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Regulation of Informed Consent to Human Experimentation

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Developments

Regulation of Informed Consent to Human Experimentation

I. INTRODUCTION

Experimentation with human subjects is necessary for the advancement of medical knowledge. Although medical research may begin in the laboratory and knowledge may be gained through experimentation with animals, all new therapies and drugs intended for human use eventually must be tested on man. Today, biomedical researchers are about to begin gene therapy experiments on humans in an attempt to treat and cure inherited diseases which cause one-half of all miscarriages, one-fifth of all infant deaths, and up to eighty percent of all mental retardation. This need to perform medical experiments on humans must be balanced against the need for protection of the individual who is to serve as the subject. In order to safeguard the individual's right to determine what is to be done with his body, informed consent must be obtained prior to the initiation of any experimental procedure.

Federal regulations address experimentation with human sub-
jects. However, these regulations apply only where a research program is federally funded or conducted by a federal department. Where research programs are without federal funding, the federal government's authority to regulate human experimentation ends and the state's authority begins. Only a few states, however, have statutes which comprehensively address informed consent to human experimentation. Instead, some states include informed consent to human research requirements in patients' rights statutes, or laws protecting particular groups of subjects such as the mentally ill, or professional ethics statutes which mandate obtaining a patient's consent to experimentation. In contrast to federal regulations, which explicitly define what disclosure is necessary to obtain informed consent, state statutory provisions often require only a simple statement that individuals have the right to refuse to participate in experimental research. When a project is conducted without federal funds, in a jurisdiction with no statutory provision for human experimentation, regulatory oversight is nil.

This article examines the doctrine of informed consent and its relationship to experimentation with human subjects. Next it surveys both federal and state statutory regulation of informed

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Additionally, the Food and Drug Administration (FDA) is authorized to approve "new drug" experimentation with human subjects that involves interstate commerce. 21 U.S.C. § 355(a) (1982). A "new drug" is defined as an article intended to cure, mitigate, treat or prevent disease. 21 U.S.C. § 321(p) (1982). Recombinant DNA gene therapy would thus fall under the purview of FDA regulations because the "good segment of DNA" that is inserted into the "bad cells" is an article intended to cure or treat a disease. McGarity & Shapiro, Public Regulation of Recombinant DNA Gene Therapy, 3 J. LEGAL MED. 185, 194-203 (1982).

10. The FDA and HHS regulations may sometimes overlap state statutes; both sets of regulations explicitly state that they are not intended to preempt applicable state or local laws. 21 C.F.R. § 50.25(c) (1985); 45 C.F.R. § 46.116(e) (1985).


12. See infra note 107 and accompanying text.
13. See infra note 109 and accompanying text.
14. See infra note 106 and accompanying text.
15. 45 C.F.R. § 46.116 (1985); see infra notes 73-90 and accompanying text.
consent to human experimentation and analyzes the different judicial standards which have been applied to determine the scope of disclosure. Finally, this article recommends that states adopt legislation which comprehensively addresses informed consent to human experimentation, and advocates the use of a standard of disclosure that recognizes the autonomy of the individual.

II. BACKGROUND

A. Some History of Human Experimentation

Medical experimentation using humans as subjects is as old as the science of medicine itself. However, until the post World War II Nuremberg trials of Nazi physicians accused of conducting unethical research, there was no widespread public awareness of legal problems posed by medical research with human subjects. The Nuremberg Code, articulated in the court opinion that resulted from those trials, was subsequently adopted by the United Nations General Assembly. The code placed primary importance on the concept of individual consent.

17. Hippocrates, while treating a boy whose cortex was exposed, "gently scratched the surface of the cortex with his fingernail" and observed the resulting convulsions on the opposite side of the boy's body. Katz, *The Education of the Physician-Investigator*, 98 DAEDALUS 480, 481 (1969).

18. See R. GALLAGHER, NUREMBERG: THE THIRD REICH ON TRIAL 159-205 (1961); A. MITSCHERLICH & F. MIELKE, DOCTORS OF INFAMY: THE STORY OF THE NAZI MEDICAL CRIMES (1949). The Nuremberg trials were conducted by the International Military Tribunal established by an agreement among the United States, Great Britain, Russia, and France. *INFORMED CONSENT*, supra note 7, at 7.

19. The United Nations General Assembly adopted the Nuremberg Code on Dec. 11, 1946. The Code was also used as the basis for the Declaration of Helsinki, thus leading to the conclusion that the court opinion can properly be characterized as customary international law. *INFORMED CONSENT*, supra note 7, at 8.


The voluntary consent of the human subject is absolutely essential. 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, 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. 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
In the United States during the 1960's, well publicized reports of research projects involving abuses of the rights of human subjects generated great concern.\textsuperscript{21} One of the most infamous examples of disregard for human subjects was the Tuskegee syphilis experiment, conducted from 1932 to 1972 by the United States Public Health Service.\textsuperscript{22} In Macon County, Alabama, 400 black men suffering from syphilis were deliberately deprived of treatment in order to enable researchers to study the effects of allowing the disease to take its natural course.\textsuperscript{23} Even though penicillin, discovered in 1929, had been found to be an effective treatment for syphilis, the drug was purposely withheld and at least 28 and perhaps as many as 107 men died as a direct result of the disease.\textsuperscript{24}

Another notorious case of human experimentation was the Willowbrook study in which live hepatitis virus was injected into institutionalized retarded children in an effort to develop a vaccine.\textsuperscript{25} The researchers justified their study by noting that hepatitis was rampant throughout the institution and that a new resident would probably contract the disease shortly after admission.\textsuperscript{26} Despite extensive publicity in medical literature,\textsuperscript{27} the study continued until the early 1970's, even after a treatment for hepatitis was discovered.\textsuperscript{28}

personal duty and responsibility which may not be delegated to another with impunity.

\textit{Id.}


\textsuperscript{22} Barber, \textit{The Ethics of Experimentation with Human Subjects}, 234 SCI. AM. 25, 26 (1976).


