



UNC
SCHOOL OF LAW

NORTH CAROLINA LAW REVIEW

Volume 58 | Number 1

Article 7

10-1-1979

Health Policy-Ensuring Informed Consent in Human Experimentation: A Comparison of the Approaches of Two States

Nancy M. P. King

Follow this and additional works at: <http://scholarship.law.unc.edu/nclr>



Part of the [Law Commons](#)

Recommended Citation

Nancy M. King, *Health Policy-Ensuring Informed Consent in Human Experimentation: A Comparison of the Approaches of Two States*, 58 N.C. L. REV. 137 (1979).

Available at: <http://scholarship.law.unc.edu/nclr/vol58/iss1/7>

This Note is brought to you for free and open access by Carolina Law Scholarship Repository. It has been accepted for inclusion in North Carolina Law Review by an authorized editor of Carolina Law Scholarship Repository. For more information, please contact law_repository@unc.edu.

NOTES

Health Policy—Ensuring Informed Consent in Human Experimentation: A Comparison of the Approaches of Two States

In 1976, New York enacted the first comprehensive state legislation regulating research¹ using human subjects—the Protection of Human Subjects Article (New York Article).² California followed suit in 1978 with the enactment of the Protection of Human Subjects in Medical Experimentation Act (California Act).³ The central focus of

1. Research, or experimentation, is a medical or scientific intervention that, unlike medical or psychiatric therapy or treatment, is not undertaken in order to benefit directly the health of the subject, or that makes use of procedures other than those established and accepted by the medical community. *Compare* New York's statutory definition of "human research":

any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject.

N.Y. PUB. HEALTH LAW § 2441(2) (McKinney 1977), *with* California's definition of "medical experiment":

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, . . . electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject.

(b) The investigational use of a drug or device

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject.

CAL. HEALTH & SAFETY CODE § 24174 (West Cum. Supp. 1979).

For example, the testing of a new drug, device, or procedure on normal human subjects to determine its safety or effectiveness is research, as is the use of the standard electrocardiogram to gather new data about a certain type of heart impairment in affected patients. Research can be further classified as therapeutic or nontherapeutic. The New York and California statutory definitions of research, however, appear to encompass only nontherapeutic research. Research is therapeutic if the researcher intends to benefit his subjects. For example, the use of a new drug to induce labor is intended to benefit the subject directly and immediately, as is a kidney or heart transplantation, so these interventions would be considered therapeutic. Nevertheless, they are more like research than like treatment, because of the unknown risks involved or the newness of the procedures utilized. Although discussion here will be limited to nontherapeutic research, definitional disputes over whether a particular intervention constitutes research or therapy are not uncommon. *See, e.g.,* Karp v. Cooley, 349 F. Supp. 827 (S.D. Tex. 1972), *aff'd*, 493 F.2d 408 (5th Cir. 1974) (first artificial heart implantation in human not an experiment).

2. Protection of Human Subjects Article, ch. 450, § 1, 1975 N.Y. Laws 89, *codified at* N.Y. PUB. HEALTH LAW §§ 2440-2446 (McKinney 1977).

3. Protection of Human Subjects in Medical Experimentation Act, ch. 360, 1978 Cal. Legis. Serv. 997, *codified at* CAL. HEALTH & SAFETY CODE §§ 24170-24179.5 (West Cum. Supp. 1979).

both acts is the requirement of informed consent⁴ by subjects involved in human experimentation. A comparison of these two statutory schemes thus provides insight into the philosophical and practical problems surrounding informed consent in the research setting—why it is important and how it should be obtained.

Research with human subjects is taking place on an enormous scale and has become an important source of scientific information. The California-based Institute for the Study of Medical Ethics estimates that at least 100,000 persons per year are used as subjects in medical experiments in that state alone.⁵ Despite this great volume of

4. There is no universally accepted definition of informed consent. Perhaps the simplest one is Mr. Justice Blackmun's in *Planned Parenthood v. Danforth*: "the giving of information to the patient as to just what would be done and as to its consequences." 428 U.S. 52, 67 n.8 (1976). Beyond this bare outline, the specific elements of an informed consent are a matter of statutory and case law, developed primarily in the context of medical malpractice—that is, for consent to therapy rather than consent to research. At least twenty-three states currently have statutes defining informed consent for the purposes of medical malpractice actions, J. LUDLAM, INFORMED CONSENT 41 n.1 (1978), and literature and case law on therapeutic consent abound. See, e.g., Plante, *An Analysis of Informed Consent*, 36 FORDHAM L. REV. 639 (1968); Comment, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396 (1967); Comment, *Medical Malpractice in North Carolina*, 54 N.C.L. REV. 1214, 1235 (1976); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533 (1970); and cases discussed therein. Definitions of informed consent to research are much rarer. A few scattered statutes exist defining informed consent in specific and limited kinds of experimental procedures, e.g., Oregon's psycho-surgery statute, OR. REV. STAT. § 426.715(2) (1973). New York and California appear to have the only comprehensive definitions of informed consent to research. N.Y. PUB. HEALTH LAW § 2441(5) (McKinney 1977); CAL. HEALTH & SAFETY CODE § 24173 (West Cum. Supp. 1979).

