental treatment in addition to the standard treatment.[105] The physician's interest in pursuing a medical breakthrough and thereby enhancing both his or

102. *See* Beecher, *supra* note 12, at 1357; sources cited *supra* note 6.

103. *See supra* note 102 and accompanying text; *infra* notes 104–06 and accompanying text. The inexact fit between conflict of interest rules and the research setting is developed at *infra* notes 129–61 and accompanying text, in which an alternate ground, "conflict of value," is proposed.

104. It is well known that teaching hospitals often draw patients from the poor, minorities, and the elderly—groups whose members may be vulnerable to coercion.

105. *See, e.g.*, Almquist, *When the Truth Can Hurt: Patient-Mediated Informed Consent in Cancer Therapy*, 9 U.C.L.A.-Alaska L. Rev. 143 (1980) (urging interactive multistage consent for this reason among others).

her own reputation and that of the department and university may lead the physician to seek less than fully informed consent.[106] The experimenter may be tempted to misrepresent the risk of the new treatment, misrepresent the extent to which the treatment has been accepted by the medical community, or withhold information regarding alternative treatments.[107] Because of this risk of conflicting interests, it seems wise to hold physician-researchers to a strict standard of disclosure and to limit their ability unduly to influence subjects or patients.[108]

B. *New Reasons for Protecting Informed Consent Highly in Human Experimentation*

We offer three new reasons for intensified protection of informed consent in human experimentation as an addition to the four conventional reasons. First, experimental settings call for heightened protection because failure to obtain the patient's consent deprives the patient's act of moral meaning. Second, in many research settings, a conflict of value may exist between the researcher and the human subject. Finally, the researcher often occupies a fiduciary role with respect to his or her subject; thus, he or she owes the human subject a duty of fair dealing and will be held to a high standard of conduct.

1. Conscripting human research subjects deprives their acts of moral meaning

Outside a few special situations, our legal system recognizes no general duty of beneficence.[109] Sometimes this is expressed in the maxim that there is no duty of rescue.[110] This is illustrated by the familiar hypothetical of a passerby

106. *See, e.g.*, Burton v. Brooklyn Doctors Hosp., 88 A.D.2d 217, 452 N.Y.S.2d 875 (1982); *infra* notes 129–72 and accompanying text (describing "conflict of value" in the research setting).

107. *See* cases discussed *supra* notes 57–76 and accompanying text.

108. Of course, not every research setting will present this kind of conflicting interest. But when a research setting does, it makes sense to hold the physician-researcher to a strict standard of obtaining informed consent.

109. W. PROSSER & W. KEETON, *supra* note 66, § 156; Lipkin, *Beyond Good Samaritans and Moral Monsters: An Individualistic Justification of the General Duty of Rescue*, 31 UCLA L. REV. 252 (1983).

110. W. PROSSER & W. KEETON, *supra* note 66, at 375–77; Lipkin, *supra* note 109, at 253–54; *see* Shultz, *supra* note 1, at 277.

who sees a child drowning. The passerby could easily rescue the child at little cost or danger to himself or herself, but ignores the child's plight and the child drowns. As long as the passerby is not the child's parent or guardian, he is not responsible for the child's plight. Our legal system holds the passerby blameless, under both tort and criminal law. The no-duty rule's origins are obscure, and the rule has been criticized sharply.[111] Yet it remains deeply rooted in our legal system and seems unlikely to be abandoned.

Whether to volunteer as a research subject is similar in many respects to the decision to rescue another. If the research proves successful, the benefit often will inure to other persons, but the risks are borne by the subject. Moreover, the human subject generally has no special relationship with the future beneficiaries of the research that would compel the subject to render service.[112] In addition, participation as a research subject is not one of those few affirmative duties that has been imposed for the common good. Consequently, serving as a human subject of biomedical or behavioral research must be considered purely voluntary, like making a charitable gift or assisting a stranded motorist. Society approves of and encourages this behavior, but does not compel it. Legal restrictions on human experimentation support this conclusion. The HHS guidelines, like the case law which preceded them, require the subjects' consent[113] and restrict experimentation among certain populations—such as children, prisoners, the mentally ill, and the poor—who possess a limited ability to make a free choice.[114] Furthermore, institutions sometimes offer incentives for persons to volunteer, for example, payment[115] or treatment in the event of injury.[116] These incentives would arguably not

111. *See, e.g.*, sources cited *supra* note 110.

112. That is, the future beneficiaries generally will be neither close family members nor persons to whom the research subject owes a special duty.

113. *See* 45 C.F.R. §§ 46.116, 46.117 (1985).

114. *Id.* §§ 46.305, 46.401–.409; *see also* UCLA POLICIES AND PROCEDURES, *supra* note 51, at 7 ("special consideration" given to proposals for research with subjects "whose competence may be subject to question").

115. *See* UCLA POLICIES AND PROCEDURES, *supra* note 51, at 9 (Informed Consent Forms, item 23, requiring explanation of payment and description of circumstances under which payment may be withheld).

116. *Id.* at 7, item 18 (explanation of policy of providing "any and all medical treatment reasonably necessary for any injury or illness which [the subject suffers] as a direct result of . . . participation in the research project, except when the

be necessary if serving as a human subject were a duty.

Because serving as a human subject is not a duty, the decision whether to volunteer must be left to the individual. What factors enter into the subject's decision? One important factor is the costs and dangers of the research. For this reason, informed consent rules require disclosure of known risks. In a few cases, 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, for example, a side effect from a drug being tested, embarrassment, or the loss of privacy from behavioral research.[117]

Since some risk often will attach to human research, what will the subject have to weigh against this risk? In nontherapeutic research, the only benefit often will be the subject's satisfaction from having acted for the good of humanity—having exposed himself or herself to risk in order to help develop knowledge that one day may save lives or relieve suffering.[118] This benefit, however, is denied when the human subject does not autonomously choose to participate in the research or chooses to participate unaware of the risk the research presents.

When the research subject does not choose freely to participate, his act loses its moral meaning. Participation in the research is not something given by the subject; rather, it is something extracted. When told what has happened, the subject normally is outraged. The subject does not feel like a hero, but like a tool—something that has been used. In these cases, there is no positive moral value to balance the negatives of risk and cost.[119]

The current rules for human research recognize this imbalance to some extent in their treatment of "deception re-

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injury or illness is a consequence of a research procedure which is designed to benefit [the subject] directly.").

117. *See supra* note 49 and sources cited therein; *see also* PRESIDENT'S COMMISSION, *supra* note 1, at 79–80 (estimating the number of patients injured by research); Houston Chronicle, Feb. 13, 1986, § 4A, at 4, col. 3 (noting a secret Swedish research project that monitored the social and sexual behavior of more than 15,000 people for more than 33 years).

118. *Cf.* R. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1971) (making similar point about human blood donors).

119. *Cf.* MAKING HEALTH CARE DECISIONS, *supra* note 1, at 63, 71 (stating that autonomy is the state in which "we define our nature, give meaning and coherence to our lives, and take responsibility for the kind of person we are"; protection of autonomy is a central purpose of informed consent); Jonas, *Philosophical*

search." Deception research, by its nature, requires that the subject be kept uninformed, or actively misinformed in some cases, about the nature or purpose of the research.[120] Stanley Milgram's studies of obedience to authority[121] and Laude

Reflections on Experimenting with Human Subjects, in EXPERIMENTATION WITH HUMAN SUBJECTS, 1–4, 9–14 (P. Freund ed. 1970).

This is not to say that the balancing of interests is impermissible in human experimentation. The law of informed consent is riddled with exceptions. These exceptions (e.g., the emergency exception, the unconscious patient rule) show that our legal system is prepared to balance short-term and long-term autonomy gains and losses, but only for the individual patient or subject. Our moral system rebels against the idea of balancing losses of autonomy for some individuals against gains for others, especially when the person who experiences the losses does not consent. *But see* A. HOLDER, LEGAL ISSUES IN PEDIATRIC AND ADOLESCENT MEDICINE 152 (2d ed. 1985) (arguing that children forced to participate in research "may be learning something about altruism and sympathy"); *id.* at 154 (forcing child to give blood is morally permissible).

120. Professor Joan Sieber defines deception research as follows:

> Deception research is research in which subjects are purposely allowed to or caused to have false beliefs or assumptions or to accept as false that which is true, and in which the research studies their reactions; the reactions and the study of those reactions are made possible by the incorrect beliefs or assumptions of the subjects.

Sieber, *Deception in Social Research I: supra* note 47, at 2. *See generally* S. BOK, LYING: MORAL CHOICE IN PUBLIC AND PRIVATE LIFE 182–203 (1978); THE ETHICS OF SOCIAL RESEARCH: FIELDWORK, REGULATION, AND PUBLICATION (J. Sieber ed. 1982); THE ETHICS OF SOCIAL RESEARCH: SURVEYS AND EXPERIMENTS (J. Sieber ed. 1982).

Deception research also includes observation and collection of data from subjects who are unaware they are being observed. For example, Stockholm's Institute of Sociology gathered data on 15,000 Swedes for twenty years, including information about "social background, education, employment, marriage, . . . children, . . . illnesses, alcohol-related difficulties, and criminal activity." *Swedish Action Will Terminate Big Social Study: Agency Orders Destruction of Clues to 15,000 People,* CHRON. OF HIGHER EDUC., Mar. 18, 1986, at 1, col. 3. The Swedish government ordered the destruction of clues to the identity of those in the study, but sociologists will continue to study the files.

121. Milgram, an experimental psychologist, advertised in newspapers for research volunteers. He told them that the purpose of the experiment was to study memory, and that the volunteers would participate as either "teachers" or "learners." The volunteers, however, were all cast as teachers and 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. Actors performed the roles of learners and 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 learn how susceptible the volunteers were to the experimenters' directions—sixty-two percent of the volunteers completely obeyed the experimenters' commands. Equally disturbing to some, however, was the revelation of the duplicitous research design and methods. S. MILGRAM, OBEDIENCE TO AUTHORITY: AN EXPERIMENTAL VIEW (1974); Mil-

Humphreys' study of "watch queens"[122] are well-known examples.

The federal rules exempt most social science deception research, provided that it does not invade privacy, deal with sensitive aspects of behavior, expose the subject to civil or criminal liability, or damage financial standing or employability.[123] Otherwise, the rules permit unconsented-to deception research if the following conditions are met: The value of the knowledge the research is intended to generate must outweigh the risks to the subjects, the information sought cannot practicably be gained in any other way, and the experimental team must "debrief" the subject when the research is concluded.[124] The intent of the debriefing rule, and the way in which most IRBs interpret it, is to minimize the embarrassment and the sense of betrayal subjects may feel as a result of the deception.[125] But the rules treat these responses as just another cost of experimentation. Debriefing is intended to soothe the subject's emotions, and

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gram, *Some Conditions of Obedience and Disobedience to Authority*, 18 HUM. REL. 57 (1965).

122. Similarly, Humphreys' participant-observer study of "impersonal sexual acts with one another in public restrooms" (Humphreys volunteered to watch for the approach of police or strangers) has been widely criticized for its deceptive methodology. Sieber, *Deception in Social Research I*, *supra* note 47, at 4. Humphreys spied on unconsenting subjects and risked their arrest through subpoena of his records. His findings showed that a large number of the subjects were neither committed homosexuals nor bisexuals. Fifty-four percent of the subjects were married men who lived with their wives and who apparently led otherwise exemplary lives. Thirty-eight percent followed birth-control methods approved by their religions—rhythm and abstinence. Hence they sought outlets that would not threathen their marital and paternal relationships. The results of this study led to a reduction in the number of homosexual arrests in the United States. L. HUMPHREYS, TEAROOM TRADE: IMPERSONAL SEX IN PUBLIC PLACES (1970); Humphreys, *Tearoom Trade: Impersonal Sex in Public Places*, 7 TRANS-ACTION 15 (Jan. 1970); Sieber, *Deception in Social Research I*, *supra* note 47.

123. *See* 45 C.F.R. § 46.101(b) (1985).

124. *See id.* § 46.116(d)(4) (1985). Apparently, many researchers debrief subjects even when the regulations exempt deception research from this requirement. *See supra* note 48. *See generally* Dresser, *supra* note 47, at 3–4; Sieber, *Deception in Social Research III*, *supra* note 47 (discussing application of this section to deception research).