\textsuperscript{24} Barber, \textit{supra} note 22, at 26; N.Y. Times, July 26, 1972, § 1, at 1, col. 1; \textit{Id.}, Sept. 12, 1972, § 1, at 23, col. 1.


\textsuperscript{26} Rothman, \textit{supra} note 23, at 6.


\textsuperscript{28} J. KATZ, \textit{Experimentation With Human Beings} 1007 (1972). Parental consent was obtained; there is controversy, however, as to whether the institution coerced the parents into giving their consent. Although Willowbrook was closed to all new admissions due to overcrowding, the hepatitis project, which occupied its own space in the institution, continued to solicit patients. Parents later alleged that they consented out of fear that their children would be denied admission. See Ratnoff, \textit{supra} note 25, at 490.
In the Jewish Chronic Disease Hospital experiment, researchers injected twenty-two elderly debilitated patients with live cancer cells without obtaining their voluntary informed consents. The Attorney General of New York brought an action before the state's Board of Regent's Discipline Committee, which found the principal investigators guilty of fraud, deceit, and unprofessional conduct. The doctors were punished not for performing experiments that resulted in harm to the patients, but for failing to obtain informed consent before proceeding.

These notorious cases of human experimentation resulted in growing public indignation and increasing advocacy of government regulation of research involving human subjects. The Nuremberg Code, which requires that the informed consent of the experimental subject be competent, voluntary, and understanding, formed the basic structure for federal regulation of experimentation with human subjects.

B. The Doctrine of Informed Consent

Informed consent means the "knowing" consent of a person or his legally authorized representative. An individual cannot consent to participate as an experimental subject unless he first understands for what he is volunteering. Informed consent has been found not to exist where the individual did not understand the

29. INFORMED CONSENT, supra note 7, at 20.
31. INFORMED CONSENT, supra note 7, at 20.
32. Mulford, supra note 30, at 100.
33. Id. (the patients suffered no actual harm).
34. Id. at 102. The physicians' medical licenses were initially suspended for one year, but the suspensions were later stayed and the physicians were instead placed on probation for one year. Id. at 100. The Board of Regent's Discipline Committee emphasized that this case involved an experimenter/subject relationship in which the exercise of professional judgment may sometimes provide a basis for withholding the disclosure of certain risks (therapeutic privilege). The committee stated further that in an experimenter/subject situation, a subject cannot be said to have volunteered for an experimental procedure unless he first understood for what he was volunteering. INFORMED CONSENT, supra note 7, at 21. All information that is material to a prospective subject's decision concerning participation in experimental research must therefore be disclosed to the subject. Id. at 22.
36. INFORMED CONSENT, supra note 7, at 7; see supra note 20.
38. Id. at 81.
39. Id.
words\textsuperscript{40} or the language\textsuperscript{41} used. Therefore, where language, educational or cultural differences exist between the researcher and the subject, the researcher should exercise precautions to ensure that the subject understands the proposed procedure. A subject's signature on a consent form does not necessarily constitute informed consent.\textsuperscript{42}

Informed consent consists of a dialogue between the prospective experimental subject, or his representative, and the researcher.\textsuperscript{43} The prospective subject gives the researcher information about himself which may be crucial to the experiment, and the researcher informs the prospective subject of basic details concerning the treatment so that the subject may decide whether or not to participate.\textsuperscript{44} This exchange of information serves as a check against unnecessary or inappropriate procedures from the perspectives of both the subject and the researcher.\textsuperscript{45} The subject is better able to discern whether the proposed procedure is in his best interests\textsuperscript{46} and the researcher, by providing substantiated information about known and unknown risks of the experiment, may benefit by reevaluating his own notions of the procedure's efficacy.\textsuperscript{47} Additionally, a well informed patient knows more about his own condition and may feel freer to communicate such information.\textsuperscript{48}

The doctrine of informed consent was developed to protect the right of every individual to participate in decisions about his own medical care.\textsuperscript{49} To deprive an individual of the power to accept or

\textsuperscript{40} Corn v. French, 71 Nev. 280, 289 P.2d 173 (1955). Although the plaintiff was informed that a mastectomy would be performed and gave her consent, the court found informed consent not to exist since the plaintiff had not understood the word "mastectomy" when she signed the consent form. \textit{Id.} at 284-85, 289 P.2d at 175-76.

\textsuperscript{41} Reyes v. Wyeth Laboratories, 498 F.2d 1264, \textit{cert. denied}, 419 U.S. 1096 (1974). The court held that because of the plaintiff's seventh grade education and the language barrier (plaintiff's primary language was Spanish), she may have lacked the "linguistic ability" to understand the significance of the consent form that she signed. \textit{Id.} at 1270.

\textsuperscript{42} R. GREENWALD & M. Ryan, supra note 37, at 81. Communication problems can be obviated by explaining procedures in lay terms and by using interpreters or translators where necessary. R. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 90 (1981).

\textsuperscript{43} F. ROZOVSKY, CONSENT TO TREATMENT: A PRACTICAL GUIDE 3 (1984).

\textsuperscript{44} \textit{Id.}


\textsuperscript{46} F. ROZOVSKY, supra note 43, at 3.

\textsuperscript{47} Andrews, supra note 45, at 170.

\textsuperscript{48} J. Katz & A. Capron, CATASTROPHIC DISEASES: WHO DECIDES WHAT?, at 89, 90 (1975); see also Schneyer, Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practice, 1976 Wis. L. REV. 124 (discussing patients' desires for treatment information).