A medical malpractice action for failure to obtain the patient's informed consent to therapy is almost universally recognized to be a negligence action. Historically, the cause of action began as one for battery—an intentional tort—but that cause of action survives today only in limited circumstances, such as the failure to obtain any consent at all. See, e.g., McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381 (1957). A failure to obtain informed consent is generally a failure to provide the patient with all the information necessary to make a reasoned, independent decision about whether to undergo a particular therapy. What information must be revealed in any given situation depends not only on the circumstances of the case but also on the standard of disclosure employed—either the professional standard, whereby the physician is obligated to tell the patient only what doctors in the community believe ought to be revealed (the current majority position in the courts, see Comment, *Informed Consent in Kentucky After the Medical Malpractice Insurance and Claims Act of 1976*, 65 KY. L.J. 524, 530 (1976)), or the material risk standard, which focuses on those risks that a reasonable patient would not ordinarily be aware of and would consider significant (a growing minority view, see Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628, 640 (1970)). Under either standard disclosure may be limited by invocation of the therapeutic privilege, which allows the physician to withhold information he reasonably believes would harm the patient or impede therapy; see note 73 *infra*. The different nature of the research context—where the risks may be unknown, where the usual doctor-patient relationship does not or ought not exist, and where direct, immediate benefit to the subject is not expected or even sought—suggests that a more complete disclosure should be required to satisfy the requirements of informed consent to research, and that the therapeutic privilege should never be invoked to justify the withholding of information about the research. See authorities cited notes 62-63 *infra*.

5. Between 1974 and 1976, the Department of Health, Education and Welfare (HEW) provided federal funding for more than 2100 projects involving human subjects in California alone.

experimentation, there have been no modern appellate court decisions in the United States recognizing subjects' rights to informed consent.⁶ This lack of case law is not, however, an accurate measure of the safety or acceptability of human experimentation for several reasons. First, even in the ordinary medical malpractice action, failure to obtain informed consent to treatment frequently is not alleged⁷ because a claim based on lack of informed consent is not an easy one to prove.⁸ Second, the injury suffered must be substantial in order to make the suit financially feasible.⁹ Finally, problems peculiar to the research setting make it less likely that human experimentation suits will be brought successfully: when their consent is uninformed or not obtained at all, many subjects may not be able to discover the identity of the responsible researcher; they may not even be aware that they have participated in an experiment.¹⁰

Injuries to research subjects and violations of subjects' rights do indeed occur,¹¹ however, as illustrated by two paradigm cases—*Halushka v. University of Saskatchewan*¹² and *Hyman v. Jewish Chronic Disease Hospital*.¹³ In *Halushka*, a student volunteered for a university

According to the National Institute of Health, however, 60% of the research conducted nationwide is funded by sources other than HEW. In addition, some uses of experimental drugs and procedures are not included in agency calculations as experiments. The Institute for the Study of Medical Ethics arrived at its estimate of the number of research subjects in California using HEW and NIH figures and a Michigan survey for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which indicates that the number of subjects averages 50 per experiment. P. ROBINSON, HUMAN EXPERIMENTATION WITHOUT INFORMED CONSENT 57-58 (1978).

6. G. ANNAS, L. GLANTZ & B. KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION 18 (1977) (hereinafter cited as G. ANNAS). The cases discussed in text accompanying notes 12-18 *infra* are the only two modern experimentation decisions on record. One is a Canadian decision and the other, a state court review of an administrative procedure, deals only with disciplinary action against researchers and not the elements of any subject's claims against them.

7. Failure to obtain informed consent was alleged in only 14% of all medical malpractice suits in 1974. J. LUDLAM, *supra* note 4, at 61.

8. In a medical malpractice action alleging failure to obtain informed consent, the plaintiff must prove that a risk of the procedure that should have been revealed to him was not revealed, that a reasonable person, had he known of that risk, would not have consented to the procedure, and that the unrevealed risk materialized to his injury. *See, e.g., Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); *Miller v. Kennedy*, 11 Wash. App. 272, 522 P.2d 852 (1974).

9. *See* P. ROBINSON, *supra* note 5, at 61.

10. *See* text accompanying notes 17-18 *infra*.

11. The Institute for the Study of Medical Ethics has collected ample statistical and anecdotal evidence of research without proper informed consent, much of which contained serious undisclosed risks and some of which resulted in severe injury. *See* P. ROBINSON, *supra* note 5.

12. [1965] 52 W.W.R. 608 (Sask. Ct. App.), reproduced in part in J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 569-73 (1972).