125. *Cf.* BELMONT REPORT, *supra* note 12, at 12; PROTECTING HUMAN SUBJECTS, *supra* note 53. For a discussion of the harm to subjects caused by these studies, see Sieber, *Deception in Social Research II*, *supra* note 47; Warwick, *Types of Harm in Social Research*, in ETHICAL ISSUES IN SOCIAL SCIENCE RESEARCH 106 (T. Beauchamp, R. Faden, R. Wallace & L. Walters eds. 1982); sources cited *supra* note 48.

thus to minimize one cost of research.[126] In reality, however, the subject's reaction is more than just a cost or a minor violation of autonomy experienced as a negative emotion that can be dissipated by counseling or the passage of time. Rather, the reaction cancels any benefit that might accrue to the subject from participating in the research.

Participation that is either involuntary or based on misapprehension has no moral meaning for the individual subject. In many cases, the satisfaction that results from freely submitting to research will be the only gain that can be balanced against the risks and inconveniences of research. This moral meaning cannot be restored by after-the-fact explanations or counseling.[127]

2. The experimenter and the human research subject have a "conflict of value"

When 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. However, in human experimentation the interests of the researcher and the subject may be opposed.[128] The scientist wants to pursue medical breakthroughs that will help other patients and add to the scientist's reputation and academic standing.[129] The research subject may have a different set of goals and values.

The subject ordinarily has little interest in the researcher's professional reputation, academic advancement,

126. *See* Sieber, *Deception in Social Research II*, *supra* note 47 (describing debriefing as aimed at treating subject's "upset"); *see also* BELMONT REPORT, *supra* note 12, at 12, §§ 23–38 to 23–41; PROTECTING HUMAN SUBJECTS, *supra* note 53.

127. Debriefing cannot achieve this because an after-the-fact explanation by the researcher cannot alter the character of the subject's act which is already complete. Nor can debriefing alter the spirit in which the act was performed. This is true regardless of whether the subject was duped or coerced.

128. *See infra* notes 130, 132 and accompanying text.

129. For an excellent study of the motivations and attitudes of some academic researchers, see B. BARBER, J. LALLY, J. MAKARUSHKA & D. SULLIVAN, RESEARCH ON HUMAN SUBJECTS: PROBLEMS OF SOCIAL CONTROL IN MEDICAL EXPERIMENTATION (1973) [hereinafter B. BARBER]. For examples of the attitude of some researchers toward informed consent, see Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MED. 465–66 (1972) (subjects rarely understand what is told them, requirement of informed consent should be abolished or modified); Levine, *Informed Consent in Research and Practice: Similarities and Differences*, 143 ARCH. INTERN. MED. 1229 (1983) (purpose of informed consent is to protect institution against liability).

or ability to obtain new grants. The subject's interests 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 caused by the research; assisting humanity; making a small amount of money (if the research provides for payment); escaping boredom if the subject is confined or institutionalized; and helping scientists find a cure for the disease that afflicted a friend or family member.

Many writers and some courts have cited this opposition of interests as a reason for imposing stricter standards of disclosure in research than in the standard medical setting.[130] Yet the conflict of interest theory that most invoke[131] fits the research setting only inexactly.[132] At the

130. Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978) (the essential framework of this case is a conflict of interest analysis); *see also* Schwartz v. Boston Hosp. for Women, 422 F. Supp. 53 (S.D.N.Y. 1976) (alleging physician-researcher performed curettage for experimental study withou consent); Shultz, *supra* note 1, at 259; *supra* notes 6, 102–05 and accompanying text, *infra* note 132 and sources cited therein.

131. *See supra* notes 102–04 and accompanying text. At least one suit has been filed by research subjects on grounds of breach of fiduciary duty. Moore v. Regents of the Univ. of Cal., No. B021195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986); *see also* Royston, *Cell Lines from Human Patients: Who Owns Them? A Case Report,* 33 CLINICAL RES. 442 (1985) (discussing patient's claim of ownership of cell lines developed from her tissues). At least one commentator has categorized "the inherent conflict between the subject's interests and the researcher's quest for new information" as a researcher-subject conflict of interest. *See* Robertson, *The Law of Institutional Review Boards, supra* note 7, at 486 n.17; *see also* Capron, *supra* note 1, at 13, 21–23. Some judicial opinions analyze the duty of researchers toward their subjects in terms of conflict of interest. *See, e.g.,* Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978).

132. Conflict of interest rules, in general, seek to ensure that persons who act on behalf of others do so without conflicting self-interests. For an analysis of the rules and policies relating to fiduciary relationships, see Frankel, *Fiduciary Law,* 71 CALIF. L. REV. 795 (1983). For example, corporate directors are required to manage corporate interests and business according to standards of law. Tenison v. Patton, 95 Tex. 284, 67 S.W. 92 (1902) (analogizing director to trustee). Trustees must scrupulously follow both the terms of the trust and the applicable state law that protects beneficiaries. *See, e.g.,* UNIF. TRUSTS ACT § 5, 4 U.L.A. 76 (1962) ("No trustee shall directly or indirectly buy or sell any property for the trusts from or to itself or an affiliate; or from or to a director, officer, or employee of such trustee or of an affiliate; or from or to a relative, employer, partner or other business associate."); *see also* 1 A. SCOTT, THE LAW OF TRUSTS § 1 (3d ed. 1967). These principles respond to four simple, highly intuitive moral notions. The first notion is that one should be able to count on the integrity and fidelity of those upon whom one relies or in whom one confides. Hamby v. St. Paul Mercury Indem. Co., 217 F.2d 78, 80 (4th Cir. 1954); Commissioner v. Owens, 78 F.2d 768, 773 (10th Cir. 1935); State *ex. rel* Shriver v. Ellis, 47 Ohio App. 380, 387, 75

heart of conflict of interest doctrine is the idea that an individual in a position of trust must not take advantage of his role for his own personal (especially pecuniary) gain.[133] In human experimentation, however, neither the researcher nor the subject ordinarily has a direct economic interest in the outcome of the research;[134] their objectives usually are

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N.E.2d 704, 710 (1946); Kinzbach Tool Co. v. Corbett-Wallace Corp., 138 Tex. 565, 568, 160 S.W.2d 509, 512, 513, (1942); *see, e.g.*, BLACK'S LAW DICTIONARY 564 (5th ed. 1979) (describing fiduciary relationship as "reposing of faith, confidence and trust, and the placing of reliance by one upon the judgment and the advice of the other"). Trust and confidence alone, of course, do not invoke fiduciary duties.

The second moral notion is that because of this trust those who act for others are obligated to act in good faith and with regard only to the other's interest. Justice Benjamin Cardozo expressed the fiduciary duty of loyalty in this way: "A trustee is held to something stricter than the morals of the marketplace. Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior." Meinhard v. Salmon, 249 N.Y. 458, 464, 164 N.E. 545, 546 (1928); *see also* State v. Hagerty, 251 La. 477, 493–94, 205 So. 2d 369, 374 (1967), *cert. denied*, 391 U.S. 935 (1968); Nagel v. Todd, 45 A.2d 326, 327, 185 Md. 512, 516 (1946).

This duty of loyalty responds to the difficulty of attempting to achieve fairness when a person acts in two or more conflicting capacities on behalf of more than one interest in the same transaction. G. BOGERT, TRUSTS AND TRUSTEES § 543, at 203–04 (2d ed. 1978). The duty is imposed on trustees not because of any terms of the trust, but because of the relationship created by the trust. A. SCOTT, *supra*, § 170, at 1297–98. As a result of the relationship, the trustee is held to the highest fiduciary standard:

> (1) The trustee is under a duty to the beneficiary to administer the trust solely in the interest of the beneficiary.
>
> (2) The trustee in dealing with the beneficiary on the trustee's own account is under a duty to the beneficiary to deal fairly with him and to communicate to him all material facts in connection with the transaction which the trustee knows or should know.

RESTATEMENT (SECOND) OF TRUSTS § 170 (1959); *see also* Smith v. Ogilvie, 127 N.Y. 143, 27 N.E. 807 (1891); State *ex. rel.* Shriver v. Ellis, 47 Ohio App. 380, 75 N.E.2d 704 (1946); Kinzbach Tool Co. v. Corbett-Wallace Corp., 138 Tex. 565, 160 S.W.2d 509 (1942); Gortario v. Cantu, 7 Tex. 35, 44 (1851).

The third moral notion is that the actor should not influence or pressure the dependent party in order to benefit himself or prejudice the other. *See, e.g.*, BLACK'S LAW DICTIONARY 564 (5th ed. 1979).

The fourth moral notion is that the person in the superior position is accountable to the dependent party and must disclose personal interests that conflict with his duty. *See, e.g.*, Wendt v. Fisher, 243 N.Y. 439, 443, 154 N.E. 303, 304 (1926) ("If dual interests are to be served, the disclosure to be effective must lay bare the truth, without ambiguity or reservation, in all its stark significance . . . ."); *see also* RESTATEMENT (SECOND) OF AGENCY §§ 381 comment d, 387, 390 comment a (1958).

133. *See, e.g.*, Meinhardt v. Salmon, 249 N.Y. 353, 363–64, 164 N.E. 545, 546 (1928). *See generally* Frankel, *supra* note 132.

134. *But see* Siris, *In Search of Funding: The Clinical Investigator and the Drug Company*, 5 INST. REV. BD. 1 (Nov./Dec. 1983); *supra* note 132.

intangible.[135] Conflict of interest rules also ordinarily are reserved for conduct that is self-serving and clearly reprehensible. Failure to inform a research subject fully of the purposes and risks of research, while unfortunate, ordinarily will not rise to the level of immorality required to invoke the conflict of interest doctrine. Indeed, a failure to inform often will be inspired by humanitarian motives[136] or by paternalism.[137]

A better approach invokes what one writer has called "conflict of value."[138] Although this author was writing about standard medical therapies, the notion of conflict of value applies with even greater force to human experimentation. As the term implies, a conflict of value arises when two or more participants in a human venture place different values either on the outcomes or objectives of their common effort, or on the means to be employed in achieving those outcomes or objectives.[139]

Conflict of value is closely related to, but is not identical to conflict of interest. In a 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 position.[140] In a conflict of value, the opposition between the two persons is not as stark or "crystallized";[141] in particular, it rarely can be captured by a win-lose formula. Nor is the problem completely captured by the concept of divided loyalties. Researchers currently are not charged to any great extent with protecting the subject's health, finances, or well-being. Their relationships with subjects are brief and "transactional": when the experiment ends, both parties go their separate ways. In all these respects, the experimenter-subject relationship approaches, but does not

135. *See infra* notes 144–61 and accompanying text (goals of researcher and subject).

136. For example, the researcher may cut corners with consent in order to advance science or to hasten the development of a cure or a breakthrough. *See* Shultz, *supra* note 1, at 274.

137. *E.g.*, "I didn't disclose because I knew it would just worry him or her." *See id.* at 274–75; *see, e.g., supra* note 72 and accompanying text.

138. Shultz, *supra* note 1, at 272–76.

139. *Id.* at 272–74; *see also* Robertson, *supra* note 7.

140. *See generally* Frankel, *supra* note 132, at 809–11.

141. The term "crystallized," which expresses the subtle difference between conflict of interest and conflict of value, was coined by Shultz, *supra* note 1, at 272–73.

completely satisfy, traditional conflict of interest criteria; however, it does illustrate a conflict of value. A conflict of value exists when the parties to a transaction have significantly different goals, aspirations, intangible desires, or preferences. Neither party desires to profit from the other in the typical conflict of interest sense, like a physician who conceals his own negligence in order to avoid a malpractice suit.[142] A conflict of value is more like what happens in a bad marriage, or in a business partnership when the partners have different ideas about the purposes and goals of the joint enterprise.

Contemporary views of biomedical and behavioral experimentation emphasize protecting the patient's autonomy and individuality.[143] But the current federal guidelines inadequately protect this recognition of a plurality of values, life settings, and personal and group-related vulnerabilities. In subsection (a) we show how a conflict of value arises between an experimenter and a human subject by describing the mindsets of a typical human subject and a typical researcher, in brief anecdotal form. In subsection (b) we review the federal regulations and related materials to show that they intend both to protect pluralistic values in research settings and to limit the scope of professional expertise when it conflicts with patients' autonomy.

a. *How Conflict of Value Arises.* Generalizing about human subjects is more difficult than generalizing about the doctors and scientists who conduct research. Subjects often are solicited from different age and population groups, depending on the experiment's objectives.[144] Even so, most

142. For a proposal that a physician should be required to disclose evidence of malpractice, see Vogel & Delgado, *To Tell the Truth: Physician's Duty to Disclose Medical Mistakes,* 28 UCLA L. REV. 52 (1980).

143. *See, e.g.,* 45 C.F.R. §§ 46.109, 46.116 (1985) (purporting to protect consent and the rights of human subjects in federally-funded research); BELMONT REPORT, *supra* note 12; MAKING HEALTH CARE DECISIONS, *supra* note 1; UCLA POLICIES AND PROCEDURES, *supra* note 51, at 8–9; Shultz, *supra* note 1. *See generally* sources cited *supra* note 77.