\textsuperscript{49} Curran, Foreword to F. ROZOVSKY, supra note 43, at xxxi.
Regulation of Informed Consent

refuse medical treatment that may affect his physical or psychological well being is to treat that individual as an object and not as a person. 50 The concepts of autonomy and individuality are long-standing central values in Anglo-American society and law. 51 In addition, there is evidence that a patient benefits both physically and psychologically by receiving information about a proposed treatment. 52 Although the medical profession traditionally has not recognized patient autonomy, even physicians are beginning to acquiesce to patient demands for control and information. 53

The adequacy of consent to a pure experiment or to experimental treatment raises more issues than consent to an established therapy simply because less is known about the risks involved in an experimental procedure. 54 Although there exists no absolute guarantee that even an established treatment will be effective and will not cause harm, the risks are significantly increased when the proposed therapy is experimental. 55 Therefore, a prospective subject must be made aware that little is known about the possible risks and consequences of participation in any aspect of human experimentation. 56

C. Institutional Review Boards

In the area of human experimentation, the researcher’s goal of acquiring new information and the subject’s rights may inherently conflict. 57 The researcher or physician may be more interested in advancing medical knowledge than in protecting the well being of the human subject. 58 Furthermore, the establishment of a researcher’s professional identity and career advancement may de-

50. Id.
52. See Andrews, supra note 45, at 165. In studies conducted with elective surgery patients, the disclosure of information concerning the nature of the procedure and the predicted postsurgery sensations enhanced the patients’ ability to adjust to postoperative stress and decreased the amount of pain medication and the number of hospital recovery days. Id. (discussing I.L. Janis, Psychological Stress: Psychoanalytic and Behavioral Studies of Surgical Patients (1958); I.L. Janis & L. Mann, Decision Making: A Psychological Analysis of Conflict, Choice, and Commitment (1977)).
55. Id.
56. Id.
57. Robertson, supra note 21, at 487.
58. Mulford, supra note 30, at 105.
depend on research productivity. This conflict is exemplified by the one human experiment with gene therapy conducted to date, in which the researchers failed to conduct preliminary animal tests before proceeding with the human experiment. In that case, it is apparent that the researchers' personal ethical restraints were insufficient to prevent them from attempting to effect a premature cure.

Such experiments led to a fear that reliance upon an investigator's sense of ethical responsibility is an insufficient safeguard of the human subject's rights. In response to this fear, institutional review boards ("IRB's") were developed to provide outside review of proposed research projects. IRB's consist of lay persons and professionals, and are typically established by institutions such as hospitals, universities, and private research centers. Currently, all institutions that receive federal research grants for human subject research are required to establish IRB's. IRB's are established as a safeguard, in addition to informed consent, to ensure that experimental subjects are fully informed of risks and that they are given the opportunity to forego participation.

IRB's must determine if the risks involved in an experiment are reasonable compared to the anticipated benefits for both the prospective subjects and the public in general. IRB's must also determine whether legally effective informed consent has been obtained and whether the rights and welfare of research subjects have been adequately protected. Additionally, IRB's must periodically review any ongoing research projects. Although IRB's obtain their primary mandate from governmental regulations, each group must implement the basic principles according to the nature of the research.

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59. Robertson, supra note 21, at 487.
60. Sun, Cline Loses the NIH Grants, 214 SCI. 1220 (1981).
A team of researchers at the University of California at Los Angeles attempted to treat two patients suffering from beta-zero thalassemia (a life threatening disease attributed to a single gene defect) with recombinant DNA techniques. "Id.
62. McGarity & Shapiro, supra note 9, at 186.
66. Note, supra note 35, at 137.
68. Robertson, supra note 21, at 491.
69. "Id."
III. DISCUSSION

A. Federal Regulation of Informed Consent to Human Experimentation

In 1974, the Department of Health & Human Services ("HHS") promulgated regulations which apply to all research carried out or funded by the department. These regulations identify eight basic elements of informed consent for research projects utilizing human subjects. The purpose of these eight elements is to ensure that a prospective subject receives information sufficient to enable him to make an informed decision. The prospective subject should receive: (1) an explanation of the purpose of the research and notification that the procedure to be followed represents a departure from established practice; (2) a description of the risks and discomforts which may reasonably be expected; (3) a description of any benefits to the subject or others which may reasonably be expected; (4) a statement describing the extent to which the confi-
dentiality of the subject's records will be preserved;\(^78\) (5) a statement of whether any alternative treatments exist;\(^79\) (6) a description of the availability of medical therapy or compensation in case of injury incurred as a result of the experiment;\(^80\) (7) an opportunity to ask questions concerning the experiment;\(^81\) and (8) an assurance that the subject is free to refuse to participate or to withdraw his consent and discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled.\(^82\)

In addition to these elements, the HHS regulations require that the following information must be provided to each subject when appropriate: a statement that the procedure may involve unforeseeable risks, the anticipated circumstances under which the subject's participation may be terminated, the consequences of a subject's decision to withdraw from the research, and a statement that any information concerning significant new discoveries developed during the course of the experiment will be provided to the subject.\(^83\)

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\(^79\) 45 C.F.R. § 46.116(a)(4) (1985); 21 C.F.R. § 50.25(a)(4) (1985); R. Levine, supra note 42, at 80. Informed consent should include a statement of whether any alternative treatments exist so that the prospective subject can evaluate the benefits and risks of participating. \(\text{Id.}\) In research situations where the subject is also a patient, it is important to informed him of which treatments would be used if he did not consent to participate in the experiment. \(\text{Id.}\) at 74. The prospective subject can then decide whether he wishes to subject himself to possible inconveniences or risks as a result of superfluous experimental procedures. \(\text{Id.}\) This is especially important where the subject will be foregoing a more traditional therapy as a result of the time that elapses during the experimental period. \(\text{Id.}\) at 80.

\(^80\) 45 C.F.R. § 46.116(a)(6) (1985); 21 C.F.R. § 50.25(a)(6) (1985); see Robertson, Compensating Injured Research Subjects: II The Law, 6 Hastings Center Rep. 29 (1976). The physician or researcher should emphasize that it is not always possible to restore the health of people who are injured or become ill as a result of participating in experimental research. \(\text{Id.}\) at 30. If a subject is not informed that he bears the risk of physical injury, his consent cannot justify risks that are undertaken wholly or partially for the benefit of others. \(\text{Id.}\) at 29.