13. 42 Misc. 2d 427, 248 N.Y.S.2d 245, *rev'd per curiam*, 21 App. Div. 2d 495, 251 N.Y.S.2d

hospital experiment in order to earn fifty dollars. The experiment consisted of cardiac catheterization,¹⁴ a hazardous procedure, to test a new anesthetic agent for the first time.¹⁵ Plaintiff Halushka, misinformed about the nature of the procedure and the severity of the risks involved, gave his consent, and suffered a cardiac arrest during the experiment.¹⁶

In *Jewish Chronic Disease Hospital*, twenty-two chronically ill, elderly hospital patients were given injections of live cancer cells to see how long it would take for their bodies to reject the cells.¹⁷ Although there was no chance of the subjects' developing cancer from the injections, the researchers did not inform them of the nature of the cells, fearing that no one would consent if the word "cancer" were mentioned.¹⁸

Halushka and *Jewish Chronic Disease Hospital* demonstrate both pragmatic and philosophical reasons for obtaining informed consent in human experimentation. The reasons for ensuring informed consent—to promote individual autonomy and to encourage rational decision-making¹⁹—serve both as means of protecting human subjects from harm and as ends desirable in themselves. If Halushka had been more fully apprised of the risks associated with the catheterization experiment, it is highly unlikely that he would have consented. In addition, faced with a requirement of full disclosure, the researcher himself arguably would have been forced to examine the risks involved more closely and might have modified his experiment accordingly.²⁰ Thus, had the opportunity for informed consent been afforded in *Halushka*, the ultimate goal of harm prevention would probably have been achieved. In contrast, the subjects in *Jewish Chronic Disease Hospital* were not physically harmed. Nevertheless, their right to receive

818 (1964), *rev'd*, 15 N.Y.2d 317, 206 N.E.2d 338 (1965). Materials from this administrative disciplinary hearing are reproduced extensively in J. KATZ, *supra* note 12, at 41-44.

14. Cardiac catheterization is the passage of a hollow tube into the heart through a vein or artery to measure different aspects of heart function. STEDMAN'S MEDICAL DICTIONARY 238 (23d ed. 1976).

15. J. KATZ, *supra* note 12, at 569-70.

16. *Id.* at 570.

17. *Id.* at 10, 42.

18. *Id.* at 11, 25-26, 42.

19. G. ANNAS, *supra* note 6, at 33-34. Annas condenses the six functions of informed consent postulated in J. KATZ & A. CAPRON, CATASTROPHIC DISEASE: WHO DECIDES WHAT? 82-90 (1975) to the two functions mentioned in text. Katz and Capron's six functions are: "to promote individual autonomy," to protect the subject's humanity, "to avoid fraud and duress," "to encourage self-scrutiny" by the researcher, "to encourage rational decisionmaking, and to involve the public."

20. See G. ANNAS, *supra* note 6, at 35-37.

information, as well as the researchers' duty to convey it, was disregarded,²¹ leaving some subjects confused and angry. Such violations of human dignity and autonomy are themselves injuries.²²

Both the New York and California human experimentation statutes express the dual goals of protecting the autonomy interests of human subjects and preventing harm to them.²³ Their different definitions of informed consent and their different means of ensuring that such consent is obtained, however, fulfill those goals in varying degrees.

An informed consent has three components: the capacity of the subject to give consent, the context in which consent is sought (how, when, and where consent is sought, for example), and the content, the information given to the subject as the basis for consent.²⁴ The New York and California definitions of informed consent are primarily concerned with content.²⁵ Both statutes contain similar noninclusive lists

21. See J. KATZ, *supra* note 12, at 40-41.

22. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . ." Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 105 N.E. 92, 93 (1914). See also Gray, *Complexities of Informed Consent*, 437 ANNALS AMER. ACAD. PSYCH. SOC. SCI. 37, 45-46 (1978). Plainly, autonomy encompasses the right to make decisions for any reasons, including "bad" ones. Complete disclosure in *Jewish Chronic Disease Hospital*, however, could have reduced the likelihood of irrational, phobic refusals by affording prospective subjects ample information and opportunity for rational questioning, explanation and discussion.

23. See N.Y. PUB. HEALTH LAW § 2440 (McKinney 1977); CAL. HEALTH & SAFETY CODE § 24171 (West Cum. Supp. 1979).

24. A portion of the judgment in *United States v. Brandt, Trial of War Criminals Before the Nuremberg Military Tribunals, Vols. 1 & 2, "The Medical Case"* (1948), the Nuremberg trial of Nazi physicians, is widely known as the Nuremberg Code. It set forth the ethical principles of human experimentation, which include:

[T]he 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, over-reaching, 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.

J. KATZ, *supra* note 12, at 305 (the trial testimony is excerpted extensively beginning at *id.*, 292). The World Medical Organization's *Declaration of Helsinki* also recognizes that:

The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.

Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent, the consent of the legal guardian should be procured.

The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

J. KATZ, *supra* note 12, at 312-13.

25. Concentration on the "laundry list" of consent information items may tend to mask the problem of a researcher's failure to convey information effectively. See G. ANNAS, *supra* note 6, at 43 ("the end is the *process of decision-making*," not merely the documentation of consent); Gray, *supra* note 22, at 43; note 59 and accompanying text *infra*.

of information that must be conveyed, such as an explanation of the procedures and their purposes, the expected risks and/or benefits, the available alternative procedures, an offer to answer questions and an instruction about the subject's freedom to withdraw.²⁶ The California Act, however, has some important additional requirements. Subjects must be informed whether a placebo is being used in the experiment (but not that they personally will or will not receive it)²⁷ and must be given the names and institutional affiliations of the researchers,²⁸ the sponsors or funding sources,²⁹ and the manufacturers of any drugs or devices being tested.³⁰