144. For example, learning studies often are conducted on students; studies of the effects of poverty, on the poor; studies of occupational disease, on workers; studies of medical conditions and disease, on patients. *See* J. KATZ, *supra* note 1, at 149–75, 378–79, 466–68, 560–61, 629–34; P. RAMSEY, THE PATIENT AS A PERSON (1970); Boffey, *Thousands in US Receive Treatment in Experiments,* N.Y. Times, Jan. 17, 1986, § 2, at 15, col. 5; Holder, *Case Study: Research on Unemployment: When Statutes Create Vulnerability,* 6 INST. REV. BD. 6 (Mar./Apr. 1984).

subjects generally are either young, poor, or ill.[145] These individuals typically have less power and socioeconomic status than members of the research team.[146] They often are solicited from university undergraduate classes or from the rolls of a social service agency.[147] Medical research subjects, for example, often are obtained from the patient populations of hospitals or clinics.[148] In some cases the subjects are paid, in others they are not. For most, the incentive to serve as a research subject is not monetary gain, but the prospect of helping humanity, pleasing the doctor or professor, achieving a break in the daily routine, or attaining a cure when all other treatment fails.[149] Most subjects also are concerned with avoiding the negative consequences of research. But their wariness often is tempered by their tendency to trust the scientist or physician in charge of the experiment, who is generally a person of high prestige and authority.[150]

Medical sociologists and others have written more extensively about the goals and world views of researchers than of research subjects; therefore, more is known about researchers as a group. Most researchers in both biomedicine and the behavioral sciences share an outlook known as "professionalism," the tendency to identify with

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145. *See* J. KATZ, *supra* note 1, at 311, 437–38, 633–34, 648; Miller, *A Survey of Introductory Psychology Subject Pool Practices Among Leading Universities*, 8 TEACHING OF PSYCHOLOGY 211 (1981) (near-universal use of undergraduates for social research); Parsons, *Epilogue to the Doctor-Patient Relationship*, in THE CHANGING HEALTH SCENE 445–46 (E. Gallagher ed. 1978).

146. *See* sources cited *supra* notes 13, 144.

147. *See* Miller, *supra* note 145; sources cited *supra* notes 13, 144; *cf.* P. RAMSEY, *supra* note 144.

148. J. KATZ, *supra* note 1, at 437–38, 461, 466–38, 560–61, 629–31; *see* Ingelfinger, *supra* note 129.

149. *See* Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rept. 147 (1976), 2 Pris. L. Rep. 433 (1973) (suggesting that prisoners suffer "institutionalization" and volunteer as research subjects to break the routine of prison life and to get attention from prison staff and doctors). At times, the subject will demand the experimental treatment, but the researcher should reject the subject unless he or she meets the desired criteria. Interview, *supra* note 39; sources cited *supra* notes 144–48; Stason, *The Role of Law in Medical Progress*, 32 LAW & CONTEMP. PROBS. 563, 587 (1967).

150. *See, e.g.*, Halushka v. University of Saskatchewan, 53 D.L.R.2d 436, 52 W.W.R. 608 (Sask. Ct. App. 1965), *reprinted in* J. KATZ, *supra* note 1, at 569; Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rptr. 147 (1976), 2 Pris. L. Rptr. 433 (1973) (patient agreed to serve as a subject of experimental psychosurgery on the vague assurance of researcher that it might help him). *See generally* J. KATZ, *supra* note 1; Parsons, *supra* note 145.

the values of one's occupational group.[151] This unanimity of outlook has been explained as caused by the group's small size and cohesiveness, the frequency of contact among the members, and the similarity of the members' professional training.[152]

The professional creed of researchers emphasizes efficiency and primacy of discovery.[153] The object is to have a "good" experiment—one that will lead to interesting, publishable results. Efficiency is not valued only for its own sake; it is linked with a belief that scientific progress will promote the good of humanity.[154]

Traditions of self-regulation and peer review reflect and intensify the researcher's adherence to professional values.[155] It is believed that outside authority cannot understand scientific values, the experimental method, or other norms of professional conduct.[156] The technical issues

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151. *See* J. KATZ, *supra* note 1, at 185–235; SILENT WORLD, *supra* note 1, at vi–xvii, 1–47; McClellan, *Informed Consent to Medical Therapy and Experimentation: The Case for Invoking Punitive Damages to Deter Infringement of Personal Autonomy*, 3 J. LEGAL MED. 81 (1982); *see also* B. BARBER, *supra* note 129, at 3–5 (social values and norms of competition); W. BROAD & N. WADE, BETRAYERS OF THE TRUTH 66–87 (1982); Capron, *supra* note 1, at 354–60; Levine, *supra* note 129 (the purpose of informed consent in research is to protect institution against liability).

152. *See* B. BARBER, *supra* note 129, at chs. 6, 7, 9, 10; W. BROAD & N. WADE, *supra* note 151, at 78–87; J. KATZ, *supra* note 1, at 185–235; Capron, *supra* note 1, at 356–60.

153. *See* Merton, *Priorities in Scientific Discovery*, 22 AM. SOC. REV. 635 (1957); sources cited *supra* note 151. *See generally* Karp v. Cooley, 493 F.2d 408 (5th Cir.) (illustrating the pressures surrounding development of the artificial heart), *cert. denied*, 419 U.S. 845 (1974).

154. *See* BELMONT REPORT, *supra* note 12; Capron, *supra* note 1, at 356–58; Harris, *Research on Human Subjects: Problems of Access to a Powerful Profession*, 21 SOC. PROB. 103 (1973). *See generally* B. BARBER, INFORMED CONSENT IN MEDICAL THERAPY AND RESEARCH (1980).

155. *See* J. KATZ, *supra* note 1, at 185–235; Capron, *supra* note 1, at 354–55, 370; Nelkin, *Threats and Promises: Negotiating the Control of Research*, 107 DAEDALUS 191, 191–92 (Spring 1978); *supra* notes 22–27 and accompanying text (describing IRBs as an institution that operates to large extent as peer review); *see also* Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974), *vacated*, 565 F.2d 722 (1977) (egregious violations in public hospitals of autonomy and the patients' rights to choose justified by the doctors' belief that sterilizations were in the patients' best interests); E. FREIDSON, THE PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE 71–72 (1972); McClellan, *supra* note 151, at 82–83 (1982) (noting a culture of high-handed, arrogant treatment of human subjects by some researchers).

156. *See* E. FREIDSON *supra* note 155, at 71–72; J. KATZ, SILENT WORLD, *supra* note 1, at 12 (reluctance of doctors to share information or authority with patients); MAKING HEALTH CARE DECISIONS, *supra* note 1, at 168 (similar findings

posed by scientific governance also are difficult to understand. Consequently, scientists have demanded and have received a large measure of autonomy in regulating themselves through peer review, professional associations, and codes of ethics.[157]

In addition to being insulated and self-governing, academic research is highly competitive.[158] Researchers vie for grants, laboratory space, and the best graduate students. Recognition and achievement are rewarded by promotion, tenure, and jobs at leading universities and research centers.[159] 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."[160] Recent research by Barber and others shows a widespread tendency to undervalue informed consent and patient autonomy, to cut corners and to overlook the "niceties" of disclosure and consent.[161]

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with respect to physicians); Katz, *Informed Consent: Is It Bad Medicine?*, 126 W.J. MED. 426, 430 (1977).

157. Nelkin, *supra* note 155, at 191–92 (scientific community resists public control; reporting poll of scientists on objections to outside regulators); *see* 45 C.F.R. Title 46—Protection of Human Subjects (1985) (peer review through IRBs); B. BARBER, *supra* note 129, at 145–69, 188; J. BERLANT, PROFESSION AND MONOPOLY: A STUDY OF MEDICINE IN THE UNITED STATES AND BRITAIN (1975); W. BROAD & N. WADE, *supra* note 151, at 70–78 (noting self-regulation occurs, in theory, through replication of one's work by peers but arguing that replication rarely either occurs or catches error and fraud); E. FREIDSON, *supra* note 155, at 71–72; DuVal, *supra* note 7, at 573–76 (reporting that IRBs were established because of scientists' demand for freedom from outside control); Stason, *supra* note 149, at 587–95 (discussing codes of conduct). *But see* Comment, *Ties That Bind: Conflict of Interest in University-Industry Relations*, 17 U.C. DAVIS L. REV. 891 (1984) (California conflict of interest regulations applied to certain university researchers).

158. *See* B. BARBER, *supra* note 129, at 81–93; W. BROAD & N. WADE, *supra* note 151, at 86–87; Capron, *supra* note 1, at 360 ("personal motivations are an ever-present concomitant of advances in science"); sources cited *supra* notes 3, 151.

159. *See* sources cited *supra* note 158.

160. *See* B. BARBER, *supra* note 129, at 6–7; MAKING HEALTH CARE DECISIONS, *supra* note 1, at 168, 226 (physicians); J. KATZ, *supra* note 1 (documenting the reluctance of researchers to disclose information to subjects); SILENT WORLD, *supra* note 1, at 58; Baumrind, *supra* note 56, at 23–49 (most scientists do not believe that deceptions and failure to obtain informed consent are serious ethical violations); Beecher, *supra* note 12; Levine, *supra* note 129.

161. B. BARBER, *supra* note 129, at 6–7, 65; MAKING HEALTH CARE DECISIONS, *supra* note 1, at 226; SILENT WORLD, *supra* note 1, at 1–47; Barnes, *Ethical and*

b. *The Protection of Pluralistic Values Under the Current Rules.* As we have seen, experimenters and human subjects bring different values and objectives to the research setting. The values and objectives of patient-subjects are more diverse 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.[162]

Current thinking about human experimentation, like that regarding medical treatment, places primary importance on the preferences and wishes of the human subject.[163] In part, this focus is linked to our society's emphasis on personal autonomy and individual rights.[164] It also reflects a broader recognition that all patients do not want to get well in the same way with equal intensity. Patients value differently the risks, benefits, and side effects of treatment, pain, and disability caused by their affliction.[165] The variability of preferences held by the nonscientist participants probably is even greater in connection with experimentation than it is with medical treatments. The current federal rules recognize these differences to some extent, but the actual guidelines inadequately protect subjects' decision making.

Political Compromises in Social Research, 21 WIS. SOC. 100 (1984) (compromises inevitable and not necessarily to be deplored); *see* H. BEECHER, *supra* note 12 (scientists believe enforcement of informed consent would block progress); SILENT WORLD, *supra* note 1, at 3, 58; Fellner & Marshall, *Kidney Donors—The Myth of Informed Consent,* 126 AM. J. PSYCHIATRY 1245 (1970) (patients are impulsive and impressionable; informed consent rarely occurs); Baumrind, *supra* note 56, at 23–49; Benson, Roth & Winslade, *Informed Consent in Psychiatric Research: Preliminary Findings from an Ongoing Investigation,* 20 SOC. SCI. & MED. 1311, 1339 (1985) (patients often have little comprehension of science or the subtleties of consent; thus the choice to hinder science by efforts to promote autonomy is "a question of values"); Capron, *supra* note 1, at 354–55 (physicians and researchers undergo little socialization in the ethics of human experimentation), 357–58, 360; McClellan, *supra* note 151, at 95–96; sources cited *supra* notes 12–13. *But see* Interview, *supra* note 39 (medical researchers were more cautious than social science researchers about using human subject; when patients demand access to experimental therapy, doctors should reject them unless they meet the strict criteria of the research project).

162. *See* B. BARBER, *supra* note 129, at 9 (diversity of values and life plans); *supra* notes 144–50 and accompanying text.

163. *See infra* notes 166–72 and accompanying text.

164. *See, e.g.,* Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body."). *See generally* W. PROSSER & W. KEETON, *supra* note 66, § 18, at 101.

165. Shultz, *supra* note 1, at 118.

The federal rules and commentary purport to give central importance to protecting the subject's desires and preferences. The National Commission's Belmont Report asserts that respect for a person's right of self-determination is an elemental principle for evaluating research with human subjects.[166] The rules themselves require both that the subject must be told the purposes of the research,[167] and that the subject must be free to withdraw from the experiment at any time without penalty or loss of benefits.[168] In some instances, the rules also provide that the subject must be told of significant new findings that might affect his desire to continue participating.[169]

Protecting human autonomy in conflict of value situations thus is recognized as a central problem for the federal regulation of human research.[170] In a few key respects, however, the rules allow excessive leeway for professional discretion. For example, the researcher is permitted to devise the method by which he will obtain the subjects' informed consent. Often this is done in one meeting, which does not give subjects sufficient time to absorb and reflect upon the information received.[171] Furthermore, the researcher and the IRB decide beforehand whether subjects actually will be at risk—without giving the subjects an opportunity to participate in this crucial decision. Research that presents minimal or low risk often is exempt from federal informed consent requirements.[172] Thus, the current approach to

166. BELMONT REPORT, *supra* note 12, at 6.

167. 45 C.F.R. § 46.116(a)(1) (1985); *cf.* Capron, *supra* note 1, at 370 (rules evidence a generalized distrust of scientific zeal, thus embrace a Miranda-style, per se approach to disclosure).