\(^82\) 45 C.F.R. § 46.116(a)(8) (1985); 21 C.F.R. § 50.25(a)(8) (1985); R. Levine, supra note 42, at 88. The right to withdraw is derived from the premise that the subject is doing something for the benefit of others and that such gratuitous acts are generally not obligatory. This right is especially important in situations where the relationship between the researcher and the subject is that of physician-patient or faculty-student because the subject in such circumstances is susceptible to coercion. \(\text{Id.}\) at 84.

\(^83\) 45 C.F.R. § 46.116(b) (1985).
The regulations state that consent must be obtained from prospective research subjects or their legally authorized representatives, and there must be written documentation that information concerning the proposed procedure was given. In obtaining consent, no undue influence or coercion may be used. All information presented to the prospective subject or his representative must be in understandable language. The regulations further provide that neither the researcher, the institution, nor the sponsor may be released from liability through the subject's oral or written consent. The regulations also specifically address research involving fetuses, pregnant women, human in vitro fertilizations, and children.

According to the regulations, institutions conducting federally funded research must have an IRB to review and approve research projects. The regulations specify the composition of the IRB. The duties of the IRB are to include approving information given to prospective subjects and ensuring that the subjects receive any information that, in the judgment of the IRB, is relevant to the rights and welfare of the subject.

The Food and Drug Administration ["FDA"] has promulgated regulations which are very similar to those of HHS. The FDA
sets forth the same eight basic elements of informed consent. There are, however, some differences in the FDA regulations. First, the subject must be informed that his records may be inspected by the FDA. Second, the written consent requirements may be waived when it is determined that the research poses no more than a minimal risk of harm to the subjects or where the procedure is one for which written permission normally is not required outside the research setting. Finally, the general requirements for informed consent do not apply where obtaining informed consent is not feasible prior to the procedure, or where the procedure is necessary to preserve the life of the subject and there is not adequate time to seek an independent assessment.

B. State Regulation of Informed Consent to Human Experimentation

State statutory treatment of informed consent to human experimentation runs the gamut from comprehensive, specific coverage of the issue to general treatment in informed consent statutes. California, New York, and Virginia have enacted legislation which specifically addresses informed consent to human experimentation. These states require that in order to obtain proper in-

97. 21 C.F.R. § 56.102(i) (1985) (minimal risks are defined as risks not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
98. 21 C.F.R. §§ 50.27, 56.109(c) (1985).
99. 21 C.F.R. § 50.23 (1985) (this provision regulates the use of any “test article,” which is defined as any drug, medical device for human use, human food additive, color additive, or electronic product. 21 C.F.R. § 50.3(k) (1985)).
100. 21 C.F.R. § 50.23 (1985).

The statutes of New York and Virginia provide that researchers conducting experimentation in compliance with federal regulations concerning the protection of human subjects are exempt from the state requirements. N.Y. PUB. HEALTH LAW § 2445 (McKinney 1985); VA. CODE § 37.1-237 (1984).

California provides that researchers conducting investigations within institutions holding federal assurances who obtain informed consent as required by federal regulations are exempt from the requirements except for the bill of rights provisions concerning the elements of informed consent, CAL. HEALTH & SAFETY CODE § 24172 (West 1984), and penalties (CAL. HEALTH & SAFETY CODE § 24176 (West 1984). These sections set forth fines and terms of imprisonment for any person who is primarily responsible for the conduct of an experiment (including a representative or employee of a pharmaceutical company who is directly responsible for contracting with the subject) and who negligently allows such an experiment to be conducted without the subject’s informed consent, or
formed consent, researchers must provide the following information to subjects: an explanation of the procedures, drugs, or devices to be used in the experiment; a disclosure of appropriate alternatives; a description of any risks and discomforts that might be expected; an explanation of possible benefits; an offer to answer the subject's questions concerning the experiment and its effects; and an instruction that the individual's consent to participate in the experiment may be withdrawn at any time without prejudice. In order to provide the prospective subject free power of choice, these statutes also require that the informed consent be obtained without force, deceit, fraud, duress, constraint or coercion. The California statute requires that the prospective subject be informed of available treatments in the event that injury or illness results from participation in the experiment. New York and Virginia require that any institution or agency which conducts or proposes to conduct research with human subjects must establish an IRB.

Louisiana and Florida have also passed legislation which deals specifically with informed consent to human experimentation. Both of these states require informed consent before an experiment with a human subject may be performed. Unlike the states dis-

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105. N.Y. Pub. Health Law § 2444 (McKinney 1985). This statute dictates the composition of the board and prohibits its members from reviewing research in which they have a conflicting interest. Id. The board must review each proposed research project, evaluate the costs and benefits to the prospective subjects and ensure that the risks are outweighed by the importance of the knowledge to be gained. Id.
discussed above, however, neither Louisiana nor Florida provides any detailed guidance regarding what information must be given to the prospective subject.

Some states have enacted legislation concerning human experimentation as part of general patients' rights laws. Many such statutes provide only that the patient has the right to refuse to serve as a research subject, and do not require the informed consent of the patient. Some patients' rights laws require that the prospective subject receive information concerning the experimental procedure, but do not specify what information must be included to obtain informed consent. Other statutes address research on human subjects in miscellaneous provisions, but do not set forth any informed consent requirements.

The majority of states have not dealt specifically with informed consent to human experimentation, but have instead enacted general informed consent statutes. In states without human experi-


The following states provide that research on human genetics will be conducted: Minn. Stat. Ann. §§ 144.91-144.94 (West 1970); Mo. Ann. Stat. § 191.310-191.331 (Vernon Supp. 1986) (all testing results will be confidential).


