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MEDICAL RESEARCH AND PERSONAL PRIVACY*

BERNARD R. ADAMS†

As the right to privacy continues its expansive development in the legislatures and the courts, decision-makers are becoming more aware of the importance and difficulty of balancing an individual's right to privacy against the needs of society. Professor Adams here examines the right to privacy in the context of personal information contained in medical records. He begins by assessing both the existing controls on medical research and privacy controls that could be applied in the medical research context, including the right of confidentiality, the right of privacy based in tort and constitutional law, and statutory protections. Concluding that current controls are inadequate to protect fully a patient's privacy in his medical records, Professor Adams proposes a model that will afford the patient sufficient privacy protection and at the same time provide for the needs of the medical community.

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I. INTRODUCTION

CONTEMPORARY American legal standards are in a state of tension. Much of this tension results from the balancing of individual rights against societal needs. While such balancing always has been a part of our constitutional decision-making process, it has become more problematic in recent years as our courts give increasing protection to individual rights and liberties, while at the same time they recognize the impact that the exercise of those rights has on other necessary societal conduct.

Tension between individual and societal expectations is a key consideration in the protection of an individual’s privacy. While our society encourages the full and free dissemination of information, it recognizes that our “need to know” may be circumscribed at times by an individual’s reasonable expectation that certain information will not be disclosed. Courts and legislatures have placed their imprimaturs on such expectations, declaring that individuals indeed possess certain rights of privacy.1

While the doctrines relating to the protection of privacy have arisen in a variety of settings, they have not been expanded sufficiently to deal with the release to scientific researchers of information contained in medical records. Medical research is a vitally important societal activity that yields many benefits to the community at large. At the same time, it is well recognized that the individual patient or research subject has rights that must be safeguarded during research. Such protection, however, can prevent or impede the progress of research. In balancing individual rights against societal needs, safeguards have been developed that incorporate basic community values while purporting to ac-

1. As used in this article, the term “privacy” is the “right to be left alone,” and is a personal right asserted under tort, statutory, and constitutional law. This definition conforms with the meaning traditionally given to the term “privacy.” See, e.g., Kapellas v. Kofman, 1 Cal. 3d 20, 35, 459 P.2d 912, 921-22, 81 Cal. Rptr. 360, 369-70 (1969). “Confidentiality,” as used here, is an expectation that information will not be divulged that is based on the interpersonal relationship in which the information was created and supported by protective standards found in the Hippocratic Oath or specific statutory provisions. The use of the term “confidentiality” in this article is consistent with its use in case law. See, e.g., Clark v. Geraci, 29 Misc. 2d 791, 208 N.Y.S.2d 564 (Sup. Ct. 1960). See generally Annot., 20 A.L.R.3d 1109 (1968). Even though these two terms derive from different legal sources, they are often used interchangeably to refer to areas where an individual has an expectation that data will not be divulged. For a further discussion of these terms, see infra notes 39-145 and accompanying text.
commodate the legitimate needs of both patient and researcher. Yet, to date, most of these patient protections have been aimed only at the prevention of physical harm. The intangible harm that can result from disclosure of information in a patient's medical records in the course of medical research has received only scant attention.

An individual's medical records contain a vast amount of sensitive information that, if released to the general public, could be the source of serious harm or embarrassment. Nevertheless, many third parties, such as health insurers, have a legitimate need for access to this information in order to act for the benefit of the patient or society. Similarly, scientific research relies on access to patient medical records in order to achieve medical advances.

The use of medical records in medical research bodes many potential problems for the patients involved, setting in stark re-

2. As used in this article, the term "medical records" refers to all files, charts, and other documents in the custody of health care providers—both individual doctors and institutions—that contain data about the individuals identified in the documents.

3. As used in this article, the term "medical research" refers to systematic scientific studies conducted to test certain assumptions or hypotheses regarding problems for which satisfactory answers currently do not exist.

4. A government study led by Professor Alan F. Westin of Columbia University documents these problems and contains an exhaustive survey of the use and abuse of health data. See A. Westin, Computers, Health Records, and Citizen Rights (1976). Professor Westin's study team carefully documented instances of loss of employment, denial of insurance, setbacks in the course of medical treatment, and other detrimental effects of unrestricted sharing of medical information among agencies. The study concludes that legislation is sorely needed to protect patient privacy in the face of pervasive and increasingly detailed medical record-keeping and the dissemination of private information.