168. 45 C.F.R. § 46.116(a)(8) (1985).

169. *Id.* § 46.116(b)(5).

170. *See, e.g., id.* § 46.116 ("An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.").

171. *See, e.g.*, B. GRAY, HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION: A SOCIOLOGICAL STUDY OF THE CONDUCT AND REGULATION OF CLINICAL RESEARCH (1975) (high percentage of subjects who signed consent forms did not understand that they were participating in a research project).

172. 45 C.F.R. § 46.116(d) (1985). There is a different attitude toward disclosure of minimal or low risk expressed in case law and administrative proceedings. *See supra* text accompanying notes 70–76; *see also* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.) (1% risk of injurious side-effect of surgery), *cert. denied*, 409 U.S. 1064 (1972); Cobbs v. Grant, 8 Cal. 3d 729, 592 P.2d 1, 104 Cal. Rptr. 505 (1972)

federal regulation of human research inadequately advances the objectives of managing conflicts of value and giving primacy to the patient's desires and goals.

3. The researcher has a fiduciary relationship with the human subject

Fiduciary law protects the autonomy of persons who entrust their power to act for themselves to others: fiduciaries who possess greater skill, expertise, capacity, or who merely have more time.[173] Fiduciary rules serve to discourage abuse of this delegated power and to reveal abuse when it occurs.[174] These rules help prevent conflicts of interest and conflicts of value by discouraging self-dealing.[175] Remedies for violations of fiduciary duties are among the strongest the law provides because they are meant not only to compensate the betrayed entrustor but also to punish the offending fiduciary.[176] For example, profits realized by a dishonest fiduciary may be shifted to the entrustor who might not have been able to obtain them under any other circumstances (including ones that prohibit him or her from gaining them directly).[177]

(minimal risks); Gates v. Jensen, 92 Wash. 2d 246, 595 P.2d 918 (1979) (suspicion of glaucoma).

173. *See generally* Frankel, *supra* note 132; *see also* 36a C.J.S. *Fiduciary* 387 (1967) and cases cited therein.

174. Professor Frankel characterizes the two essential elements of fiduciary relationships as the "Substitution Role of the Fiduciary" and the central problem of the resulting potential for abuse of delegated power. Frankel, *supra* note 132, at 808–11.

175. *See, e.g.*, Clay v. Thomas, 178 Ky. 199, 296, 198 S.W. 762, 765 (1917) (court had no authority to permit trustee's self-dealing); *see also* Aberdeen Ry. v. Blakie, 1 Macq. H.L. 461, 472 (Scot. 1854), *cited with approval in* Pacific Vinegar & Pickle Works v. Smith, 145 Cal. 352, 365, 78 P. 550, 554 (1904) (en banc) (prohibiting self-dealing whether or not beneficiary would actually benefit). In contrast, corporate directors may self-deal with corporate assets when disinterested directors and shareholders give informed consent. *See, e.g.*, DEL. CODE ANN. tit. 8, § 144(a) (1974). *See generally* RESTATEMENT (SECOND) OF AGENCY § 112 (1958); 2 A. SCOTT, *supra* note 132, § 168, at 1296 (trustees may self-deal with trust property only with the informed and independent consent of the beneficiary).

176. *See, e.g.*, RESTATEMENT (SECOND) OF TRUSTS §§ 205, 206, at 458–63 (1958) (trustee held accountable for any profit gained or loss incurred by a breach of the trust); *see also* A. SCOTT, *supra* note 132, at 1304. Criminal law penalizes the fiduciary's conversion of property as embezzlement. *See* R. PERKINS & R. BOYCE, CRIMINAL LAW 353–54 (3d ed. 1982).

177. *See, e.g.*, Central Nat'l Bank v. Connecticut Mut. Life Ins. Co., 104 U.S. 54, 71 (1881); Diamond v. Oreamuno, 24 N.Y.2d 494, 501–02, 248 N.E.2d 910, 914 301, 47 N.Y.S.2d 850 (1969) (profits from prohibited self-dealing belong to cor-

Our moral-legal system makes *A* a fiduciary of *B* when *A* can be reasonably charged with the duty to act in *B*'s best interest. The relationship may arise without a contract or a written instrument because the classification of the relationship and its legal consequences are determined by law, not by the parties.[178] The intent of the parties actually is irrelevant to a court's finding of a fiduciary obligation, and a court can insist upon supervising the relationship.[179] Courts will require the fiduciary to act in the best interest of the other party,[180] to possess certain levels of skill or knowledge,[181] to account for the use of the delegated power,[182] and to exhibit high standards of moral behavior.[183]

Physicians generally are considered fiduciaries of their patients. When doctors dispense standard medical treatments, they must act in their patients' best interests.[184] The

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poration); *see also* Securities Exchange Act of 1934, § 16(b), 15 U.S.C. § 78(b) (1982) (profits from prohibited insider trading belong to corporation); 36a C.J.S. *Fiduciary* 382 (1967) and cases cited therein.

178. Fiduciary relationships are not bounded by the circumstances in which they may arise. *See* 36a C.J.S. *Fiduciary* 385 (1967) and cases cited therein.

179. *See, e.g.*, State v. Compton, 92 Idaho 739, 744, 450 P.2d 79, 84 (1969) (McQuade, J., dissenting) ("[I]t is hornbook law that when an agency exists it does so irrespective of the label parties may apply to it."); Clay v. Thomas, 178 Ky. 199, 206, 198 S.W. 762, 765 (1917) (fiduciary duties based not on parties' understanding but on "principles"); *see also* Highway Truck Drivers & Helpers Local 107 v. Cohen, 182 F. Supp. 608, 620 (E.D. Pa.), *aff'd*, 284 F.2d 162 (3d Cir. 1960), *cert. denied*, 365 U.S. 833 (1961) (despite union members' approval vote, union officials are prohibited from using union funds to defend against charges of graft).

180. Under common law, the fiduciary is not entitled to compensation. *See, e.g.*, Hamberg v. Barsky, 355 Pa. 462, 466–67, 50 A.2d 345, 347 (1947) (unpaid fiduciary must perform his obligations); *see also* 5 W. FLETCHER, FLETCHER'S CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS § 2109 (rev. perm. ed. 1976) (corporate directors and trustees are entitled to compensation only when provided for in the charter, the by-laws, or a board resolution.); 3 A. SCOTT, *supra* note 132, §§ 242–43.

181. *See, e.g.*, Employment Retirement Income Security Act of 1974 (ERISA), § 404(a)(B), 29 U.S.C. § 1104(a)(1)(B) (1982) (skills of pension managers); RESTATEMENT (SECOND) OF AGENCY § 379 comment c (1957).

182. *See* 2 A. SCOTT, *supra* note 132, § 173 (duty to furnish information); RESTATEMENT (SECOND) OF AGENCY § 381 (1957) (same).

183. *See, e.g.*, Henley v. Birmingham Trust Nat'l Bank, 295 Ala. 38, 47, 322 So. 2d 688, 695 (1975); Meinhard v. Salmon, 249 N.Y. 458, 463–64, 164 N.E. 545, 546 (1928) (Cardozo, J.).

184. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir.) (informed consent is an aspect of a doctor's fiduciary duty of disclosure), *cert. denied*, 409 U.S. 1064 (1972); Hammonds v. Aetna Casualty & Sur. Co., 237 F. Supp. 96, 102 (N.D. Ohio 1965); Cobbs v. Grant, 8 Cal. 3d 229, 242, 502 P.2d 1, 9, 104 Cal. Rptr. 505, 513 (1972); Lockett v. Goodil, 71 Wash. 2d 654, 656, 430 P.2d 589, 591 (1962); RESTATEMENT (SECOND) OF AGENCY § 387 (1957). Commonly recognized duties

doctrine of informed consent is one aspect of the doctor-patient fiduciary relationship. It is akin to the fiduciary principle that the entrustor has a legal right to information about the activities of the fiduciary.[185]

Are biomedical researchers fiduciaries of their human subjects?[186] No American court has so held, but the relationship meets the requirements of fiduciary status.[187] When the patient agrees to be a research subject, he or she is likely to view the relationship in terms of expectations derived from the typical physician-patient relationship. Moreover, most subjects are poorly equipped to evaluate the researcher's performance. They frequently depend upon the greater skill or knowledge of the researcher to fulfill their goals, and they must trust the researcher to protect their interests.[188]

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that seem derived from or related to the fiduciary principle include the following: Beneficence (the principle that the doctor should not harm, but should help the patient); nonabandonment; and informed consent.

185. *See supra* note 182; *see also* Holder, *Do Researchers and Subjects Have a Fiduciary Relationship?*, 4 INST. REV. BD. 6 (Jan. 1982) (raising the possibility that researchers and subjects have a fiduciary relationship).

186. Katz concludes that the researcher-subject relationship is fiduciary. *See* J. KATZ, *supra* note 1, at 319–21; *see also* BELMONT REPORT, *supra* note 12, at 3–7 and 3–82; Holder, *supra* note 185.

187. *See, e.g.*, Moore v. Regents of the Univ. of Cal., No. B021195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986); LeBlang & King, *Tort Liability for Nondisclosure: The Physician's Legal Obligations to Disclose Patient Illness and Injury*, 89 DICK. L. REV. 1, 24–26 (1984) (a broad fiduciary principle is emerging in the doctor-patient relationship that seemingly could include the researcher-subject relationship as well); *see also* Mink v. University of Chicago, 460 F. Supp. 713, 718–20 (N.D. Ill. 1978), *aff'd*, 727 F.2d 1112 (7th Cir. 1984).

188. This reality starkly contrasts with the partnership characterization inherent in the definition of informed consent as "active, shared decisionmaking," which the President's Commission adopted in MAKING HEALTH CARE DECISIONS, *supra* note 1, at 36–39 (1982); *see also* Hollander, *Changes in the Concept of Informed Consent in Medical Encounters*, 59 J. MED. EDUC. 783 *passim* (1984) (comparing MAKING HEALTH CARE DECISIONS to the 1978 BELMONT REPORT).

A partnership analogy may be useful for analyzing the relationship between researcher and subject, at least with regard to physician-researchers. Both partnerships and physician-patient relationships are voluntary fiduciary relationships that may begin with a contract and are based on trust and confidence. They require the highest moral standards to attain mutually desired goals. The unique feature of partnerships is that each partner is both a principal and an agent, a trustee and a beneficiary; therefore the duties of loyalty and fidelity are required in all dealings associated with the relationship. Beane, *The Fiduciary Relationship of a Partner*, J. CORP. L. 483, 488 (1980).

This dual role of autonomy and responsibility in many ways resembles the ideal physician-patient relationship described as "shared decisionmaking" in the 1982 President's Commission Report. In particular, the relationship of partners

In this respect, researchers, whether physicians or not, are like other professionals charged with fiduciary duties.[189] 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 by 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 the amelioration of social ills. Because of this service, the profession is ennobled and accorded deference and support within society.

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as joint venturers provides an especially apt analogy because research unites in a common enterprise researchers and subjects whose motivations often diverge. This relationship is characterized as one of trust and confidence, freely entered into by knowledgeable and informed parties. This characterization accords with the elementary principles of partnership illustrated, according to Professor Beane, in *Mitchell v. Reed*, a New York Court of Appeals decision:

> The relation of partners with each other is one of trust and confidence. Each is the general agent of the firm, and is bound to act in entire good faith to the other. The functions, rights and duties of partners in a great measure comprehend those both of trustees and agents, and the general rules of law applicable to such characters are applicable to them. Neither partner can, in the business and affairs of the firm, clandestinely stipulate for a private advantage to himself . . . . Every advantage which he can obtain in the business of the firm must enure to the benefit of the firm. These principles are elementary, and are not contested.

61 N.Y. 123, 126 (1874) (decided prior to enactment of the Uniform Partnership Act); *see also* Van Hooser v. Keenon, 271 S.W.2d 270, 273 (Ky. 1954) (total fairness required of partners). *See generally* Beane, *supra*, at 490 n.49 and treatises cited therein.

The partner's duty to disclose information is judged by the highest standard—partners must disclose information without demand. Similarly, the evolving concept of informed consent requires broad disclosure by the physician of information material to a prospective patient's decision making.