Regulation of Informed Consent

1986]

mentation legislation, these general statutes will control. Many informed consent statutes address experimentation with particular groups such as the mentally disabled or children. Other stat-


113. Ariz. Rev. Stat. Ann. § 36-561 (1986) (no experimental drugs shall be administered by the department of health services to any patient); Ark. Stat. Ann. § 59-1416(15) (Supp. 1979) (patients have the right to refuse to participate); Cal. Health & Safety Code § 24175 (West 1984) (informed consent given by a person other than the subject is limited to medical experiments related to maintaining or improving the health of the subject or to obtaining information about the subject’s pathological condition); Del. Code Ann. tit. 16, §§ 5171-5176 (Supp. 1984) (pharmaceutical research; no mentally ill patient may be approached to participate if he is incapable of understanding the nature and consequences of his consent; informed consent shall include information concerning the nature of the proposed procedure, risks, and alternatives); D.C. Code Ann. § 6-1969 (1981) (informed consent required); Fla. Stat. Ann. § 393.12(6), (7) (West Supp. 1986) (informed consent shall be obtained from the patient, if competent, or his parent or legal guardian; the consent shall include information concerning the nature and consequences of the proposed procedure; the risks, benefits, and purposes; and whether alternative procedures are available); Hawaii Rev. Stat. § 334E-1 (Supp. 1984) (informed consent must be obtained before any nonemergency treatment for mental illness can commence); Hawaii Rev. Stat. § 334E-2(10) (Supp. 1984) (patients have the right to refuse to participate); Ill. Rev. Stat. ch. 91/2, § 2-110 (1985) (informed consent required); Kan. Stat. Ann. § 59-2929(6) (1983) (consent of patient and parent or guardian is required); Me. Rev. Stat. Ann. tit. 34, § 2143(8) (1978) (informed consent shall be obtained from the patient, if competent; if incompetent, the consent of his guardian shall be obtained; the consent shall include information concerning the nature and consequences of the experimental procedures, the risks, benefits and purposes, and available alternate procedures); Mo. Ann. Stat. §§ 630.192-630.198 (Vernon Supp. 1986) (biomedical or pharmacological research is prohibited unless it is intended to relieve or prevent a disabling condition or there is a reasonable expectation of direct therapeutic benefit to the patient; no involuntarily committed patient shall participate in any research; the patient must receive information concerning the risks, benefits and procedures); Mo. Ann. Stat. § 630.115 (Vernon Supp. 1986) (informed consent of patient or his parent or guardian is required); Mont. Code Ann. § 53-20-147 (1985) (informed consent of patient, if he is capable, and of parents or guardian is required); N.J. Rev. Stat. § 30:4-24.2(d)(2) (1981) (express informed consent must be obtained before partici-
utes focus on research involving particular drugs such as contraception in experimental research; if the patient has been adjudicated incompetent, a court hearing must be held to determine the necessity of the procedure; a patient may not participate unless the research is directly related to specific goals of his treatment; N.M. STAT. ANN. § 43-1-15(A) (1979) (informed consent of patient or guardian is required); N.Y. PUB. HEALTH LAW § 2444 (McKinney 1985) (informed consent required); N.C. GEN. STAT. § 122C-57(f) (Supp. 1985) (informed consent of the patient or his guardian is required); N.D. CENT. CODE § 25-01.2-11 (Supp. 1985) (court must determine that the experimental procedure is in the best interests of the recipient and that no less drastic measures are feasible); N.D. CENT. CODE § 25-03.1-40(12) (1978) (informed consent of patient or patient’s guardian is required); OHIO REV. CODE ANN. § 5122.271 (Baldwin 1985) (informed consent to unusually hazardous treatments is required); OR. REV. STAT. § 426.385(2) (1983) (informed consent to unusual treatment is required); OR. REV. STAT. § 475.325(6) (1983) (experimental drug research; where a patient is unable to give informed consent and consent is obtained from third parties, experimental drugs may be administered only for the purpose of diagnosing, treating, or mitigating a disease or injury of the patient); S.C. CODE ANN. § 44-23-1010 (Law. Co-op. 1976) (the patient has the right to refuse any treatment not recognized as standard psychiatric treatment); S.D. CODIFIED LAWS ANN. §§ 27A-12-20, 27A-12-21 (1984) (informed consent must be obtained from the patient if 18 years of age or older, from the guardian or the parent if the patient is less than 18 years of age); TEX. MENTAL HEALTH CODE ANN. § 5547-90(b)(3) (1986) (patients have the right to refuse to participate); VA. CODE § 37.1-235 (1984) (informed consent of subject, witnessed by subject’s legally authorized representative, is required; representative may not consent to nontherapeutic research unless a review committee approves); WIS. STAT. ANN. § 51.61 (West Supp. 1985) (informed consent of patient and guardian is required); WYO. STAT. §§ 25-5-132(d)(ii) (1982) (patient has the right to refuse to participate in experimentation unless he or his guardian (if the patient is a minor) have given informed consent).


114. CAL. HEALTH & SAFETY CODE § 2668.4 (West 1984) (experimental use of drugs; parent or guardian’s consent must be obtained; if the subject is seven years of age or older, then both her consent and that of the parent or guardian must be obtained; consent is limited to experimentation is related to the maintenance or improvement of the subject’s health or to gathering information about the subject’s pathological condition); ILL. REV. STAT. ch. 91 1/2, ¶ 2-110 (1985) (the child’s parent or guardian is authorized, only with the approval of the court, to provide informed consent for the child); N.Y. PUB. HEALTH LAW § 2442 (McKinney 1985) (written consent must be obtained from the minor’s parent or guardian); OR. REV. STAT. § 475.325(5) (1983) (experimental drug research; parent’s or guardian’s consent must be obtained); VA. CODE § 37.1-235 (1984) (if minor is capable of giving voluntary, informed consent, then the consent of both the
C. Judicial Regulation of Informed Consent to Nontherapeutic Experimentation

Little if any American case law exists concerning the topic of informed consent to nontherapeutic human experimentation, that is, research pursued for the acquisition of basic knowledge, minor and his legally authorized representative must be obtained; no legally authorized representative may consent to nontherapeutic experimentation unless an IRB determines that such research will not pose a hazardous risk to the subject).

Experimental research utilizing children as subjects raises issues of consent because many children are incapable of sufficiently comprehending information concerning the experiment to meet the standards of consent. See R. Levine, supra note 42, at 156. Testing on children is, however, necessary because adequate information cannot always be obtained through experimentation with adult subjects. Informed Consent, supra note 7, at 63. Children cannot be treated as "little people" because, for example, drug tests performed on adults will not give information as to the effect on children of toxicity, dosage, side effects, or efficacy. Id.