The Privacy Commission's report set forth detailed examples of personal deprivations suffered by individuals when information obtained from their medical records reached entities that make decisions based on such data. School or military records containing observations purporting to be medical but in fact made by teachers or commanding officers who have no medical training are a problem of particular concern. Privacy Commission Report, supra, at 247-49. Such supposed health data are disseminated into society, having acquired a professional patina of true medical judgment. Id. Thus, a child adjudged "hyperactive" or "retarded" by a school counselor may encounter difficulty obtaining a
lief the conflict between societal benefits and personal privacy. Researchers glean much of their experimental data from patient records containing “private” personal information. Such records often include patient-identifiable data that are not or cannot be disguised adequately. This information, in turn, may be disclosed to the researchers or their associates during data collection or to other parties through publication of research results. The use of sensitive patient information for research purposes, by parties other than health care providers who engage in direct treatment of the patient’s condition, raises important legal and ethical questions. These questions relate primarily to the protection of the patient’s privacy and confidentiality, as well as to the patient’s control of access to medical records and to his or her informed consent to the proposed research.

This article will attempt to set forth a mechanism that recognizes the patient’s personal privacy interests in medical records but that also accommodates society’s need for scientific progress by allowing medical research to go forward under proper controls. In the sections that follow, the existing controls on medical research will be discussed and evaluated. It will be seen that even though medical research is highly regulated, the present means of protecting patients’ interests in privacy and confidentiality are inadequate. For example, while the most recent report of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President’s Commission) recognizes patients’ privacy interests and the need to protect them from unwarranted intrusion by researchers, both the current federal regulations and the President’s Commission’s

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5. The general practice of hospitals is to give hospital personnel free access to “charts” for bona fide purposes. Limited access is granted other “legitimately” interested parties such as health insurance carriers or employers. This practice, however, does not entirely eliminate abuses. See supra note 4, infra notes 43-46 & 94-96 and accompanying text. A patient has a legitimate cause for concern because his access authorization is generally secured before a record exists and before he knows whether sensitive information is recorded therein. The authorization usually is in blanket form, further limiting the patient’s protection and control. For a discussion of patients’ right to access to their records, and to limit third-party access, see infra notes 178-83 and accompanying text. See also A. Westin, supra note 4, at 18-31, 47-51, 79-81; Privacy Commission Report, supra note 4, at 299-300.

6. For a discussion of informed consent as it pertains to protection of and access to confidential patient information, see infra notes 24 & 193-200 and accompanying text.
proposals leave the problem to state regulation or private disposition. Those applying these standards look for guidance from other areas of the law that are incomplete, inconsistent or inadequate, and that fail to provide the effective controls needed to solve the privacy dilemma.

After the flaws in the existing legal framework have been explored, the final section of the article will develop a model for providing protections at an acceptable social cost while still allowing medical research to progress. This model can be incorporated into the mechanisms that already govern medical research, either through legislation or, initially, through administrative regulation. If adopted, this proposal will ensure protection from unwarranted invasions of the patient's privacy and at the same time will recognize the needs of the medical researcher to obtain data.

II. CURRENT FEDERAL CONTROLS ON MEDICAL RESEARCH

Formal experimentation with human subjects for the purpose of improving medical treatment has been pursued since at least the eighteenth century. The impetus for regulations controlling such research activities first appeared in the middle of the twentieth century in response to an increasing number of research projects involving human subjects and to the Nuremberg Trials' revelation of Nazi atrocities undertaken during World War II in the name of medical science. The first formal expression of ethical considerations was the President's Commission on the Study of Ethical Problems in Medical Research. The commission was charged with the task of developing a set of rules to govern the conduct of medical research. The commission's final report, published in 1983, recommended a number of measures to protect the rights of human subjects and to ensure the confidentiality of medical records.


At the request of then President Jimmy Carter, a commission (President's Commission) was empaneled in 1980 to analyze the ethical and legal implications of medical care and research. The President's Commission was mandated to study issues which included the privacy interests of patients. Accordingly, the President's Commission conducted a hearing in which researchers, practitioners, and members of the Privacy Commission testified on current and proposed mechanisms for ensuring the confidentiality of patient medical records. The President's Commission retained Professor William Winslade as a consultant to study the philosophical aspects of privacy.