Although the primary focus of the new human experimentation legislation is upon the content of informed consent, there are also provisions in both statutes that concern the capacity of the subject to give consent and the context in which it is sought. Both statutes provide for consent by persons other than the subject when the subject is legally incompetent to give consent;³¹ California, however, does not permit such representatives to consent to procedures that are not designed to benefit the subject.³² Both statutes assert that consent should be obtained in circumstances that are not characterized by force or fraud,³³ but neither specifies how to avoid such coercion or deceit. The California Act requires that in addition to a consent form the subject must be given a copy of an "experimental subject's bill of rights."³⁴ California

26. N.Y. PUB. HEALTH LAW § 2441(5) (McKinney 1977); CAL. HEALTH & SAFETY CODE § 24173(c) (West Cum. Supp. 1979). See also HEW Regulations on the Protection of Human Subjects, 45 C.F.R. § 46.103(c)(1)-(6) (1978). The New York Article closely resembles the HEW regulations, which apply to all research institutions receiving federal funds nationwide. The California Act parallels them in part but also is designed to overcome some perceived shortcomings of the HEW approach. See P. ROBINSON, *supra* note 5, at 45-53.

27. CAL. HEALTH & SAFETY CODE § 24173(c)(1) (West Cum. Supp. 1979). The subject's right to know is thus considered more important than the possible, although probably slight, interference with the placebo effect that such knowledge might engender.

28. *Id.* § 24173(c)(8).

29. *Id.* § 24173(c)(9).

30. *Id.* Subsections 24173(c)(8) and (9) of the California Act help to ensure that the subject knows he is part of an experiment and help to facilitate further questioning by the subject, but their primary purpose is to let the subject know against whom he can proceed in case his statutory rights have been violated. Since it is the subject who bears the responsibility for enforcing the informed consent requirement in California, such provisions are appropriate. *Id.* § 24176. Under the New York statute, on the other hand, they are unnecessary because a human research review committee bears that responsibility instead. See notes 42-43 and accompanying text *infra*.

31. N.Y. PUB. HEALTH LAW § 2442 (McKinney 1977); CAL. HEALTH & SAFETY CODE § 24175(e) (West Cum. Supp. 1979).

32. CAL. HEALTH & SAFETY CODE § 24175(f) (West Cum. Supp. 1979).

33. N.Y. PUB. HEALTH LAW § 2441(5) (McKinney 1977); CAL. HEALTH & SAFETY CODE §§ 24172(j), 24173(e) (West Cum. Supp. 1979).

34. CAL. HEALTH & SAFETY CODE § 24172 (West Cum. Supp. 1979). The experimental sub-

also requires that an oral explanation of the material contained in the consent form be given,³⁵ in a language in which the subject is fluent,³⁶ and witnessed.³⁷ Both of these requirements are apparently designed to minimize intimidation and maximize comprehension.

Although the statutory informed consent requirements of New York and California are intended to apply to all human experimentation taking place within each state,³⁸ there are important differences between the two statutes in their methods of enforcement, reflecting a difference in the interests they are intended to protect. New York's enforcement mechanism focuses primarily on protecting subjects from harm,³⁹ whereas California's is directed primarily toward safeguarding the subject's autonomy and the decisionmaking process.⁴⁰ The New York Article requires all researchers to affiliate themselves with an institution conducting research.⁴¹ All research institutions must in turn have a human research review committee,⁴² which must examine all

jects' bill of rights resembles patients' bills of rights, which came into vogue with the American Hospital Association's A PATIENT'S BILL OF RIGHTS (1972). That document strongly resembles the statement of patients' rights in JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, PREAMBLE, ACCREDITATION MANUAL FOR HOSPITALS 1970 UPDATED 1973, 21 (1973). See K. WING, THE LAW AND THE PUBLIC'S HEALTH 109 (1976). A number of states have codified similar patients' rights bills. See, e.g., N.Y. PUB. HEALTH LAW § 2803-c (McKinney 1977).

35. CAL. HEALTH & SAFETY CODE § 24173(c) (West Cum. Supp. 1979).

36. *Id.* §§ 24172, 24173(c).

37. *Id.* § 24173(d).

38. See N.Y. PUB. HEALTH LAW § 2440 (McKinney 1977); Legislative Counsel's Digest accompanying Protection of Human Subjects in Medical Experimentation Act, ch. 360, 1978 Cal. Legis. Serv. 997 ("No existing law regulates all medical experimentation in this state on human beings."). Both statutes were enacted to supplement the HEW regulations; see note 26 *supra*. HEW regulations are applicable only to research conducted in those institutions that seek federal grants, 45 C.F.R. § 46.101(a) (1978), leaving an estimated 60% of research unregulated nationwide (except for voluntary self-reviewing systems); see note 5 *supra*.

California's definition of medical experiment does not appear to include psychological research, whereas New York's definition explicitly does (if "psychological intervention . . . upon the body of the subject" can be so construed). See definitions quoted in note 1 *supra*.

39. N.Y. PUB. HEALTH LAW § 2440 (McKinney 1977) states in part: "Human research may effect dangerous and unanticipated results causing irreversible damage to the human subject. Accordingly, it shall be the policy of this state to protect its people against the unnecessary and improper risk of pain, suffering or injury resulting from human research conducted without their knowledge or consent."