118. T. Christoffel, supra note 54, at 291 (most cases are settled out of court or result in mild punishments); Sabiston, The Boundaries Between Biomedical Research Involving Human Subjects and the Accepted or Routine Practice of Medicine, with Particular Emphasis on Innovation in the Practice of Surgery, in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, App. vol. 1, at 17-1 (1978).
not intended to benefit directly the subject. However, one Canadian case involved a nontherapeutic experimental procedure about which the human subject did not receive adequate information.\footnote{Halushka v. University of Saskatchewan, 53 D.L.R.2d 436 (Sask. 1965). Some commentators believe that United States courts would probably analyze this case in the same manner as did the Canadian appellate court. \textit{INFORMED CONSENT}, supra note 7, at 18.} The subject was told that the experiment employed a new drug which was "perfectly safe," that the test had been conducted many times previously, and that it involved a simple incision in his arm and the insertion of a catheter.\footnote{Halushka v. University of Saskatchewan, 53 D.L.R.2d 436, 437-38 (Sask. 1965).} The subject signed a consent form which stated that he fully understood the proposed procedure and which purported to absolve the researchers, technicians, and institution of all liability.\footnote{Id. at 438.} The actual experimental procedure was more complex than that described to the subject,\footnote{Id. at 439 (the catheter was inserted into the subject's arm and threaded through his heart and into the pulmonary artery; anesthesia was then introduced into the artery).} and it resulted in the cessation of the subject's heart beat, necessitating immediate surgery and a fourteen-day hospital stay.\footnote{Id. at 436.} The subject received $22,500 in damages in a jury verdict which was appealed by the researchers.\footnote{Id. at 443-44. The court noted that the subject had not been informed that the particular anesthetic used had never been tested before or that there were specific risks involved. \textit{Id.} at 444. The court used the "reasonable man" standard in determining that the subject of medical experimentation is entitled to be fully informed of all the facts and probabilities which a reasonable man might be expected to consider before giving his consent. \textit{Id.}} Finding that the subject was inadequately informed, the appellate court held that the duty of disclosure in an experimental setting is "as great as, if not greater than" the usual duty of disclosure between a physician and his patient.\footnote{Owens v. McCleary, 313 Mo. 213, 223, 281 S.W. 682, 685 (1926) (failing to use methods followed or approved by a physician's school of practice evidences either ignorance or experimentation); Sawdey v. Spokane Falls & N. Ry., 30 Wash. 349, 360, 70 P. 972, 975 (1902) (the physician must not experiment but must instead treat the patient with a therapy that is recognized by the medical profession); Allen v. Voje, 114 Wis. 1, 22-23, 89 N.W. 924, 932 (1902) (treatments which are not established by professional practice should be employed only when the patient's condition is critical and death would certainly occur absent experimentation).}

\textbf{D. Judicial Regulation of Informed Consent to Therapeutic Experimentation}

Although courts have traditionally emphasized the importance of following standard medical procedures,\footnote{Id.} a Michigan court ac-
knowned, in dicta, that there must be experimentation in order to further the progress of medicine.\textsuperscript{127} The court added, however, that such experimentation must be done with the subject's knowledge and consent.\textsuperscript{128}

The requirements of informed consent to therapeutic experimentation, that is, experimental therapy intended to be of direct benefit to the subject,\textsuperscript{129} have traditionally been less stringent than those imposed in the nontherapeutic setting, particularly where a doctor-patient relationship is involved.\textsuperscript{130} This relaxation of informed consent requirements is due in part to a therapeutic privilege which assumes that a physician is dedicated to the principle of first doing no harm,\textsuperscript{131} and that safeguards are therefore not necessary to protect the interests of a patient in a therapeutic setting.\textsuperscript{132} Although the application of the therapeutic privilege does not preempt the patient's right to decide whether to consent to treatment, in practice the privilege has been used in place of rather than in conjunction with informed consent.\textsuperscript{133}

Jurisdictions differ as to the standard to be applied in determining the extent of required disclosure for consent to therapeutic experimentation.\textsuperscript{134} The majority of jurisdictions apply the standard of the "reasonable physician."\textsuperscript{135} Under this standard, the physician must disclose the level of information that practitioners of his discipline would normally disclose.\textsuperscript{136} The medical community

\textsuperscript{128} Id.
\textsuperscript{129} INFORMED CONSENT, supra note 7, at 2.
\textsuperscript{130} Id. at 21. See Salgo v. Leland, 317 P.2d 170, 181, 154 Cal. App. 2d 560, 578 (1957) (the mental and emotional condition of a patient may be critical; a physician may therefore exercise discretion in discussing risk with the patient).
\textsuperscript{131} Mulford, supra note 30, at 104-05. (this principle is reflected in the professional maxim: \textit{primum non nocere}—"first of all do no harm").
\textsuperscript{132} Id.
\textsuperscript{133} See Andrews, supra note 45, at 211-15.
therefore determines the nature and scope of disclosure. Plain-tiffs alleging a lack of informed consent usually must present expert testimony by medical practitioners both to establish the standard and to prove that the risk at issue was "material" to the patient's decision to participate.\textsuperscript{138}

For example, in a 1974 case, the patient signed a consent document agreeing to the temporary use of a mechanical heart and subsequent human and animal heart transplants in the event that cardiac surgery was unsuccessful.\textsuperscript{139} Both transplants failed and the patient died.\textsuperscript{140} The patient's widow sued, alleging that the physicians had failed to obtain adequate informed consent.\textsuperscript{141} The trial court directed a verdict for the physicians and the decision was affirmed by the Fifth Circuit.\textsuperscript{142} The court applied the "reasonable physician" standard in determining whether the physicians had obtained informed consent.\textsuperscript{143} The appellate court based its decision on the fact that the plaintiff had not presented expert testimony establishing a higher standard of disclosure.\textsuperscript{144}