In its final report, however, the President's Commission treated the issue of patient privacy hesitantly. Acknowledging the tension between the law and ethics of medical privacy and the need for detailed empirical exploration, the President's Commission merely encouraged health care providers to give greater attention to privacy concerns. It explained that the construction of a set of statutory or administrative rules that would resolve the tension in the existing law as a necessary task, but one too great for the President's Commission's existing resources. Id. at 37.

8. See United States v. Brandt (The Medical Case), 2 Trials of War
cal guidelines for conducting research with human subjects was the Declaration of Helsinki, issued by the World Medical Association in 1964. The Helsinki Declaration emphasized the rights of the individual subject, the concept of informed consent, and the principle that the “importance of the objective [be] in proportion to the inherent risk to the subject.”

Two years after the issuance of the Declaration of Helsinki, the Surgeon General of the United States Public Health Service (PHS) issued a memorandum mandating that local institutional committees on human investigation review and approve all research and training grants supported by PHS and involving human subjects. Such institutional peer review was to “assure an independent determination of (1) the rights and welfare of the individual or individuals involved, (2) the appropriateness of the method used to secure informed consent, and (3) the risks and potential medical benefits of the investigation.” In response to comments from both grantor and grantee institutions, these guidelines were refined in 1971. However, the guidelines’ basic objectives—protection of subject rights and assurance that benefits justified risks—remained the central focus of the review process. These objectives continue to be the key areas of inquiry under federal regulations issued in 1974 in response to the 1974 National Research Act.

The 1974 regulations govern all federally funded projects involving human subjects. They also govern research that makes use of patients’ medical records. Any entity doing human subject research funded by the Department of Health and Human Services (HHS) is required to create an institutional review board.

Criminals Before the Nuremberg Military Tribunals 181-82 (Military Tribunal I, 1947).

9. World Medical Ass'n, Human Experimentation: Code of Ethics of the World Medical Association, Declaration of Helsinki, 2 Brit. Med. J. 177 (1964). The Helsinki Declaration enunciated the principles (1) that clinical research should be based on adequate scientific background and experimental design, and responsible investigators should be “scientifically qualified persons;” and (2) that a fundamental distinction exists “between clinical research in which the aim is essentially therapeutic for a patient, and clinical research the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.” Id. at 177.

10. Id.


12. Id.


14. See id. § 46.101.
The IRB’s express function is to protect the rights and welfare of the human subject. Nearly all federal agencies that support or conduct such research and have standards to govern that research have adopted the basic HHS standards and procedures spelled out in the 1974 National Research Act.

In practice, research studies governed by the HHS guidelines originate when institutional staff members are confronted with a medical question for which no satisfactory answer exists. The institutional review boards (IRB) are established to review and monitor the research studies that fall under the regulations. The IRB’s express function is to protect the rights and welfare of the human subject.

15. The federal regulations governing protection of human subjects set forth the following definitions:

“Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. “Intervention” includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. “Interaction” includes communication or interpersonal contact between investigator and subject. “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

16. IRB REPORT, supra note 15, at 94. The report states that of 19 federal entities (apart from HHS) that have regulations governing human subject research, 17 have adopted HHS standards (four strictly, eight strictly but with additions, and five approximately). Id. However, approximately one third of the federal agencies have no policies at all on human subject research. Id. at 94-95. Two of these, the Law Enforcement Assistance Administration and the Department of Housing and Urban Development, support research involving intervention in the subjects’ lives without reviewing the “ethical acceptability of such research . . . [nor] assuring the adequacy of informed consent.” Id. at 95.
vestigator, often in conjunction with colleagues in areas of shared interest, will develop a hypothesis and devise a method for testing that hypothesis. In order to gain government funding to support the proposed research, the investigator must prepare two documents, called "protocols," that describe the experiment. One protocol discusses the proposal's scientific background and a methodological approach to be used. It will describe the human subject population to be studied, the type of analysis or intervention to be done, a rationale for working with a particular population and for selecting the study method, the manner in which data will be analyzed, the pitfalls in study design that may affect the generation and interpretation of data, and the potential significance of the research.17

The second protocol focuses on the ethical issues attending performance of the research. This document states the study's purpose, the human subject population at risk, the basis for selecting that population, the nature of risks, the measures for reducing potential risks, the anticipated benefits, and the manner in which informed consent will be obtained.18

The HHS regulations stipulate that the institution requesting HHS funds for research involving human subjects "shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in [the] regulations."19 The department will conduct or fund research within the scope of the regulations only if it has approved the institution's written assurance and if the institution has certified that the research has been reviewed and approved by an appropriate IRB.20