40. "The Legislature . . . finds and declares that medical experimentation on human beings . . . shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies." CAL. HEALTH & SAFETY CODE § 24171 (West Cum. Supp. 1979). See also notes 68-74 and accompanying text *infra*.

41. N.Y. PUB. HEALTH LAW § 2444(3) (McKinney 1977).

42. *Id.* § 2444(1) provides in pertinent part:

Such committee shall be composed of not less than five persons . . . who have such varied backgrounds as to assure the competent, complete and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. . . . No committee shall consist entirely of persons who are of-

proposed and ongoing research for scientific merit and compliance with informed consent requirements.⁴³ The California Act has a markedly different emphasis. It bypasses committee review entirely and instead provides civil and criminal penalties—enforceable against the person primarily responsible for the research—for negligent or wilful failure to obtain the subject's informed consent, regardless of whether the subject was actually injured.⁴⁴ These sanctions are intended to make recovery available to otherwise uninjured subjects from whom consent was not obtained, but they are not meant to supplant the existing common-law negligence action for failure to obtain informed consent, which can be

ficers, employees, or agents of, or who are otherwise associated with the institution or agency, . . . and no committee shall consist entirely of members of a single professional group.

In the literature such committees are most often referred to as institutional review boards (IRBs).

43. *Id.* § 2444(2) provides in pertinent part:

The committee shall review each proposed human research project to determine (1) its necessity; (2) that the rights and welfare of the human subjects involved are adequately protected; (3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained; (4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate; and (5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified.

This review committee is essentially identical to the institutional review boards required by the HEW regulations. See 45 C.F.R. § 46.106(b) (1978).

44. Section 24176 provides in part:

(a) Any person who is primarily responsible for conduct of a medical experiment and who negligently allows such experiment to be conducted without a subject's informed consent . . . shall be liable to such subject in an amount not to exceed one thousand dollars (\$1,000), as determined by the court. The minimum amount of damages awarded shall be fifty dollars (\$50).

(b) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent . . . shall be liable to such subject in an amount not to exceed five thousand dollars (\$5,000) as determined by the court.

(c) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent . . . and thereby exposes a subject to a known substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of ten thousand dollars (\$10,000) or both.

(d) Any representative or employee of a pharmaceutical company, who is directly responsible for contracting with another person for the conduct of a medical experiment, and who has knowledge of risks or hazards with respect to such experiment, and who willfully withholds information of such risks and hazards from the person contracting for the conduct of the medical experiment, and thereby exposes a subject to substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of ten thousand dollars (\$10,000) or both.

CAL. HEALTH & SAFETY CODE § 24176 (West Cum. Supp. 1979). It is interesting to note that earlier versions of the California Act provided only criminal penalties—at one time felony status, with imprisonment of two to four years, and later misdemeanor status, with the only option being one year of imprisonment. See P. ROBINSON, *supra* note 5, at 122.

brought only when actual injury has occurred.⁴⁵ A research subject injured through the failure of the researcher to obtain informed consent should thus find both causes of action available in California.⁴⁶

New York's statute apparently reflects a legislative preference for the philosophical and practical advantages of the committee review system for ensuring informed consent. There are three distinct but related arguments for the superiority of the committee review system. First, requiring review of proposed research protocols maximizes the prospective researcher's opportunity to consider ethical issues. The emphasis in protocol review is on promoting rational decisionmaking on the part of the researcher. Furthermore, the mere existence of the committee may discourage researchers from even proposing protocols of dubious ethical or scientific merit.⁴⁷

Second, the emphasis in a committee review system is prophylactic; it is directed toward keeping informed consent cases out of the courts by taking care of potential problems before they arise. The committee review system in the New York Article is likely to be more effective than the California Act in this respect, despite the Act's substantial deterrent potential, simply because it mandates consideration by third parties before research begins.

Third, in addition to review of the informed consent procedure, the committee provides review of the scientific merit of a proposed experiment. This review is intended to prevent experimentation that is unnecessary or unnecessarily dangerous (*i.e.*, experiments in which the risks outweigh the potential benefits).⁴⁸ Merely requiring informed consent does not always accomplish this desirable end, unless the disparity between risks and benefits is properly explained to prospective subjects in the consent process. Even after a complete explanation it is conceivable that a competent person could consent to be a research

45. Negligence actions for failure to obtain informed consent have generally been brought only in the ordinary medical malpractice context. See note 4 and accompanying text *supra*. *Halushka* exemplifies the emerging cause of action in the research setting. See text accompanying notes 12-16 *supra*. It is to be expected that as both the statutory and common law causes of action develop in California, they will be modeled on that state's medical malpractice cases.

46. CAL. HEALTH & SAFETY CODE § 24176(g) (West Cum. Supp. 1979) provides: "Nothing in this section shall be construed to limit or expand the right of an injured subject to recover damages under any other applicable law."

47. Interview with Dr. Edward Bishop, Chairman, Committee on the Protection of the Rights of Human Subjects, University of North Carolina School of Medicine, North Carolina Memorial Hospital, Chapel Hill (January 15, 1979). Self-censorship can occur for many reasons, with fear of professional embarrassment probably foremost.