A minority of jurisdictions apply the "reasonable patient" standard, also known as the "materiality standard."\textsuperscript{145} Under the "reasonable patient" standard, the duty to inform is determined by the informational needs of patients in general.\textsuperscript{146} A risk is material when a reasonable person in the patient's position would attach significance to particular information in deciding whether to forego the proposed treatment.\textsuperscript{147} In deciding to apply the "reasonable patient" standard instead of the "reasonable physician" standard, the Court of Appeals for the District of Columbia Circuit held that

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  \item \textsuperscript{137} Cowan & Bertsch, supra note 134, at 232.
  \item \textsuperscript{138} Waltz & Scheuneman, Informed Consent to Therapy, 64 NW. U.L. REV. 628, 640 (1970). A risk is material when a reasonable person in the patient's position would be likely to attach significance to the risk in deciding whether or not to undergo a proposed treatment.
  \item \textsuperscript{139} Karp v. Cooley, 493 F.2d 408, 412-13 (5th Cir.), \textit{cert. denied}, 419 U.S. 845 (1974).
  \item \textsuperscript{140} \textit{Id.} at 420.
  \item \textsuperscript{141} \textit{Id.} at 411.
  \item \textsuperscript{142} \textit{Id.} at 408.
  \item \textsuperscript{143} \textit{Id.} at 420.
  \item \textsuperscript{144} \textit{Id.} at 421.
  \item \textsuperscript{146} Cowan & Bertsch, \textit{supra} note 134, at 232.
\end{itemize}
issues involved in nondisclosure cases are not absolutely within the domain of the medical profession.\textsuperscript{148} The court, in applying the "reasonable patient" standard, dispensed with the expert witness requirement.\textsuperscript{149}

A third standard for disclosure is the "individual patient standard," whereby the scope of disclosure is determined by an individual patient's need to know enough to make an intelligent decision.\textsuperscript{150} A determination of materiality is based on whether knowledge of the risk at issue would have affected the patient's decision.\textsuperscript{151} The plaintiff must prove not only that he was injured as a result of undergoing treatment, but also that he would not have consented had he been informed of a particular material risk.\textsuperscript{152}

For example, in a recent case\textsuperscript{153} the plaintiff alleged that she did not give an informed consent to surgical treatment because the physician did not disclose that there was a viable alternative to surgery.\textsuperscript{154} Applying the "reasonable patient" standard, the trial court determined that a reasonable person would have consented even if apprised of the alternative and therefore ruled in favor of the physician.\textsuperscript{155} The Supreme Court of Oklahoma reversed the decision, finding that there was no informed consent because the plaintiff herself would not have consented if adequately informed.\textsuperscript{156} In an earlier case, the supreme court had stated that where the plaintiff would have foregone the proposed therapy if adequately informed, but a "reasonable patient" would have consented under the same circumstances, application of the "reasonable patient" standard would result in an irrevocable loss of the patient's right of self-determination.\textsuperscript{157}

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  \item \textsuperscript{148} Id. (the patient had not been informed that total loss of hearing was a possibility in stapedectomy operations).
  \item \textsuperscript{149} Id.
  \item \textsuperscript{150} Only Oklahoma has explicitly adopted this standard at present. See Scott v. Bradford, 606 P.2d 554 (Okla. 1979); cf. Fain v. Smith, 479 So. 2d 1150 (Ala. 1985) The Fain court applied a different version of the "reasonable person" test: the trier of fact must consider "what a reasonable person with all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs, would have done under the same circumstances." Id. at 1155. This variation is actually closer to the "individual patient" standard than the "reasonable person" standard. Id. at 1164 (Adams, J., dissenting).
  \item \textsuperscript{151} Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979).
  \item \textsuperscript{152} Id.
  \item \textsuperscript{154} Id. at 287-88 (the plaintiff underwent a hysterectomy and was not informed that treatment by hormonal therapy was a viable alternative).
  \item \textsuperscript{155} Id. at 288.
  \item \textsuperscript{156} Id.
  \item \textsuperscript{157} Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979).
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Researchers will soon begin experimenting with recombinant DNA gene therapy as a way of altering the genetic structure of living human beings.\(^{158}\) There are many unanswered questions regarding the risks inherent in the manipulation of human genes.\(^{159}\) Thus, there is a great danger that subjects will agree to participate in genetic experimentation without knowing enough about the risks involved to give informed consent.\(^{160}\) Safeguards are necessary not only to preserve the autonomy of the individual,\(^{161}\) but also to guide researchers and physicians and protect them from liability. A requirement of informed consent and IRB approval of proposed research and the consent process would ensure that the prospective subject is apprised of the risks and that the researcher is not performing experiments with human subjects prematurely.

### A. The Necessity for State Legislation

In order to provide guidance to researchers and physicians attempting to obtain valid informed consent, states should enact legislation which sets forth with specificity the required elements of informed consent. While federal regulations cover research situations where federal funding is involved\(^{162}\) and a few states have statutorily mandated informed consent to human experimentation,\(^{163}\) the majority of states fail to provide any detailed guidance to researchers and physicians applying new therapies.\(^{164}\)

There is little disagreement concerning the basic elements of in-
formed consent.\textsuperscript{165} The federal regulations and the statutes of California, New York, and Virginia contain most of the same elements.\textsuperscript{166} However, there are differences. None of the state statutes requires that the subject receive information concerning the extent of confidentiality to be preserved. This element will become increasingly necessary as exploration of gene therapy increases,\textsuperscript{167} since an individual's genetic background will be the object of treatment.

Only federal and California regulations require that the prospective subject receive information concerning the availability of medical treatment in the event that injury or illness results from participation in an experiment.\textsuperscript{168} This information is critical since it determines whether the subject has any recourse beyond monetary compensation. Although it may not always be possible for the researcher to predict what might go wrong in an experiment, much less to predict what treatments might be available to correct the injury, the researcher should at least disclose that those factors are unknown and thus allow the subject to decide whether to assume unknown risks.