Criteria for IRB approval include determinations that risks to the subjects have been minimized,21 that such risks are reasonable in light of the anticipated benefits and the importance of the knowledge to be gained,22 that selection of subjects is equitable,23

18. Id. at 539-40.
19. 45 C.F.R. § 46.103(a) (1984). The Secretary is to evaluate and then approve or disapprove each assurance submitted by institutions intending to conduct research. Id. § 46.103(d), (e).
22. Id. § 46.111(a)(2).
23. Id. § 46.111(a)(3). In making this determination, the IRB is to look to
and that informed consent will be obtained and documented according to the guidelines set forth in the regulations. Where appropriate, the research plan also must make adequate provisions for monitoring the data. Similarly, there must be provisions assuring confidentiality of data as well as the protection of the subjects’ privacy. Finally, where some or all subjects are likely to be vulnerable to coercion or undue influence, additional safeguards are mandated.

In 1978 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) published a report (IRB Report) in which it evaluated the HHS regulations and made a number of recommendations. It is clear from the IRB Report that the National Commission viewed the protection of subjects from physical risk as its paramount concern. Only general reference was made to dangers inherent in the privacy area. One recommendation, for example, suggested that an IRB “be particularly attentive to the adequacy of provisions [in the protocol] to protect the confidentiality of the data.” The IRB Report also noted that an IRB should make certain that the record keeper has balanced “the importance of the research . . . [against] the risk to the individual from additional exposure of the record or information contained therein,” and imposed appropriate safeguards against unauthorized disclosure of the patient’s health data. Beyond this

24. Id. § 46.111(a)(4), (5). The federal regulations specifically set forth general guidelines for informed consent. Id. § 46.116. These include: (1) a statement that the study involves research; (2) a description of risk; (3) a description of benefit; (4) a disclosure of alternative procedures; (5) a statement describing the extent to which confidentiality of records identifying the subject will be maintained; (6) for research involving more than minimal risk, a statement with respect to compensation, if any, and treatment for injury should it occur; (7) an explanation of who to contact for answers to questions; and (8) a statement that participation is voluntary. Id. The regulations also provide that the IRB may approve a less extensive consent procedure in certain cases or waive the requirement altogether. Id. § 46.116(e), (d).

25. Id. § 46.111(a)(6). The underlying purpose of this requirement is to ensure the safety of subjects. Id.

26. Id. § 46.111(a)(7).

27. Id. § 46.111(b). The subjects entitled to these additional protections include those with severe physical or mental illness and those who are educationally or economically disadvantaged. Id.


29. Id. at 31.

30. Id. at 29.

31. Id.
general counsel, however, the report failed to give guidance for handling or avoiding risks to privacy.

Remarkably, the most recent HHS regulations display even less concern with patients' privacy rights than does the IRB Report. As revised, the regulations actually exempt from IRB scrutiny a number of categories of research involving no physical harm. These new exemptions include research involving "the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, [either] directly or through identifiers linked to the subject."  

The focus of the regulations on physical harm is understandable because much human subject research involves actual patient contact through, for example, clinical observation, the taking of tissue samples, or the administration of drugs. However, in many other types of research, the use of medical records may precede or even replace patient contact, with the researcher simply using preexisting patient records as part of a research project. Such retrospective review of patient data without patient contact raises the risk of intrusion into a patient's privacy. Yet, these non-physical risks have been ignored substantially in recently promulgated regulations. Under the present design an IRB simply does not review research proposals with a view to protecting the individual from the dissemination of confidential or private information when there is no prospect of actual physical danger to the patient.

Both the relevant federal regulations and the most recent report of the Privacy Protection Study Commission (Privacy Commission) appear to expect the needed privacy controls to come from other areas of the law. Unfortunately, however, neither

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33. 45 C.F.R. § 46.101(b)(5) (1984). For a further discussion of these exemptions, see supra note 15.
36. For a discussion of the intent of federal regulatory agencies to depend on other law for information access controls and privacy protections, see supra note 15. For a discussion of the Privacy Commission, its duties, and its purpose, see supra note 4 and accompanying text.
existing statutory protections nor common law principles adequately address the privacy concerns of patients whose medical records may be available to researchers. Although a number of statutes and common law concepts do deal with the privacy question tangentially, none provides a comprehensive or consistent set of guidelines. Concepts governing issues such as patient access to records and informed consent are relevant but fall far short of providing effective guidance: Access to records remains a continuing source of controversy between patient and physician; and informed consent, generally given before any treatment begins or any record is developed, is a specious concept in the context of protecting such records, because a patient has insufficient knowledge to consent to the dissemination of personal information in advance. Other aspects of the law involving medical research that merit more careful attention include the right of confidentiality between patient and physician, the patient's right to privacy, and statutory developments of the right to privacy. The next section will discuss and evaluate these aspects as potential vehicles with which to protect personal privacy in the field of medical research.