While the partnership analogy is helpful in analyzing the researcher-subject relationship, there are significant differences between the two. First, partners are viewed as equals and are charged with equal fiduciary duties to each other. In contrast, the fiduciary duties in most other relationships apply only to one party (for example, the researcher in the researcher-subject relationship). Second, unlike the purpose of most partnerships, the goal of most research is not profit. If the orientation of research is changing to incorporate concerns for profit, however, it is at least arguable that the researcher has a corresponding duty to so inform research subjects, particularly if the research design is likely to "offer little academic return." *See* Siris, *In Search of Funding: The Clinical Investigator and the Drug Company*, 5 INST. REV. BD. 1, 3 (Nov./Dec. 1983).

189. *See* B. BLEDSTEIN, THE CULTURE OF PROFESSIONALISM (1976); McClellan, *supra* note 151, at 94–95.

Researchers' training and education enable them to predict the risks, the benefits, and the range of possible applications of their research far more accurately than the subject can. The subject frequently is entirely dependent on the researcher for predictions about the outcome and the potential applications of the research. He or she is obliged to trust that his or her own personal motives for participating as a subject will be realized through the researcher's efforts.[190] The researcher, of course, has independent goals in pursuing research: the pursuit of knowledge, personal enjoyment or fulfillment from the activity, advancement of his or her own career, and possibly even pecuniary gain.[191] However, we still may properly consider the researcher a fiduciary who is charged with a high standard of conduct—just as we consider lenders,[192] corporate directors,[193] accountants,[194] sellers of securities,[195] and pension managers,[196] all of whom on occasion may have a divergence of interest or a conflict of value with the lay persons with whom they deal.

The law recognizes the potential for conflict and usually provides that a fiduciary relationship should not be imposed on an unwilling fiduciary.[197] Accordingly, by apt words and

190. Because fiduciaries have an advantage in terms of expertise and knowledge (i.e., unequal bargaining power), they have "an unwaivable obligation of fairness toward the other party." Anderson, *Conflicts of Interest: Efficiency, Fairness and Corporate Structure,* 25 UCLA L. REV. 738, 760 (1978).

191. For studies of value conflicts among biomedical researchers, see B. BARBER, *supra* note 129; W. BROAD & N. WADE, *supra* note 151; R. FOX, EXPERIMENT PERILOUS (1977); S. PERRY, THE HUMAN NATURE OF SCIENCE (1966).

192. *See* Truth in Lending Act, 15 U.S.C. §§ 1601–1693r (1982).

193. *See, e.g.,* Diamond v. Oreamuno, 24 N.Y.2d 494, 501–02, 248 N.E.2d 910, 914, 301 N.Y.S.2d 78, 84 (1969) (corporate fiduciaries may not use inside information for their own profit).

194. *See* Ultramares Corp. v. Touche, Niven & Co., 255 N.Y. 170, 188–89, 174 N.E. 441, 448 (1931).

195. *See, e.g.,* S.E.C. v. Texas Gulf Sulphur Co., 401 F.2d 833 *passim* (2d Cir. 1968) (discussing the disclosure provisions of the two acts), *cert. denied,* 394 U.S. 976 (1969), *cert. denied,* 404 U.S. 1005 (1971); Securities Act of 1933, § 17(a), 15 U.S.C. § 77 (1982); Securities Exchange Act of 1934, § 10(b), 15 U.S.C. § 78 (1982).

196. ERISA prohibits trustees and fiduciaries who administer employee benefit funds from having conflicts of interest. S. REP. No. 93-127, 93d Cong., 2d Sess. 3, *reprinted in* 1974 U.S. CODE CONG. & ADMIN. NEWS 4838, 4839; *see also* Freund v. Marshall & Ilsley Bank, 485 F. Supp. 629, 636–37 (W.D. Wis. 1979).

197. *See, e.g.,* F. MECHEM, ELEMENTS OF THE LAW OF PARTNERSHIP § 5, at 7 (2d ed. 1920) ("The law does not choose partners for people.").

warnings, a researcher should be able to avoid assuming a fiduciary obligation to his subjects. Rules relating to consent and disclosure may serve this function. But once the relationship has begun and the terms have been set, the fiduciary must adhere to standards of conduct set by law to protect the entrustor.[198] The imposition of a fiduciary duty to help the entrustor need not cripple the professional. On the contrary, it may be argued that the stringent standards set by the courts also will protect the integrity and efficacy of the fiduciary's profession.[199] Recent highly publicized incidents of scientific fraud,[200] human subject abuse,[201] and alleged profiteering from human tissue and cell lines[202] probably have already eroded to some extent public esteem and support for science. Greater judicial monitoring of the researcher-subject relationship may help repair the damage caused by these incidents and may reduce their frequency and severity in the future.

III. 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 the evolution of the ethics of informed consent.[203] In order to protect patients' choices and value

198. *See* Frankel, *supra* note 132, at 820–21 nn.78–80 and cases cited therein.

199. For an exposition of this argument, see Cupples & Gochnauer, *The Investigator's Duty Not to Deceive*, 7 INST. REV. BD. 1, 3 (1985).

200. *See* W. BROAD & N. WADE, *supra* note 151; Bailar, *Science, Statistics and Deception*, 104 ANN. INST. MED. 259 (1986); Broad & Wade, *Science's Faulty Fraud Detectors*, PSYCHOLOGY TODAY, Nov. 1982, at 51 (discussing recent cases of scientific fraud, including ones perpetrated by well-regarded scientists at leading institutions; cases included fabrication of data, doctoring of results, alteration of laboratory animals and specimens, and disregarding evidence that tended to refute hypotheses); Petersdorf, *Pathenogenesis of Fraud in Medical Science*, 104 ANN. INST. MED. 252 (1986); Woolf, *Pressure to Publish and Fraud in Science*, 104 ANN. INST. MED 254 (1986); *Researcher Admits Tampering with Data*, 130 SCIENCE NEWS 340 (Nov. 29, 1986); *Researchers Retract Immune System Data*, Southern Illinoisan, Nov. 22, 1986, at 6, col. 1; *Misconduct by Scientists Said to Be More Common than Many Believe*, Chron. of Higher Educ., May 21, 1986, at 7, col. 1.

201. *See, e.g., Case Studies*, *supra* note 12.

202. *See, e.g.*, Moore v. Regents of the Univ. of Cal., No. B021195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986), discussed *supra* notes 77–84 and accompanying text.

203. *See supra* Part II of this Article notes 89–202 (reasons for stringent protection); Part I.B of this Article, *supra* notes 30–55 (inadequacies of current regula-

pluralism in research settings, the current federal guidelines should be amended to minimize the broad leeway given researchers in obtaining informed consent. More effective judicial remedies also should be devised to deter breaches of the duty to obtain informed consent. Section A proposes interpretations of the existing regulations and a number of amendments that reflect the evolution of the ethics of informed consent. Section B describes a judicial remedy that could be used when researchers violate the federal regulations and infringe upon their subjects' right of self-determination.

A. *Proposed Amendments to the Federal Regulations*

Two federal agencies publish regulations designed to protect human subjects of research that is funded in whole or in part by the federal government. The regulations of the Department of Health and Human Services (HHS)[204] and the Food and Drug Administration (FDA)[205] are very similar, but the FDA regulations are slightly stricter regarding exceptions to or waivers of the consent requirement.[206] Although we propose revisions to the HHS regulations, most of our suggestions would apply to the FDA regulations as well.

As a basis for restructuring informed consent law, federal agencies may look to a 1982 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[207] This report urged that the ethical basis for informed consent should be

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tions). Many of the recommendations of the 1982 President's Commission report, MAKING HEALTH CARE DECISIONS, *supra* note 1, have not yet been incorporated into the federal regulations.

204. 45 C.F.R. § 46 (1985).

205. 21 C.F.R. § 50 (1986). The FDA has jurisdiction under the commerce clause over all research involving FDA-regulated products, whether or not the research is federally funded. In contrast to HHS's contractual assurances, the FDA also uses inspections and audits to ensure compliance with regulations. The FDA regulations also provide a possibile waiver of IRB review in some circumstances. *Id.* § 56.105. For a discussion of the FDA regulations, see Nightingale, *The Food and Drug Administration's Role in the Protection of Human Subjects*, 5 INST. REV. BD. 6 (1983).

206. *Compare* 45 C.F.R. § 46.116(d) (1985) (HHS regulations for IRB approval of modified consent procedures) *and id.* § 46.211 (1985) (HHS provisions for modification or waiver of specific requirements) *with* 21 C.F.R. § 50.23 (1986) (FDA exceptions from general informed consent requirements).

207. MAKING HEALTH CARE DECISIONS, *supra* note 1.

respect for individuals.[208] Respect was defined in the report as incorporating the capacity to form, revise, and pursue personal plans for life.[209] This "life plan" approach offers a promising basis for the researcher-subject relationship.

Adoption of the "life plan" approach would require several changes in current practice. First, the researcher would have a duty to ascertain the subject's life plan, mind-set, or world view and to offer relevant information. Not all subjects have the same hopes, fears, expectations, and vulnerabilities. They have different levels of risk aversion and different altruistic impulses. Accordingly, the researcher would have to do more than simply offer standardized, blanket descriptions of risks and benefits. He would have to ask questions, elicit answers, and attempt to adopt the patient's objectives as his own insofar as that is possible.[210]

Yet the researcher may have a conflict of value with the subject. He may be under pressures to produce publishable results and these pressures subconsciously may disincline the researcher from giving full weight to the nuances of consent.[211] Moreover, studies of interchanges between a dominant person and a passive person[212] indicate that

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208. *Id.* at 21 n.19; *cf.* BELMONT REPORT, *supra* note 12.

209. MAKING HEALTH CARE DECISIONS, *supra* note 1, at 44; *see also* Dworkin, *supra* note 1 (autonomy includes *process* by which persons decide what they "want to want"; thus, it includes appreciation of higher-order preferences by which we determine the types of self we shall become).

210. *See* R. BURT, TAKING CARE OF STRANGERS: THE RULE OF LAW IN DOCTOR-PATIENT RELATIONS (1979) (advocating similar "dialogue" between patients and doctors, but as a substitute for hard-and-fast legal rules); *cf.* Levine, *supra* note 1, at 72 (consent a process of negotiation between doctor and patient).

211. *See supra* notes 151–61 and accompanying text. There also may be occasions on which the IRB itself is under similar pressures to discount dangers and to approve research despite defects in consent. *See* Levine & Caplan, *supra* note 1, at 8 (suggesting that the Loma Linda Medical Center review board may have approved Baby Fae xenograft because of "an interest in seeing its own institution undertake the first attempt to implant an animal heart in the chest of a newborn").

What should an IRB do when it perceives that it is in an institutional conflict of interest of this sort? It seems to us that it must request the IRB of another institution for an advisory opinion. The possibility now exists for cross-submission of research protocols, although it is not provided for in the regulations. The regulations should be amended to require cross-submission when a board realizes that it cannot render a fair decision. *Cf.* 28 U.S.C. §§ 144, 455 (1982) (recusal statutes, which require federal judges to disqualify themselves from hearing cases in which they have an interest or cannot render a fair decision).

212. The passivity of the subordinate need not be a generalized personality trait; it may result from illness, fear, or a threatening environment. *See generally* SILENT WORLD, *supra* note 1.

communication and understanding between the two often are ineffective.[213] As a result, each party tends to arrive at inaccurate conclusions about the other, himself, and the situation.[214]

For these reasons, a second change from current practice is needed. At least in some circumstances, provisions should be made for consent to be obtained by an intermediary not directly associated with the research.[215] Such an arrangement would reduce the potential for conflict of interest

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213. Some research indicates that the passive person may understand more about the relationship than the dominant person, but that both understand less than participants in more equal relationships. *See, e.g.*, Millar, Rogers-Millar, & Courtright, *Relational Control and Dyadic Understanding: An Exploratory Predictive Regression Model*, 3 COM. Y.B. 213 (1979). *Cf.* Matarazzo, *The Interview*, in HANDBOOK OF CLINICAL PSYCHOLOGY 403, 441–45 (B. Wolman ed. 1965) (describing the concept of interpersonal synchrony: the tendency of persons to synchronize their behavior with those in the more dominant role).

214. *See, e.g.*, Bandura, *Self-Efficacy Mechanism in Human Agency*, 37 AM. PSYCHOLOGY 122 (1982); Davis & Perkowitz, *Consequences of Responsiveness and Dyadic Interaction: Effects of Probability of Response and Proportion of Content Related Response on Interpersonal Attraction*, 37 J. PERSONALITY & SOC. PSYCHOLOGY 534 (1979).