Federal regulations provide that a subject must be informed that he will receive information concerning significant new discoveries which develop during the course of the experiment,\textsuperscript{169} while state statutes are silent on this element. In both the Tuskegee incident\textsuperscript{170} and the Willowbrook project,\textsuperscript{171} the experiments continued long after the discovery of medical cures. In order to prevent the recurrence of such incidents, it is essential that researchers agree to disclose such information to subjects when it becomes available.

Although federal regulations\textsuperscript{172} and some state statutes\textsuperscript{173} re-

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166. These elements include: an explanation of the procedures, drugs, or devices to be used in the experiments; a disclosure of appropriate alternatives; a description of any possible risks and discomforts which might be expected; an explanation of possible benefits; an offer to answer questions that the prospective subject may have concerning the experiment and its effect; and an instruction that the individual's consent to participate in the experiment may be withdrawn at any time without prejudice. See supra notes 66-75, 95 and accompanying text.
167. See supra notes 3-5, 158-60 and accompanying text.
168. See supra notes 80, 104 and accompanying text.
169. See supra note 83 and accompanying text.
170. See supra notes 22-24 and accompanying text.
171. See supra notes 25-28 and accompanying text.
172. See supra notes 91-93 and accompanying text.
173. See supra note 105 and accompanying text; see also supra note 113 (a summary of states requiring IRB approval of research with the mentally ill as subjects).
\end{flushleft}
quire IRB review of proposed research, most state statutes do not. In addition to the statutory safeguard of obtaining informed consent from each subject, there should be independent review of the consent process by a disinterested IRB. Regulations alone do not guarantee adherence by researchers and physicians conducting experiments with human subjects. Review by persons not involved in research can be an effective safeguard against abuse. State tort law, which requires physicians to obtain the informed consent of patients before engaging in non-routine therapy, operates only on an ad-hoc basis, after damage has occurred. IRB review provides a mechanism by which the consent process can be monitored before the experiment begins. Such review is especially critical where the subjects are members of a vulnerable group such as minors, the mentally disabled, or the institutionalized elderly, because decisions concerning the welfare of such people are often entrusted to third parties who may not fully consider the risks.

B. Informed Consent Applied to Nontherapeutic and Therapeutic Experimentation

No person should be the subject of an experiment without his informed consent. Voluntary, informed consent protects the prospective subject’s interests by allowing the individual to decide what risks he is willing to take. Such protection must extend not only to nontherapeutic experimentation on healthy subjects, but also to therapeutic experimentation. It is illogical to protect healthy subjects in the purely experimental situation while not requiring fully informed consent for persons who are intended to benefit from an experimental treatment.

175. See supra notes 64-70 and accompanying text.
176. Mulford, supra note 30, at 108.
177. Id.
179. Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972). The court noted that patients must assess benefits and risks in light of their own values, and that their judgment should control all treatment decisions. Id. at 234, 502 P.2d at 10, 11, 104 Cal. Rptr. at 515.
181. Cf. Capron, supra note 160, at 574-75 (proposing that higher requirements be imposed for consent to therapeutic experimentation than for consent to nontherapeutic experimentation because of the tendency of patient-subjects to underestimate risks and overrate benefits).
C. The Appropriate Standard of Informed Consent

By requiring informed consent, the law acknowledges that people are autonomous beings. This acknowledgement may create a conflict since Anglo-American law traditionally has deferred to the paternalistic attitude of the medical community. This deference is exemplified by judicial adherence to the "reasonable physician" standard of informed consent. Application of this test allows the medical profession to be judged by its own standards, and thus gives researchers and physicians virtually complete license to act in the interests of medical progress. This approach does not adequately protect the individual subject.

While the "reasonable physician" standard has given way in some jurisdictions to the less deferential "reasonable patient" standard, this change is not sufficient in the context of experimentation with human subjects. The "reasonable patient" standard also fails to recognize the individual's right of self-determination, since the court imposes its own view of what a reasonable patient would want or need to know, instead of determining whether the particular patient was properly informed.

Courts should apply the "individual patient" standard in determining whether the subject of a nontherapeutic or therapeutic experiment received information sufficient to constitute informed consent. This change in standard is necessitated in part by the increasing risks involved in new lines of experimentation such as genetic research, as well as by the failure of some members of the medical profession to act ethically in conducting experimentation with human subjects. Medical professionals were solely responsible for the violations of individuals' rights which occurred in the Tuskegee incident, the Willowbrook project, and the Jewish Chronic Disease Hospital case. If physicians and administrators

184. See supra notes 135-44 and accompanying text.
185. See supra notes 145-49 and accompanying text.
186. See supra note 157 and accompanying text.
187. See supra notes 150-57 and accompanying text.
188. See supra notes 17-34 and accompanying text.
189. See supra notes 22-24 and accompanying text.
190. See supra notes 25-28 and accompanying text.
191. See supra notes 29-34 and accompanying text.
have disregarded the rights of individuals in the past, as exemplified by these experiments, it can unfortunately be assumed that such violations will continue to occur unless safeguards are provided. The “individual patient” standard of informed consent provides such a safeguard.

V. CONCLUSION

Research on human subjects is vital to medical and scientific advancement. However, abuses have occurred and will continue to occur. At present, a large gap exists in regulatory oversight where research is conducted without federal funds. Most states do not have statutes that address informed consent to human experimentation. Furthermore, many states that have enacted such legislation merely require that the individual’s informed consent be obtained, without actually defining what type of information must be provided to a subject. In light of the tremendous risks inherent in upcoming experiments with genetic manipulation, it is imperative that states provide comprehensive requirements for informed consent and that regulatory oversight extend to both nontherapeutic and therapeutic research situations.

The elements of informed consent set forth by federal regulations, including IRB review, should be incorporated into every state statute. It is important that state statutes be substantially similar to federal regulations so that the researcher or physician is not forced to contend with a maze of different rules and regulations. Such regulation should not hamper medical research, but should instead guide researchers and protect them from potential liability by ensuring that the subject is apprised of the risks.

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