48. See N.Y. PUB. HEALTH LAW § 2444(2) (McKinney 1977), quoted in note 43 *supra*. The requirement of informed consent thus is only one of several means of preventing subject harm.

subject in an unnecessarily dangerous experiment. Insofar as it would prevent such experimentation, the New York Article thus sacrifices some subject autonomy in preference for direct restriction of research.

In practice, however, the committee review system has certain disadvantages.⁴⁹ First and most obvious, New York's system suffers from a lack of sanctions against noncompliance. Although the statute does provide that "[t]he commissioner shall have the power to promulgate such rules and regulations as shall be necessary and proper to effectuate the purposes of this article,"⁵⁰ apparently no rules or regulations have been promulgated.⁵¹ In addition, institutional researchers can easily bypass committee review through clandestine experimentation—a relatively common occurrence.⁵² Noninstitutional researchers need only refrain from affiliating themselves with research institutions in order to avoid committee review. Committees are not equipped with the time, manpower, training or inclination to police ongoing research within their own institutions,⁵³ and it is certainly unrealistic to expect them to play any role in identifying unaffiliated researchers. Because unaffiliated research is a large part of the informed consent problem,⁵⁴ the lack of sanctions against this researcher population may be a serious shortcoming in New York's approach.

Furthermore, because the function of a review committee is academic and ministerial, dealing only with the form and content of the research protocols and consent forms submitted to it, the nature of the follow-up a committee can do is limited to periodic, paper re-reviews of protocols for ongoing research.⁵⁵ Time and manpower limitations

49. See generally Robertson, *Ten Ways to Improve IRBs*, 9 HASTINGS CENTER REP. 29 (1979).

50. N.Y. PUB. HEALTH LAW § 2446 (McKinney 1977).

51. A 1971 draft assembly bill proposed to the New York state legislature as an amendment to the state Education Law, which never passed and parts of which may have resurfaced in the New York Article, provided that the committee could obtain injunctions and cease and desist orders against researchers as well as use "such informal and non-coercive means as it may deem appropriate." Proposed A.B. 1837 (1971), quoted in J. KATZ, *supra* note 12, at 854. Review committee members, however, do not see themselves as policemen and therefore prefer informal measures. Interview with Dr. Edward Bishop, note 47 *supra*.

52. See B. GRAY, *HUMAN SUBJECTS IN MEDICAL EXPERIMENTATION* 39 (1975). The researchers in *Jewish Chronic Disease Hospital* were able to keep their research secret even though it was conducted openly. See J. KATZ, *supra* note 12, at 15.

53. See note 51 *supra*.

54. Cooperation between pharmaceutical companies and private physicians to dispense experimental drugs for therapeutic use is common. See P. ROBINSON, *supra* note 5, at 28-42. Robinson describes physician testing of a number of experimental drugs, including thalidomide. This kind of private experimentation is often difficult to distinguish from medical treatment. See note 1 *supra*.

55. See N.Y. PUB. HEALTH LAW § 2444(2) (McKinney 1977).

again may greatly affect both original and follow-up review, and unless the committee receives a complaint, compliance with the approved protocol is up to the individual researcher.⁵⁶ Committee approval of a consent form cannot, in itself, ensure that the form will be used.⁵⁷

The role of the committee in processing research protocols tends to focus the informed consent inquiry primarily, if not exclusively, on the contents of the consent form.⁵⁸ Even conscientious researchers who comply with their approved protocols may then neglect to consider the setting in which consent is obtained, the consent capacity of their subjects, or the need for verbal as well as written presentation of information;⁵⁹ even the most complete of approved forms, therefore, may not produce informed consent. This could represent a serious problem for the uncomprehending subject, especially if, as has been suggested,⁶⁰ committee approval is offered as a defense to an informed consent suit.

A final difficulty with the committee review system inheres in the committee makeup itself. New York only requires that one member of the committee be a nonscientist.⁶¹ Thus the committee system may

56. See P. ROBINSON, *supra* note 5, at 49-50.

57. A 1976 University of Michigan study showed that subject consent was not obtained in 12% of HEW-funded research in Michigan. *Id.* at 49.

58. In a study for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 25% of the researchers interviewed at 61 institutions reported committee modification of their proposed consent forms. Gray, *supra* note 22, at 43.

59. B. GRAY, *supra* note 52, at 209 emphasizes that

the setting in which informed consent is to take place is of great importance in achieving valid consent. This obvious point has generally been overlooked in the literature on informed consent and in the regulation of human experimentation. Thus, for example, the need is not recognized for review committees to go beyond examining proposed consent forms to inquiring about the setting in which the form is to be given to subjects. However, even a clear consent form may be of little utility under unfavorable circumstances.

The author documents a labor induction study in which twenty of the fifty-one subjects interviewed did not know they were subjects, even though "all had signed a consent form approved by an active and conscientious human subjects review committee." Gray, *supra* note 22, at 43. The labor room is hardly an optimal place for obtaining informed consent, and a woman in labor may be temporarily incapable of the concentration required to comprehend a consent form. See also P. ROBINSON, *supra* note 5, at 49.