III. Other Possible Controls on Medical Research

A. The Right to Confidentiality

A patient's right to the confidentiality of his medical records has always been a basic tenet of the physician-patient relationship. Medical care providers owe their patients a duty to protect personal information from unwarranted public disclosure. This

37. Patients are increasingly insistent upon both knowing what their medical records contain and holding medical personnel accountable for all aspects of diagnosis and treatment. Physicians, on the other hand, justify restraint on patient access on the basis that the information either may be misunderstood, or, if understood, will have some detrimental effect on the patient. Patient access, however, remains important for purposes of insuring accuracy.

38. Traditionally, informed consent has involved a request for consent that is made before treatment begins. Such advance consent amounts to a virtual blanket release before a record has even been established, much less read or understood by the patient.


The physician-patient confidentiality privilege did not exist at common law. See People v. Deadmond, Colo., 683 P.2d 763, 769 (1984); Wesley Medical Center v. Clark, 234 Kan. 13, 24, 669 P.2d 209, 218 (1983). The privilege is a creature both of statute and of custom and practice within the medical profession, designed primarily to ensure communication of all necessary information between patient and physician. See State v. Santeyan, 136 Ariz. 108, 110, 664
duty, which underlies the Hippocratic Oath\(^40\) taken by all physicians, arises from the inherently intrusive character of proper diagnosis and treatment.\(^41\) The general ethical duty embodied in the Oath is either codified or established by case law in approximately nineteen states.\(^42\) There is, however, no comprehensive legal protection for the confidentiality of patient data, and patient protection generally rests on the medical profession's customary obedience to the Oath and the principles behind it.


40. In its classic form, the Hippocratic Oath provides that "[w]hat I may see or hear in the course of treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep myself holding such things shameful to be spoken about." L. Edelstein, The Hippocratic Oath: Text, Translation and Interpretation 3 (1943). See also Cooper, The Physician's Dilemma: Protection of the Patient's Right to Privacy, 22 St. Louis U.L.J. 397 (1978) (reviewing evolution of patient's right to confidentiality and privacy).

41. The American Medical Association, in response to the sensitive nature of the disclosure issue, has adopted the following as \$ 9 of its principles of medical ethics:

A physician may not reveal the confidences entrusted to him in the course of medical attendance, or the deficiencies he may observe in the character of patients, unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community.

American Medical Ass'n, Opinions and Reports of the Judicial Council 5 (1977). Commentators have suggested that the duty arising under the American Medical Association's principles of medical ethics is less comprehensive than that arising under the Hippocratic oath. See Cooper, supra note 40, at 399. Accordingly, courts may balance the patient's interest in privacy and confidentiality against competing public interests. See, e.g., People v. Florendo, 95 Ill. 2d 155, 447 N.E.2d 282 (1983) (grand jury's interest in conducting investigation outweighs confidentiality interest); Bratt v. IBM, 392 Mass. 508, 467 N.E.2d 126 (1984) (employer's valid and substantial interest in medical records outweighs employee's interest in confidentiality); State v. Kupchun, 117 N.H. 412, 373 A.2d 1325 (1977) (state's interest in determining whether commitment for mental health treatment is necessary overrides physician-patient privilege); In re Doe Children, 93 Misc. 2d 479, 402 N.Y.S.2d 958 (Fam. Ct. 1978) (child's interest in being free from neglect and abuse outweighs parent's interest in confidentiality); In re Grand Jury Investigation, — R.I. —, 441 A.2d 525 (1982) (supremacy clause interests override physician-patient privilege in Medicaid fraud grand jury investigation).

A review of state court decisions addressing the confidentiality of medical records affords meager guidance for establishing a framework for the protection of medical records. Cases in this area involve disparate factual situations and varying legal approaches, thus making it difficult to deduce a single, general pattern of protection. Some patterns, however, are discernible.