One communications scholar is investigating the effects of passive behavior on the more dominant party in an interaction. She hypothesizes that the more dominant party will perceive the submissive party as uninvolved or uninterested and will act accordingly. Telephone interview with Jill T. Nerem, R.N., M.S., doctoral candidate, Interdisciplinary Studies, Communication and Psychology, Ohio State University (Feb. 10, 1986); *see also* J.T. Nerem, *The Effect of Passive, Uninvolved Interactional Behavior in Dyadic Communication* (unpublished manuscript on file at the UCLA Law Review office). *See generally* Cegala, Savage, Brunner & Conrad, *An Elaboration of the Meaning of Interaction Involvement: Toward the Development of a Theoretical Concept*, 49 COMM. MONOGRAPHS 229 (1982); Coyne, *Depression and the Response of Others*, 85 J. ABNORMAL PSYCHOLOGY 186 (1976); Jennings & Muhlenkamp, *Systematic Misperception: Oncology Patients' Self-Reported Affected States and Their Caregivers' Perceptions*, 4 CANCER NURSING (1981); Quint, *Institutionalization Practice of Information Control*, 28 PSYCHIATRY 119 (1965); Rodin & Langer, *Aging Labels: The Decline of Control and Fall of Self-Esteem*, 36 J. SOC. ISSUES 12 (1980).

215. MAKING HEALTH CARE DECISIONS, *supra* note 1, at 38. Beginning with the Nuremburg Code, researchers have been held responsible for obtaining informed consent. *See supra* note 14. This requirement has the advantage of clear allocation of responsibility, but essentially leaves the researcher to monitor himself or herself. For an analysis of ways to improve the consent process, including the use of neutral third parties, see Robertson, *Taking Consent Seriously: IRB Intervention in the Consent Process*, 4 I.R.B. 1 (May 1982). It might be argued that requiring the researcher personally to prepare the consent forms and supervise the consent-obtaining process serves a valuable educative function for the scientist, and that this benefit should not be abandoned lightly. Unfortunately, however, there is evidence that many researchers do not experience obtaining informed consent as an educative event, but rather view it as a technical hurdle to be negotiated with as little trouble as possible, in order to get on with the research. *See supra* notes 152–61 and accompanying text.

or conflict of 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.[216] The subject also should be given the name of a person not associated with the research to whom the subject may address questions or whom the subject may notify of any injury that occurs.[217]

Providing an intermediary between the subject and researcher offers several advantages.[218] The prospective subject would be represented from the beginning of the relationship. The intermediary would serve as a conduit between the researcher and the subject, and at times would perform the function of an ombudsman.[219] The researcher also would be well-served because he or she would save valuable research time. In addition, the intermediary who obtains consent, if he or she is properly trained and has sufficient experience, could serve as a consultant to those planning research with human subjects. Identifying problems at initial stages would eliminate some of the trial and error involved in submission of projects to IRBs for approval. When sensitive information is concerned or privacy might be invaded, the subject might be allowed to choose

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216. *See supra* notes 129–69 and accompanying text; *see also* Levine, *supra* note 1, at 103–04 (suggesting that researchers be permitted to delegate consent obligations: "there is no *a priori* reason to assume that subjects will be generally better informed merely because it is the principal investigator who undertakes this responsibility."). The literature on physician-patient relationships indicates that physicians have not adequately encouraged patients to participate in decisionmaking and self-management. *See, e.g.*, SILENT WORLD, *supra* note 1; Asken, *Psychoemotional Aspects of Mastectomy: A Review of Recent Literature*, 132 AM. J. PSYCHIATRY 56 (1975); Boreham & Gibson, *The Informative Process in Private Medical Consultations: A Preliminary Investigation*, 12 SOC. SCI. & MED. 409 (1978) (medical specialists have brief, unidimensional relationships with patients); Rosen & Tesser, *On Reluctance to Communicate Undesirable Information: The MUM Effect*, 33 SOCIOMETRY 4 (1970); Waitzkin & Stoeckle, *The Communication of Information About Illness*, 8 ADVANCES IN PSYCHOSOMATIC MED. 180, 187–89 (1972) (physicians need to control the situation).

217. The researcher may be the designated person under the current regulations. 45 C.F.R. § 46.116(a) (1985).

218. Objections are discussed *infra* note 230.

219. This requirement should be enforced even when a third-party consent obtainer is not used; it is intended to be a separate requirement. Both provisions would promote the current movement toward patient advocacy and patient empowerment. *See* BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, THE NEW OUR BODIES, OURSELVES: A BOOK BY AND FOR WOMEN (1984); I. ILLICH, MEDICAL NEMESIS (1976); *Going to the Hospital? Stick Up For Your Rights*, U.S. NEWS & WORLD REP., Oct. 1, 1984, at 61.

among several prospective intermediaries.[220]

If the research takes place in a medical setting, medical social workers, presumably better trained in communication skills than physicians, would be logical choices for consent-obtaining intermediaries.[221] Communications studies reveal

220. *Cf.* Levine, *supra* note 1, at 95 (making similar suggestion regarding consent monitors).

221. Medical (sometimes called "clinical") social workers are found on the staffs of most teaching hospitals and medical research centers. Their duties may include a number of functions, including counseling patients and their families, working to ease patients' fears and anxieties, explaining procedures, and assisting patients and their families to make various adjustments. Clinical social workers ordinarily are required to possess a master's degree in social welfare and to have completed a two-year postdegree period of on-the-job training under a licensed supervisor. Their academic and professional training includes counseling, research, and consultation, and attempts to produce a professional trained to help persons solve individual and family problems that arise because of illness or incapacitation. Interview with Bernice Sokol, Professor of Social Welfare, UCLA, in Los Angeles (Apr. 21, 1986). Because of their temperament and their training, clinical social workers would seem to have the skills of empathy and communication required for the interactive process of consent obtaining we call for; moreover, they are less likely than investigators to be heavily invested in the hospital's research function. Thus, clinical social workers should prove less subject than most to the pressures and temptations to short-circuit obtaining a patient's informed consent.

In at least one research institution, the University of Texas Medical Center at Houston, "research nurses" who are part of the experimental team sometimes obtain consent from subjects. Interview with Paula Knudson, Staff Assistant, Committee for the Protection of Human Subjects, University of Texas Medical Center, Houston (May 15, 1986). The personnel at medical research centers often also includes "quality control" nurses, who are not part of the research team, but whose expertise and training might equip them to undertake this function. *Id.*

Concededly, the scientific complexity of certain protocols will render them beyond comprehension of a nonscientist intermediary. In these cases, it would be useful to employ a team of two (or more) intermediaries: a scientist (probably a member of the research team), and a nonscientist communications expert. The scientist would be present to explain difficult scientific concepts and to answer questions. The nonscientist would be present to assure that the prospective subject understood the scientist's explanation.

Ideally, physician-researchers should be trained in communications skills as part of their medical education. Until this takes place, the collaboration of physician-researcher and social worker (or other communications expert) is a feasible and relatively inexpensive way of ensuring that the autonomy of human subjects is respected. The prospective subject is likely to be more confident and communicative with a lay consent-obtainer. If the social worker maintains contact with the subject throughout the research period, additional benefits also may be expected. The subject may experience a greater sense of personal engagement with the venture and may be more likely to see it through. This may minimize the cost to the institution and the disruption to the research that occur when subjects drop out.

Would consigning the process of consent obtaining, wholly or partly, to a nonresearcher convey undesirable messages, either to the principal investigator

that even in the best circumstances, physicians have difficulty communicating effectively with patients[222]—they tend to talk "at and not with patients."[223] Communication skills aside, the process for obtaining consent is elaborate enough that it often will prove more efficient for a trained specialist to perform this function.[224]

The process we envision would work roughly in the following way: In the first phase, the social worker or other intermediary would consult with researchers to learn the nature of the research. Then, he or she would translate this information into easily understood terms and, if necessary, into the language of the subject.[225] Next, the social worker

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or to the research subject? With respect to the investigator, it could be objected that our proposal allows the researcher to escape responsibility too easily: the researcher can ignore the need to obtain consent, reasoning that "someone else will take care of that." The result could be lax and uncaring treatment of human subjects. This possibility could be reduced or eliminated by providing that the researcher's informed consent obligations do not cease when an intermediary obtains consent. With respect to the research subject, it could be feared that the subject might receive the message that consent is unimportant. This result can be avoided by using the team approach suggested above, in which both the researcher and the intermediary participate in the consent-obtaining process. At a minimum, the researcher should be present to answer questions at the beginning of the interview and at the final stages of the project.

222. *See, e.g.*, Jaspars, King & Pendleton, *The Consultation: A Social Psychological Analysis*, in DOCTOR-PATIENT COMMUNICATION 139 (D. Pendleton & J. Hasler eds. 1983); Maguire & Rutter, *Training Medical Students to Communicate*, in COMMUNICATION BETWEEN DOCTORS AND PATIENTS 46 (A. Bennett ed. 1976); Taylor, *Hospital Patient Behavior: Reactance, Helplessness or Control?*, 35 J. Soc. ISSUES 156 (1979). For an exploration of the dynamics of communicative interaction, see Cegala, Savage, Brunner & Conrad, *supra* note 214.

223. *See* Gray, Cooke & Tannenbaum, *Research Involving Human Subjects*, 201 SCIENCE 1094, 1101 (1978) (one-third of human subjects surveyed expressed some dissatisfaction with researchers' communication skills); MAKING HEALTH CARE DECISIONS, *supra* note 1, at 30 (quoting Katz, *Disclosure and Consent: In Search of Their Roots*, in II GENETICS AND THE LAW 122 (A. Milunsky & G. Annas eds. 1980)).

Katz notes that "nurtur[ing] the patient[s]' autonomous, adult functioning through a persistent dialogue . . . goes counter to current practices that exploit the natural regression resulting from illness and stress." *Id.* at 125–26.

224. *See supra* notes 21–29 and accompanying text (current consent requirements); Part III.A of this Article *supra* notes 204–24; *infra* notes 225–46 (proposed amendments to informed consent rules); *see also* R. LEVINE, *supra* note 1, at 95–97; Robertson, *supra* note 215.

225. It should be required that the interview occur at a location that is as uncoercive as possible. *See* Kaimowitz v. Department of Mental Health (Mich. Cir. Ct. 1973), *reprinted in* 1 Mental Disab. L. Rept. 147 (1976), 2 Pris. L. Rep. 43 (1973) (many institutional environments "inherently coercive"). Some subjects will feel cowed and submissive in the sterile waiting rooms of large medical complexes. In these circumstances, the possibility of obtaining genuine consent—

would meet and interview prospective subjects in order to elicit information about their life histories, family backgrounds, education, language facility, values, fears, life plans, and current circumstances. The social worker would explain the project to the subject, giving special attention to those aspects of the project that both a reasonable subject would want to know and that this particular subject likely would want to know.[226] The social worker should pay particular attention to the risks of the research since moral altruism is impossible without the subject's understanding of this matter. At the conclusion of the interview, the social worker would offer to answer any questions the subject has or may have in the future.[227]

Whether using an intermediary to obtain consent is more or less costly or time-consuming than the current approach,[228] it seems a better-calculated means to obtain in-

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consent that reflects the subject's wishes, values, and life plan—will decrease. Comfortable, familiar, surroundings increase the likelihood that the subject will act autonomously. The interview should take place in such settings whenever possible.

226. This would be based on information obtained in the first stage.

227. *Cf.* Robertson, *supra* note 215 (making the related argument that consent-obtaining process should be divided into a series of steps).

228. *See* Royston, *Cell Lines from Human Patients: Who Owns Them?*, 33 CLINICAL RES. 442 (1985) (pointing out waste of researcher's time when legal guidelines are unclear and litigation arises).

Because of the burdens imposed by the remedies we suggest, it might be argued that our solutions infringe upon a scientist's constitutional right to engage in research. Congress' authority both to require IRB review and to promulgate reasonable conditions for the receipt of funding is clear. *See* Steward Mach. Co. v. Davis, 301 U.S. 548 (1937); Robertson, *supra* note 7. Nonetheless, that authority must be exercised in consonance with the Constitution. A number of commentators have urged that a scientist's interest in carrying out research with willing sources and materials under his or her control is protected by the first amendment. *See* Delgado & Millen, *God, Galileo and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349 (1978); Robertson, *supra* note 7, at 506; *see also* Delgado, *Can Science Be Innoportune? Constitutional Validity of Governmental Restrictions on Race-IQ Research*, 31 UCLA L. REV. 128 (1983); Ferguson, *Scientific and Technological Expression: A Problem in First Amendment Theory*, 16 HARV. C.R.-C.L. L. REV. 519 (1981); Lederberg, *The Freedoms and the Controls of Science: Notes from the Ivory Tower*, 45 S. CAL. L. REV. 596, 606–07 (1972); Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203 (1976); Note, *Considerations in the Regulation of Biological Research*, 126 U. PA. L. REV. 1420, 1432–35 (1978).