60. B. GRAY, *supra* note 52, at 51. Analogously, a number of state therapeutic consent statutes provide that a signed consent form is prima facie or conclusive evidence that informed consent has been given. J. LUDLAM, *supra* note 4, at 42. See, e.g., N.C. GEN. STAT. § 90-21.13(b) (Cum. Supp. 1977):

A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact.

Provisions such as these are to be distinguished from a waiver or release of rights, which is prohibited under both statutes. N.Y. PUB. HEALTH LAW § 2442 (McKinney 1977); CAL. HEALTH & SAFETY CODE § 24176(f) (West Cum. Supp. 1979).

61. See N.Y. PUB. HEALTH LAW § 2444(1) (McKinney 1977), *quoted in* note 42 *supra*.

harbor a systemic bias in favor of research, often approving research protocols that contain greater risks than might be sanctioned by the average layman.⁶² The judgment of a committee composed predominantly of scientists is, therefore, no substitute for that of the hypothetical reasonable person who appears in the recent informed consent cases⁶³ in determining which risks are substantial enough that they must be revealed.⁶⁴ Because the committee decision about which risks to reveal may not coincide with what the reasonable subject wants to know, committee approval does not guarantee informed consent as measured by the modern legal standard.⁶⁵

The strengths and weaknesses of the California Act, in contrast, are diametrically opposed to those found in the New York Article. The practicality of California's approach is plain: civil and criminal causes of action for experimentation without injury will have a greater deterrent impact than does the ordinary common-law malpractice action.⁶⁶ Recognizing that committee review is presently not very effective,⁶⁷ California's legislators bypassed it entirely, thereby losing, however, the advantages of review in screening out unnecessary, nonbeneficial, and hazardous research and in supplementing the researcher's own decisionmaking process.⁶⁸ Although California's reliance on the individual researcher and subject may sacrifice earlier detection of some instances of negligent failure to obtain informed consent, which committee review might have prevented, the specificity of the Act's informed consent definition itself and its requirement of witness verification of consent should encourage thoughtful decisionmaking on the part of the conscientious researcher. The researcher will be forced to weigh carefully the risks and benefits of his experiment in formulating the information that the statute requires be given to the subject.

62. Veatch, *Human Experimentation Committees: Professional or Representative?* 5 HASTINGS CENTER REP. 31, 37 (1975).

63. The reasonable person figures in the material risk standard discussed in *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) and *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); see also note 4 *supra*.

64. Veatch, *supra* note 62, at 36.

65. See note 4 *supra*. The problem of which risks to reveal exists in the California Act as well. An atmosphere that encourages the subject to ask questions should overcome much of the difficulty by allowing each subject to probe more deeply into areas of special concern. Although patients may be reluctant to ask questions of their doctors, it is presumed that subjects who know that they are to participate in an experiment will be less reticent.

66. See P. ROBINSON, *supra* note 5, at 61, 72-73.

67. See *id.* at 53.

68. To some extent this is offset by the greater detail and specificity of California's informed consent procedures; see notes 32-37 and accompanying text *supra*.

Lack of a committee, however, should not affect the incidence of wilful failure to obtain informed consent, because the wilful violator would avoid compliance with committee-approved guidelines anyway.

The decision to forego a mandatory review committee system⁶⁹ places increased emphasis on the individual autonomy of the subject. For example, under the California Act a competent subject could consent to research that a committee might not approve. The new statutory cause of action, which subjects the researcher to liability for nondisclosure regardless of harm to the subject, reflects this emphasis as well. It resembles a battery action—a vindication for the otherwise noninjurious breach of bodily integrity—much like the one used in the earliest medical malpractice cases based on failure to obtain consent.⁷⁰ It is well established by now, however, that the common-law action for failure to obtain consent to medical treatment sounds in negligence,⁷¹ and it is this cause of action that is undoubtedly intended to serve as the model for the new statutory action.⁷²

There are, of course, important differences between research and treatment that must be accommodated if the experimentation action is to have its intended impact. The most notable of these differences—the absence of a doctor-patient relationship in experimentation and the related lack of therapeutic benefit to the research subject—have led commentators to conclude that the defense of therapeutic privilege⁷³ has no place in an action for failure to obtain consent for experimentation.⁷⁴ Thus, it is vital that as much information as possible be given to the

69. Some California institutions, however, have indicated that they will have to set up review committees in order to comply with the legislation. Interview with Assemblyman Herschel Rosenthal, California State Legislature, Sacramento (January 9, 1979). It seems unlikely, however, that institutions will be considered persons primarily responsible for the conduct of experiments under the statute, so the response may be made in the spirit of cooperation or from overcaution.

70. See generally WALTZ & INBAU, *MEDICAL JURISPRUDENCE* 152-56 (1971). MCCOID, *supra* note 4, at 417, makes the following observation:

When . . . there is no substantial showing that the conduct of the defendant has actually caused any harm to the [subject] other than the infliction of incidental pain and suffering . . . the designation of the defendant's conduct as an "assault and battery" seems justified primarily in terms of protecting the [subject's] interest in making his own decisions

71. See note 4 *supra*.

72. California has produced the most enlightened negligence standard; see cases cited in note 63 *supra*.

73. The doctrine of therapeutic privilege holds that a physician may withhold material information from his patient if he reasonably believes that disclosure would be harmful. See, e.g., cases cited note 63 *supra*.