A physician’s disclosure of confidential patient information has been held to violate the patient’s rights where a physician conveyed disparaging information to a former patient’s in-laws; where a psychiatrist published a book detailing treatment of a former patient without adequately concealing the patient’s identity; where a physician sought to publish photographs of a patient’s treatment; and where a physician forwarded a medical report on his patient to the patient’s adversary in an accident.

43. Berry v. Moench, 8 Utah 2d 191, 331 P.2d 814 (1958). In Berry, the defendant physician responded to an inquiry by another physician, who was not and did not purport to be treating the plaintiff, as to the plaintiff’s mental history. Id. at 194-95, 331 P.2d at 816. The defendant physician’s response contained several statements relating to the plaintiff’s mental health problems. Id. The court recognized that important societal interests might justify such a disclosure of confidential medical information. Id. at 196-98, 331 P.2d at 817-18. The court concluded, however, that disclosures must be exercised with caution and in good faith, reported fairly, and limited in terms of the information conveyed and the recipients thereof. Id. at 199-201, 331 P.2d at 819-21. Using those criteria, the Berry court reversed the trial court’s conclusion that the disclosure was justified, and remanded for a new trial. Id. at 201-02, 331 P.2d at 820-21.

44. Doe v. Roe, 93 Misc. 2d 201, 400 N.Y.S.2d 668 (Sup. Ct. 1977). In Doe v. Roe, the defendant physician published a book on psychiatry that, without the plaintiff patients’ consent, contained sensitive verbatim disclosures made by them during the course of their treatment. Id. at 203, 400 N.Y.S.2d at 670-71. The court concluded that the physician who agrees to render medical services impliedly covenants not to disclose information conveyed to him or her during the course of treatment. Id. at 210, 400 N.Y.S.2d at 674-75. It further concluded that disclosures of confidential information may also give rise to an action for breach of privacy. Id. at 211-13, 400 N.Y.S.2d at 675-76. Rejecting the defense that the scientific value of the publication outweighed the patients’ confidentiality or privacy interests, the court awarded compensatory damages and enjoined further circulation of the book. Id. at 214, 217-18, 400 N.Y.S.2d at 677, 679-80.

45. Clayman v. Bernstein, 38 Pa. D. & C. 543 (1940). In Clayman, the plaintiff patient sought the return of photographs that documented the effects of her illness during unconsciousness. Id. at 543-44. The photographs, taken while the plaintiff was semiconscious, showed severe facial disfigurement. Id. Relying on an invasion of privacy theory of liability, the court concluded that photographs depicting one’s facial features may not be made public without consent. Id. at 546. The court rejected the defendant’s argument that the plaintiff waived her right of privacy by entering into the physician-patient relationship. Id. at 548. Accordingly, the Clayman court ordered the physician to return all photographs and negatives. Id. at 550-51.
Because each of these fact patterns involves revelation of intimate data for use by an inappropriate third party or for financially exploitative purposes, these cases are of little precedential value in situations where such data is revealed to a medical researcher who does not use the information in any exploitative way.

Unfortunately, in cases where disclosure did not involve inappropriate third parties or exploitation, state courts often have dismissed the plaintiffs’ complaints. For example, in Clark v. Geraci, where a physician disclosed to a patient’s employer that the patient was an alcoholic, the New York Supreme Court found that the patient had waived the right to confidentiality by authorizing partial disclosure. The patient had sought a medical excuse for his absenteeism. When the physician also divulged information regarding the patient’s alcoholism, the employer dismissed the patient from employment. The patient then sued the physician for breach of confidentiality. The court construed the patient’s request for an excuse from work as a waiver by estoppel. In another New York case, Munzer v. Blaisdell, the director of a state psychiatric institution who had released a patient’s record was found not liable. The court found no physician-patient relationship between the director and the psychiatric patient, and thus did not invoke a presumed duty of confidentiality. Courts in New Jersey and Nebraska have relied on public policy justifications to uphold a physician’s disclosure of a child’s genetic heart defect to an insurance company, and a physician’s erroneous
One state case that did seem to hold promise for a confidentiality-based limitation on the dissemination of private medical information to researchers was the New York case of Doe v. Roe. The court found that a patient's right to confidentiality was violated when his psychiatrist published data that did not adequately disguise the patient's identity. The court based its decision on a number of theories, one of which was an implied covenant to avoid disclosure of information gleaned in the course of a professional relationship. Such a promise of silence, whether express or implied, has been the basis of a cause of action for breach of contract in other cases between errant physicians and patients. The Doe court also stated that the fiduciary

the alleged breach of the duty not to disclose confidential information. Id. at 331, 181 A.2d at 346. The court stated that since New Jersey had no express public policy on point, the interests at issue had to be balanced. Id. at 335, 181 A.2d at 348. It concluded that the public interest in exposing information relevant to the resolution of the plaintiffs' insurance claim outweighed the plaintiffs' interest in confidentiality, and thus denied liability for the disclosure. Id. at 336, 181 A.2d at 349.