Since additional regulations, like those we propose, would burden a constitutionally protected activity, they must be shown to promote a compelling state interest. *See* Delgado, *supra*, at 154–94; Delgado & Millen, *supra*, at 390–91; Robertson, *supra* note 7, at 506–08. It seems likely that ethical treatment of human subjects would be deemed a compelling state interest sufficient to justify

formed consent.[229] Our proposal more effectively protects value pluralism, reduces the risk of overbearing scientific zeal, and assures that subjects learn the full import of their service—including the moral meaning of their risk and self-sacrifice.[230]

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general standards of humane treatment for all research, both federally and non-federally funded. Robertson, *supra* note 7, at 509–10. Alternatively, a compelling state interest could be found in the health, safety, and autonomy of those subjected to federally sponsored research. In this case, the regulations would have to advance the protection of human subjects by means that did not encroach excessively on any protected liberty. The modest amendments and interpretations we propose seem adequate to meet this standard.

The judicial remedy we outline seems even less likely to pose constitutional problems for two reasons. First, unlike regulations, which operate as prior restraints, damages and equitable remedies are imposed after the fact; consequently they are constitutionally less troublesome. Second, the judicial remedy is controlled by a court rather than by a quasi-administrative agency (the IRB) whose lay members may be less sensitive than a judge to the nuances of constitutional doctrine and interpretation. Thus, the private action we propose should also satisfy constitutional demands.

Finally, it might be argued that tighter informed consent guidelines have another kind of "cost": if they are put into place, some individuals will exercise their freedom by declining to serve as research subjects. Research then will be more difficult to conduct, scientific progress will be thwarted, certain cures that may have been developed will be postponed, and society will be worse off.

It is not at all certain, however, that paying greater attention to informed consent will impede science. Improving the atmosphere of trust and confidence between researchers and subjects may well have the opposite effect. More basically, society has not yet decided that human subjects may be conscripted (like soldiers) without their consent. Thus, even if protecting informed consent entails losses in utility, society is prepared to make that trade-off. *See also* R. DWORKIN, A MATTER OF PRINCIPLE 208–13 (1985) (only persons who bear the burden of "instrumentality"—treatment as a means rather than an end—should make the decision to bear it).

In addition, the utility-based arguments for abrogating consent intuitively are less applicable in research settings than in settings in which standard therapies are applied. There are many exceptions to the consent requirement in the latter setting. *See, e.g.*, Meisel, *supra* note 1. The "unconscious patient" exception is one. Most agree with these exceptions and do not view it as a serious invasion of autonomy when a physician performs emergency measures on an unconscious patient (e.g., a drowning victim). Yet if a researcher came upon an unconscious person and proposed to carry out nontherapeutic research on him or her, most of us would be highly offended. Our response indicates that the utility of unconsented-to research offers little justification for it.

229. Robertson, *supra* note 215, at 4 (proposing that in hospital and biomedical studies "the IRB should require consent supplements: (1) when a lack of a meaningful consent would, because of the nature of the intervention and the risks, be a serious moral wrong; and (2) when there are reasonable grounds for thinking that barriers to a meaningful consent will operate.").

230. Patients tend to adopt or exhibit passive behavior in relating with their doctors. T. PARSONS, THE SOCIAL SYSTEM 439–79 (1951); D. ROBINSON, PATIENTS, PRACTITIONERS AND MEDICAL CARE: ASPECTS OF MEDICAL SOCIOLOGY 70 (1973);

While instituting measures like these would improve the

Szasz & Hollender, *A Contribution to the Philosophy of Medicine*, 97 ARCH. INTER. MED. 585 (1956). Some physicians have rationalized that patients who want to be informed will ask questions and act interested. *See* Roter, *Patient Participation in the Patient-Provider Interaction: The Effects of Patient Question-asking on the Quality of the Interaction, Satisfaction and Compliance*, 5 HEALTH EDUC. MONOGRAPHS 281, 287 (1977). *But see* sources cited *supra* notes 209–14 (communications and psychology studies that cast doubt on this assertion).

Our proposal for a consent-obtaining intermediary could be objected to on a number of grounds. In addition to the objections that the approach could depreciate the value of informed consent, *see supra* note 221, or violate scientists' constitutional right of free inquiry, *see supra* note 228, the following objections seem plausible: (i) The proposal would erode the basis of the researcher-subject relationship; (ii) the lay intermediary approach simply substitutes one professional for another and does not address the heart of the problem; and (iii) intermediaries will not know enough science to perform their functions effectively.

(i) The proposal will erode the basis of the researcher-subject relationship. It might be urged that interposing an outsider between the researcher and the subject could interfere with their relationship. This could make service as a research subject less appealing and decrease the subject's interest in serving in future research. But it is not clear that using intermediaries to obtain consent will have this effect any more than requiring disclosure in connection with bank loans causes consumers to fear and avoid banks. Indeed, the contrary effect is quite possible: the use of intermediaries may reassure some subjects that the research is safe and that no information is being withheld from them. Even if the researcher-subject bond is impaired somewhat, this cost may be acceptable if necessary to protect human autonomy—a value which holds a high place in our hierarchy of values.

(ii) The proposal is a mere substitution of one professional for another. It could also be argued that using intermediaries adds a level of complexity without providing any corresponding gain—one impersonal, remote professional simply substitutes for another, and the subject is left floundering just as before. The precise purpose of providing for an intermediary to obtain consent in certain cases is to increase the likelihood of understanding by the subject and to increase the chances of effective communication between the subject and the consent-obtainer. *See supra* notes 215–21 and accompanying text. Many researchers lack highly developed communications and interpersonal skills and are trained in a tradition in which the patients' or subjects' autonomy is accorded little weight. *See supra* notes 151–61 and accompanying text. Moreover, researchers often have a conflict of interest or a conflict of value regarding informed consent. Intermediaries may be selected for their empathy and communications skills and an absence of a conflict of value, thus promoting the integrity of the consent-obtaining transaction.

(iii) Lay intermediaries will not know enough science to perform their function adequately. In some medical and in much social science research it will not be the case that the intermediaries have insufficient scientific knowledge to function effectively. When the complexity of the research renders it beyond a lay intermediary's comprehension, two consent-obtainers may be used, a scientist and a nonscientist. *See supra* note 221. Reliance on this objection may betray a fundamental confusion between the technical and the moral dimensions of informed consent. The requirement of informed consent operates primarily to protect a moral value—respect for human autonomy. At its heart, obtaining informed consent is not an exercise in scientific erudition; a subject may give perfectly valid consent even if every technical detail of the research has not been explained or understood. Many scientists do not seem to grasp this fully. Instead, they perceive informed consent as a type

quality of informed consent, they would not apply to much of the research conducted today. For example, research in the social sciences that relies upon the use of deception is exempted from informed consent requirements when it is determined to be of "minimal risk" to the subject,[231] and when it will provide valuable knowledge that cannot be obtained through alternative methods. Although the latter two determinations are disturbingly open-ended and require attention, the following discussion concentrates on how minimal risk is determined.

1. The determination of minimal risk

When an IRB determines that research presents minimal risk, it may approve a consent procedure that alters some or all of the informed consent elements listed in the regulations, or it even may waive the requirement entirely.[232] In both instances, the subject, whose autonomy ostensibly is to be protected, has no role in deciding whether the risks are minimal. Furthermore, a subject may wish to be advised of minimal risks.[233] Not only is the subject under-

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of battering ram with which to beat lay participants into submission. *See* R. LEVINE, *supra* note 1, at 76 (overdisclosure sometimes used to intimidate lay patients). In short, consent-obtainers, whether lay intermediaries or scientists, need only impart *material* information—that which patients in general, and the patient at hand in particular, would want to know. Only sometimes will this require a sophisticated level of scientific knowledge.

231. The HHS guidelines define "minimal risk" as follows: " 'Minimal risk' means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(g) (1985).

232. *Id.* § 46.116(d). Under current law, IRBs and researchers easily can trivialize risk or, under the guise of a risk-benefit analysis, commit the error of balancing individual risk against the broad social benefit conferred by science in general. This is the error of using an "act utility" measure for risk but a "rule utility" measure for gain. *Cf.* ETHICAL PRINCIPLES IN THE CONDUCT OF RESEARCH WITH HUMAN PARTICIPANTS (1973), *quoted in* Baumrind, *supra* note 56, at 23-15 to 23-16, 23-28.

233. *See* Merriken v. Cressman, 364 F. Supp. 913, 920 (E.D. Pa. 1973) (survey research on students' family and drug problems—which today might qualify for reduced or no scrutiny—found to violate constitutional right of privacy in absence of "knowing, intelligent, and aware consent"). *Merriken* implies that a broad application of the HHS waiver provisions may be unconstitutional. For other instances in which courts have required disclosure in relatively low-risk settings, see Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.) (undisclosed one percent risk of paralysis), *cert. denied*, 409 U.S. 1064 (1972); Gates v. Jensen, 92 Wash. 2d 246, 595 P.2d 919 (1979) (patient not told of slight possibility of glaucoma).

represented in the risk analysis, he also has no opportunity to define or characterize the risk.[234] Both processes are controlled by IRB members, many of whom themselves are research scientists.[235] Moreover, a researcher currently is not required to seek consent from subjects of research involving educational tests, standard educational practices, direct observation of behavior, interviews, existing data, or certain types of research about public benefit and service programs.[236] A researcher also may petition for waiver of the consent requirement, or some of its elements, for other forms of research posing minimal risk.[237] The regulations implicitly permit the researcher and the IRB to decide when a prospective human subject may exercise his or her autonomy. This problem should be remedied by requiring disclosure of all known risks—especially risks that may be important to particular subjects.[238]

It might be argued that waiver rules function, in effect,

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234. The determination that a certain procedure has, for example, a four percent chance of causing blurred vision lasting three to six weeks is a scientific judgment. But the decision that that hazard is unacceptable, either absolutely or when balanced against other costs and benefits, is a personal decision only the subject can make.

235. Williams, *Success in Spite of Failure: Why IRBs Falter in Reviewing Risks and Benefits*, 6 INST. REV. BD. 1, 2 (May/June 1984) ("[T]he harm/benefit guidelines are notoriously ambiguous and contain a marked bias for approval of protocols; . . . [M]embership on review committees is comprised mainly of fellow researchers or, occasionally, nonresearchers sympathetic to the enterprise of research.").

236. 45 C.F.R. § 46.101(b)(1)–(6) (1985).

237. *Id.* § 46.116(d).

238. Our proposal would require reconsidering the current approach to deception research. *See supra* notes 45–47 and accompanying text; *supra* note 120 (defining deception research). In deception research, the subject is advised neither of the nature nor the purpose of the experiment, nor its potential risks. *See supra* note 48 and accompanying text. Indeed, in deception research the subject cannot be so advised—the "expectation effect" would destroy the experiment.

In deception research, the patient or subject who is uninformed of these matters cannot benefit from the potential moral gain from having acted altruistically. *See supra* notes 109–27 and accompanying text. For these reasons, our proposals would have a heavy impact on deception research. It may be possible, however, to permit deception research to continue by means of "informed deceit." Subjects would agree to serve in a research pool from which subjects would be drawn for both deceptive and nondeceptive research. These individuals would agree to be deceived in a certain percentage of the research projects for which they volunteer. S. BOK, *supra* note 120, at 194–95; E. DIENER & R. CRANDALL, ETHICS IN SOCIAL AND BEHAVIORAL RESEARCH 95–96 (1978); *see* Sieber, *Deception in Social Research I*, *supra* note 47, at 3. *But see* CAL. HEALTH & SAFETY CODE § 24173(c)(1) (West 1984) (requiring patient be informed if the administration of a placebo is possible); Freedman, *The Validity of Ignorant Consent to Medical Research*, 4 INST. REV. BD. 1, 2–4

as a useful form of delegation whereby subjects permit others to decide for them whether participation as a research subject is warranted. Failing to provide a means by which subjects can opt *not* to hear information about trivial risks, for example, could be argued to violate autonomy; it imposes information where it is neither needed nor wanted.

If autonomy is understood simply as an opportunity to pursue preferences, imposing unwanted information certainly impairs autonomy. But autonomy seems to include an element of self-direction. Autonomy as self-direction requires information, and any delegation or waiver is presumptively questionable. Another aspect of autonomy is rationality. Rules that force disclosure of information promote this sort of autonomy. Few legal decisions differentiate among these senses of autonomy, and to some degree

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(Feb. 1982) (casting doubt on whether informed deceit is conceptually a coherent moral notion).