74. G. ANNAS, *supra* note 6, at 31-33, 44-45; Langer, *Human Experimentation—New York Verdict Affirms Patient's Rights*, 151 *SCIENCE* 663, 665-66 (1966), reproduced in J. KATZ, *supra* note 12, at 64 (discussing *Jewish Chronic Disease Hospital*).

subject because neither the review committee nor the investigator will be assuming any of the ultimate decisionmaking responsibility and no direct benefits to the subject may exist to outweigh the risks of the experiment.⁷⁵ The statutory cause of action, as it is developed by the courts, must reflect these concerns.

Disputes over what is an experiment and who is a researcher under the Act can be anticipated.⁷⁶ Use of experimental drugs, for example, is actually research but holds potential immediate benefits for the ill subject and is undertaken under the auspices of the doctor-patient relationship. The California Act, with its explicit coverage of new drug research⁷⁷ and its requirement of identification of the drug companies involved,⁷⁸ is intended to help make subjects more aware of this common type of research⁷⁹ and to alleviate some of the abuses of the doctor-patient relationship that are occasioned by it. In this respect the California Act is superior to the New York Article because it attempts to affect researchers, including ordinary private practitioners who are unaffiliated with institutions and who are unaccustomed to thinking of themselves as researchers.

Whether this legislation can accomplish its ambitious goal is, however, open to question. Subjects of researchers who flout the statute entirely will still not know that they have been subjects, or if they do, they might not know whom to sue. Some independent mechanism for making researchers and subjects aware of the statutory scheme is thus vital to effective enforcement, especially because plaintiffs need not have suffered injury and therefore are less likely to come forward on their own initiative. With some method of information dispensation,⁸⁰ the statute may be of great help to the poor, the elderly, and the less educated, who can obtain free or low-cost legal assistance, but the often

75. Langer, *supra* note 74, at 666. See also notes 4 & 68 *supra*.

76. See note 1 *supra*.

77. CAL. HEALTH & SAFETY CODE §§ 24174(b), 24176(d) (West Cum. Supp. 1979). *But cf.* § 24174(a), defining medical experimentation as intervention "not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject." This definition seems clearly to exclude therapeutic research except that covered under subsection (b) for new drugs and devices.

For a thorough discussion of the special problems raised by therapeutic research, see J. KATZ & A. CAPRON, *supra* note 19. The authors argue that therapeutic research should be treated more like research than like therapy.

78. CAL. HEALTH & SAFETY CODE § 24173(c)(9) (West Cum. Supp. 1979).

79. See note 54 and accompanying text *supra*.

80. This could encompass anything from use of patient advocates or ombudsmen to more active committee policing of research, including the use of a review committee member as the consent witness required by CAL. HEALTH & SAFETY CODE § 24173(e) (West Cum. Supp. 1979).

nominal recovery will not encourage middle-class subjects who must pay their own legal fees.⁸¹ The former group of subjects is, however, more likely to be injured by a lack of informed consent.⁸² In any case, the statute should act as a deterrent regardless of who the plaintiffs turn out to be.

Neither the New York Article nor the California Act is intended to compensate research subjects for purely fortuitous injury.⁸³ The impact of the statutes is primarily philosophical—they are, in essence, paeans to human autonomy. Because neither statute as it stands is likely to work very well, their function is only secondarily preventive. Insofar as they are effective, however, it must be presumed that the end result will be less research. Fully informed potential subjects are less likely to consent to their being used in an experiment than those subjects who are assured that no risk is present.⁸⁴

The best way to achieve the goal of informed consent lies in a combination of the New York and California approaches. Sanctions tougher than those provided by a committee review system are needed, but some form of review appears indispensable to monitor compliance with informed consent requirements and thereby prevent lawsuits as well as deter violators. Active policing of ongoing research is also needed to ensure that consent procedures are as conducive to a free exchange of information as the consent forms promise to be. And the existence of civil and criminal causes of action tailored especially for

81. Because it will be possible for a plaintiff who suffers actual injury to bring two actions—one under this statute and one on an ordinary medical malpractice model adapted to experimentation—the California Act should help draw attention to the latter type of action as well as set standards for it. In fact, joining the two causes of action in a single suit may increase the incentive to sue in cases of less serious injuries.

82. See, e.g., B. GRAY, *supra* note 52, at 66-69 (black clinic patients with less than high school education far more likely to be unaware subjects in a labor induction study; no data available on whether this result caused by lack of effort by the investigator to communicate or by the inadequacy of honest attempts at explanation).

83. For an excellent discussion of the compensation problem and some possible solutions, see G. ANNAS, *supra* note 6, at 257-77.

84. In *id.*, at 35-36, the authors observe: "The view that such promotion of individual autonomy comes at the price of sometimes delaying advances is, we think, adequately dealt with by the oft-quoted statement of Hans Jonas:

Let us not forget that progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may become, has nothing sacred about it. Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, probably caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."³

(quoting Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 29 (1969)).