52. Simonsen v. Swenson, 104 Neb. 224, 177 N.W. 831 (1920) (per curiam). In Simonsen, the plaintiff was required to work away from home, and therefore resided in a hotel in the town in which business was to be conducted. Id. at 225, 177 N.W. at 831. Plaintiff developed sores on his body while staying at the hotel, and was seen by the defendant hotel's physician. Id. The physician concluded plaintiff had syphilis, a highly contagious disease. Id. Fearing a spread of the disease, the physician conveyed his diagnosis to the hotel manager, who promptly removed plaintiff from the hotel. Id. at 225-26, 177 N.W. at 831. In deciding the claim for breach of duty not to disclose, the court found the physician-patient relationship to be a highly confidential one. Id. at 227, 177 N.W. at 832. However, the court found the public's interest to be safe from dangerously contagious diseases to be of greater concern. Id. at 228-29, 177 N.W. at 832. Disclosure was therefore allowed because the defendant physician had reasonable grounds for his belief, limited the disclosure to reasonably necessary information, and acted in good faith. Id. at 230, 177 N.W. at 833.

53. 93 Misc. 2d 201, 400 N.Y.S.2d 668 (Sup. Ct. 1977). For a further discussion of Doe, see supra note 44 and accompanying text.

54. 93 Misc. 2d at 210, 400 N.Y.S.2d at 674.

nature of the physician-patient relationship obligated the physician to avoid unwarranted disclosure.\textsuperscript{56} The \textit{Doe} court specifically rejected the psychiatrist's defense of "scientific value," holding that public policy dictated that the "curiosity or education of the medical profession" should not be allowed to supersede the physician's duty of confidentiality.\textsuperscript{57} The court concluded that "conflicts between ethical obligations and scientific advance must be resolved in favor of the ethical consideration."\textsuperscript{58}

Because \textit{Doe v. Roe} uses the implied covenant concept and rejects the scientific value defense, the case has useful implications for patient protection against medical research disclosure. However, the court explicitly reserved comment on cases in which the identities of patients are fully concealed or the scientific discovery is too important to concede the patient's privilege of nondisclosure,\textsuperscript{59} making the case amenable to narrow interpretation. It remains the task of future courts to decide what kinds of scientific enterprise are important enough to outweigh the principle of confidentiality.

State licensure statutes provide another potential basis for a cause of action for violation of duties of confidentiality in the medical research area. The Nebraska Supreme Court observed in

\textit{Id.} at 214, 400 N.Y.S.2d at 677. The court took notice of several cases involving interests that might cause the patient's interest in confidentiality to be compromised. \textit{Id.} One such case involved a patient who clearly presented a threat to the physical safety of others. See Tarasoff v. Regents of Univ. of Cal., 13 Cal. 3d 177, 118 Cal. Rptr. 129, 529 P.2d 553 (1974) (en banc), \textit{reversed on rehearing}, 17 Cal. 3d 425, 131 Cal. Rptr. 14, 551 P.2d 334 (1976) (en banc). Another case involved a patient with a contagious disease. See Hoffman v. Blackman, 241 So. 2d 752 (Fla. 1970). The \textit{Doe} court further observed that the physician-patient privilege may have to yield in order to accommodate certain statutory enactments. See, e.g., N.Y. Penal Law \S\ 265.25 (McKinney 1975) (requiring physicians to report gunshot and other similar wounds); N.Y. Pub. Health Law \S\S 3355, 3373 (McKinney 1977) (requiring the report of the use of controlled substances in certain situations).
one case that the state's licensure statute would give rise to a civil action for damages for any "betrayal of a professional secret," but held in the same case that public health concern about syphilis overrode the patient's right to confidentiality. 60

By contrast, a Tennessee court held that a state medical licensure statute was not an appropriate vehicle for allowing a patient to maintain a civil cause of action for wrongful disclosure of medical information. 61 This decision, however, appears to represent the more unlikely outcome in any state that forbids betrayal of professional secrets in its medical licensure statutes.