Another possibility is proxy consent: an arrangement in which some individuals from a demographically similar group are consulted about deception research contemplated for others in that group. *Cf.* Crawshaw, Garland, Hines & Lobitz, *Oregon Health Decisions: An Experiment with Informed Community Consent,* 254 J. A.M.A. 3213 (1985) (citizen-based group formed to address bioethical dilemmas associated with personal autonomy).

Before approval is granted for deception research, the researcher should be required to demonstrate that there is no feasible nondeceptive alternative—that the information sought cannot be gained by nondeceptive means. Current regulations governing research on children support this general approach. 45 C.F.R. §§ 46.401–.409 (1985). *See, e.g., id.* § 46.402 (the "assent" requirement in research with children—that is, the requirement that the child not actively protest the research). Both of these requirements seek to protect autonomy in settings in which complete protection is not possible.

Our suggestion about proxy consent can be analogized to the requirement in research with children that the Secretary of HHS consult a panel of experts from a number of disciplines and solicit public review and comment. *See id.* § 46.407(b); *see also id.* § 46.405 (research must benefit the child and the benefit must be at least as favorable as any benefit afforded by alternative approaches). A provision for review would pressure researchers both to devise responsible projects and to provide a measure of public accountability. It also probably would help counter the current cynicism found in population groups frequently subjected to deception research (such as Introduction to Psychology course pools).

Compare our approach to that in Brandt, *Don't Sweep the Ethical Problems Under the Rug! Totalitarian Versus Equalitarian Ethics,* 19 CAN. PSYCHOLOGICAL REV. 63 (1978) (noting that West German human subjects are called "partners," that most West German social science research is conducted without deception; and implying that a too ready acceptance of deception research reflects and reinforces totalitarian urges in United States life and culture); *see also* Shipley, *Misinformed Consent: An Enigma in Modern Social Science Research,* 4 ETHICS IN SCI. & MED. 93 (1977) (deception research indicates a basic disrespect for human personality and is related to mechanistic view that people do not "experience," but merely "behave").

these aspects overlap. Cost-of-error considerations raise a further complication. Because of the variability of individual preferences in research settings, as well as the difficulty of verifying the appropriateness of delegation, presumptions should exist against delegation or waiver. Rules should be adopted that confine waiver and delegation to the most obvious situations. The need for those changes becomes particularly clear when one considers that most research subjects are young, poor, or ill and are unlikely to ask penetrating questions designed to get at the facts that rules against disclosing information might conceal.

2. Disclosure about the purpose of the research

The federal regulations do require that the research subject be told the purpose of the research.[239] Some researchers and IRBs, however, apparently believe that this requirement is satisfied by giving the most limited or general description of the aims of the research.[240] For example, they might state that the research concerns human responses to living spaces of different sizes and shapes when the real purpose is to design more effective configurations for submarines. Disclosure at a high level of generality may not reveal that bodily tissue or blood samples might be used in applied genetic engineering or recombinant DNA research—research to which the subject may object on personal or religious grounds.[241] Disclosure also may not reveal that the research may be exploited commercially and may result in financial gain to the research institution or the researcher.

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239. 45 C.F.R. § 46.116(a)(1) (1985). This requirement may be waived by the IRB. *Id.* § 46.116(d).

240. *See, e.g.*, Baron, *The "Costs of Deception" Revisited: An Openly Optimistic Rejoinder*, 3 INST. REV. BD. 8–10 (Jan. 1981) (arguing that researchers ethically may omit disclosing the study's true purpose). For a response to Baron, see Dresser, *supra* note 9, at 3.

241. *Cf.* Glantz, *Property Rights and Excised Tissue*, 1 I.R.B. 6 (Oct. 1979) (patients need only be told, in general terms, that their tissues might be used in research); Heath, *In a "No-Risk" Protocol, Does the Purpose Count?*, 1 INST. REV. BD. 8 (Oct. 1979) (one campus IRB decided to require that tissue donors be advised of purpose of research, even if it lacked risk); R. TITMUSS, *supra* note 118; Arrow, *Gifts and Exchanges*, 1 PHIL. & PUB. AFF. 312 (1972); Caplan, *Blood, Sweat, Tears and Profits: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine*, 33 CLINICAL RES. 448 (1985); Levine, *Research That Could Yield Marketable Products From Human Materials: The Problem of Informed Consent*, 8 INST. REV. BD. 6 (Jan./Feb. 1986); Murray, *Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purpose*, 8 INST. REV. BD. 1 (Jan./Feb. 1986).

Such a result may be repugnant to a research subject who believes that his participation in the project is a very personal, intimate gift for the betterment of humanity. Therefore, this element of informed consent either should be revised or interpreted to demand that all the goals of the research that might be material to the subject be revealed in concrete detail, not just general outline.[242]

3. Disclosure of the benefit to others from the research

As a corollary to the first two revisions, the federal guidelines should be revised to identify the "others" whom it is reasonably foreseeable that the research will benefit.[243] In particular, the words "including researchers and sponsors" should be added here, thus requiring researchers or sponsors to reveal any hoped-for personal or pecuniary gain for themselves or for their institutions. Alternatively, the assurance section of the regulations—by which institutions interested in receiving federal funds agree to abide by HHS guidelines[244]—could be amended to place a condition on federal funding providing that no employee of the institution may have a personal financial interest in the research. The regulations also could be amended to require that any profit from the research be deposited into the university's research accounts and applied for the benefit of persons like the subject or to further research into the condition described in the research protocol.[245] These requirements

242. Compare this materiality requirement with that of Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972) (requiring that physician disclose all risks that might reasonably affect a patient's decision); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.) (same), *cert. denied*, 409 U.S. 1064 (1972); R. LEVINE, *supra* note 1, at 72 (urging disclosure of full nature of research's purpose). *But see* Levine, *supra* note 241, at 7 (attacking idea that subjects have any legitimate interest in what is done with their bodily parts after the parts come into the researcher's possession and proposing that all consent forms indicate this lack of legitimate interest).

243. *See* 45 C.F.R. § 46.116(a)(3) (1985).

244. *Id.* § 46.103.

245. In some medical schools' clinical faculty practice plans, income generated by the clinical faculty's services to patients goes into university funds, some of which may be designated for research. *See generally* ASSOCIATION OF AMERICAN MEDICAL SCHOOLS, MEDICAL PRACTICE PLANS AT UNITED STATES MEDICAL SCHOOLS: A REVIEW OF CURRENT CHARACTERISTICS AND TRENDS (1977).

Some commentators have suggested that similar plans should be instituted for university researchers. *See, e.g.*, the proposal of Leon E. Rosenberg, Dean, Yale University School of Medicine, in a lecture at the AFCR Public Policy Sympo-

would extend the academic conflict of interest rules that already are in place in a number of state and local institutions[246] to research settings on a nationwide basis.

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

B. *A Proposal for a Judicial Remedy*

Most human subjects who complain of an 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 that no legally effective consent was given, the subject may be able to sue for damages on grounds of battery or negligence.[247] No court, however, has recognized that the researcher's failure to obtain informed consent is an invasion of the subject's right of self-determination and is compensable on that ground alone. To remedy this deficiency, we propose a cause of action developed from principles of fiduciary and negligence law, as well as recent scholarly commentary on the right of self-determination.

Fiduciary law is well-suited to protect a subject's intangible rights of autonomy and self-determination because it

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sium, 42d Annual Meeting, Washington, D.C. (May 6, 1985), *reprinted in* Astin, *Using Patient Materials for Product Development: A Dean's Perspective,* 33 CLINICAL RES. 452, 454 (1985); *see also* R. LINNELL, DOLLARS & SCHOLARS 130–32 (1982); Comment, *supra* note 157, at 906 n.50.

246. For a discussion of these rules, see Comment, *supra* note 157; Leskovac, *State Governance Through Conflict of Interest Rules: The California Experience,* in SCIENCE AND TECHNOLOGY (M. Goggin ed. 1986).

247. *See* Shultz, *supra* note 1 (discussing cases that provide relief when a physician fails to disclose important medical information, but arguing that these cases do not go far enough and that a new interest in medical choice should be recognized); cases discussed *supra* notes 57–88 and accompanying text. When the researcher does not touch the patient, but rather pries into a secret area of his life without the patient's consent, the remedy would be an action for invasion of privacy. If there is neither touching nor invasion of privacy but rather great humiliation, the subject may have a cause of action for negligent or intentional infliction of emotional distress. *See supra* notes 47–49 and accompanying text (deception research).

already protects these intangible rights elsewhere.[248] Fiduciary principles hold the fiduciary to the highest standards of disinterested performance and disclosure.[249] If the fiduciary acts in his or her own interest, the law requires that the dependent party be compensated.[250] In addition, a court may impose damages on the errant fiduciary, or even may award to the dependent party the profits realized by the fiduciary.[251]

In physician-patient relationships, the common law awards damages to dependent parties (patients) who bring suit on theories of battery or negligence against fiduciaries (physicians) who have breached their duties to inform and to obtain legally effective consent.[252] While the cases often recognize, at least in dicta, that the patient has two protectable interests—self-determination and competent care—compensation and damages usually are only awarded when physical injury occurs.[253]

As ethical thinking continues to evolve toward a model of informed consent that includes consideration of the patient-subject's personal values and life plans, the case law is left increasingly behind. Patients and subjects presently have a moral right to this expanded version of informed consent, but have no legal remedy when this right is invaded. Since preservation of this moral right is most compelling in research settings, the law should recognize a cause of action for victims of unconsented-to research.

Under this approach, a fiduciary obligation would arise from the relationship between human subject and researcher. The researcher would be charged with obtaining informed consent in a way that takes into account the subject's personal values and desires. The researcher would be required to disclose fully all the factors enumerated in the elements of consent presently defined in the current federal regulations, in addition to those elements contained in the amendments we propose.

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248. *See supra* notes 173–85 and accompanying text.

249. *See supra* notes 173–83 and accompanying text.

250. *See supra* note 176 and accompanying text.

251. *See supra* note 177 and accompanying text.

252. *See* Shultz, *supra* note 1, at 224–26; cases cited *supra* notes 56–88.

253. *See* Shultz, *supra* note 1 (making this point in connection with ordinary medical treatments).

If a court finds a breach of the fiduciary duty, it could apply a variety of remedies: general damages for the breach and for emotional harm to the subject;[254] punitive damages when the defendant is found to have willfully, wantonly, or recklessly disregarded a subject's right of choice;[255] or special damages for proven losses. When a researcher fails to reveal 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 channeled into the areas of research of greatest relevance to the subject.

CONCLUSION

Most writers, and the few courts that have considered the question, maintain that informed consent should be protected more highly in research settings than in those settings in which standard medical or behavioral treatments are dispensed. We have reviewed the reasons usually given for providing heightened protection and have offered a number of new reasons. The combination of new and old arguments, together with the growing commercialization of certain areas of academic research,[256] make an especially compelling case for rigorously protecting informed consent.

Without full disclosure of the risks and purposes of the research, the human subject's act loses moral meaning. Moreover, the subject often is 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 strongly motivated to obtain the subject's agreement. When the researcher himself or herself obtains

254. *Cf.* CAL. HEALTH & SAFETY CODE § 24176 (West 1984) (providing damages for failure to obtain statutorily mandated informed consent even without proof of physical harm).

255. Exemplary damages, aimed at deterring future conduct, are especially appropriate to change established practices. *See supra* notes 152–61 and accompanying text (some researchers disdain values of human autonomy, and regard the requirement of informed consent as a necessary evil to be discharged as quickly and with as little effort as possible).

256. *See supra* notes 78–83, 202 (discussing the *Moore* case), 104–05, 154–61 (conflict of interest and conflict of value in research settings), 243–45 (proposing reforms) and accompanying text; *see also* Lind, *Fee-for-Service Research,* 314 NEW ENG. J. MED. 312 (1986) (expressing concern over commercial company's plan to provide experimental treatment for cancer patients at cost of about $40,000; corporation will create monoclonal antibodies tailored to customer's disease).

consent and discloses information, as is usually the case, the danger of incomplete or halfhearted disclosure is particularly great. Furthermore, many research subjects may look to the researcher as a health care provider, or at least as a disinterested pursuer of truth who has the subject's best interest at heart, but the researcher actually may view the subject in terms of expediency and the transaction as one conducted at arm's-length.

To protect informed consent in human subject research, we have proposed a number of amendments and new interpretations of the existing HHS guidelines. We also have 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 the need to protect consent is compelling and because the current approaches are inadequate, a new, long look at informed consent in human research is in order.