Aside from licensure statutes, other state laws exist that could be employed to render a physician liable for breach of the duty of confidentiality in regard to patient information. For example, in Doe v. Roe, the court also relied on an interpretation of New York's Education, Mental Hygiene, and Public Health Laws. 62 The court stated that the legislature

intended to reinforce the public policy of this state expressed in numerous statutes and regulations . . . prohibiting physicians, persons in allied fields and medical institutions from disclosing without authorization of the patient, information discovered in attending the patient . . . [and] intended that "the statute . . . have a broad and liberal construction to carry out its policy." 63

Despite some encouraging developments at the state level, other aspects of existing statutory protections of confidentiality are less hopeful. For example, as of 1975, only twenty-one states had licensure laws that provided for revocation of a physician's license for unprofessional conduct, conduct which includes the intentional or willful revelation of health information acquired in

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60. Simonsen v. Swenson, 104 Neb. 224, 227, 177 N.W. 831, 832 (1920) (per curiam). For a discussion of the facts of Simonsen, see supra note 52 and accompanying text.

61. Quarles v. Sutherland, 215 Tenn. 651, 389 S.W.2d 249 (1965) (plaintiff sued physician alleging wrongful disclosure of medical findings to defense attorney, but disclosure was held to be not prejudicial because information would have been available to attorney on discovery).

62. 93 Misc. 2d at 208, 400 N.Y.S.2d at 673. See, e.g., N.Y. MENTAL HYG. LAW § 33.13 (McKinney 1978 & Supp. 1984). This statute requires that clinical records be maintained and that such information be kept within the State Department of Mental Hygiene, apart from certain exceptions enumerated in the statute. The primary purpose of the statute is to maintain the subject's confidentiality. Application of Hild, 124 N.Y.S.2d 271 (Sup. Ct. 1953).

63. 93 Misc. 2d at 208, 400 N.Y.S.2d at 673 (quoting New York City Council v. Goldwater, 284 N.Y. 296, 31 N.E.2d 31 (1940)) (citations omitted).
treating patients. Similarly, although most states purport to protect the confidentiality of medical records in the judicial process by way of testimonial privileges, some courts have construed the physician-patient privilege in favor of the testifying physician so long as the patient and physician are not adversaries in the litigation.

Recent proposals for statutory protection are not encouraging. For example, the Privacy Commission does not treat the confidentiality of patient data as one of its primary concerns in the medical research context. Its recommendations regarding "record-keeping in the medical care relationship" contain conflicting premises. After stating initially that "confidentiality of the medical-care relationship has been seriously eroded and clearly needs to be restored," and that there is a "lack of a legitimate, enforceable, expectation of confidentiality," the Privacy Commission Report cites only two situations involving personal

64. See Britton, Rights to Privacy in Medical Records, J. LEGAL MED., July 1975, at 32.


65. PRIVACY COMMISSION REPORT, supra note 4, at 284. This privilege allows a patient to prevent a physician from testifying about the patient's medical condition. The Privacy Commission's report observes that 43 states have testimonial privilege statutes. Id. It notes further that the contemporary trend is toward extending this privilege to records such as medical records, X-rays, and laboratory tests. Id.

Typically, testimonial privilege statutes provide as follows:

No physician shall be allowed, in any civil matter, to disclose any information which he acquired in attending the patient in a professional capacity, and which was necessary to enable him to act in that capacity, which shall tend to blacken the character of the patient, without consent of said patient, except in civil matters brought by such patient, for damages on account of personal injuries.

42 PA. CONS. STAT. ANN. § 5929 (1982).


67. PRIVACY COMMISSION REPORT, supra note 4, at 292-317.

68. Id. at 281.

69. Id. at 292.
embarrassments resulting from unwarranted disclosure in the course of research. More significantly, research qualifies as an exclusion from the enhanced protection of confidentiality that the Commission recommends for statutory enactment in the states. Similarly, a model bill on confidentiality proposed by the American Medical Association also excepts medical research from its strictures on disclosure of confidential health care information. The Privacy Commission justified the exclusion of research from the duty of confidentiality on practical grounds. It noted the difficulty of obtaining consent for use of patient records from large numbers of persons who long since may have moved away or whose refusal might skew the results of a study. Moreover, delays caused by exaggerated concern for confidentiality could stifle epidemiological research so as to pose imminent or existing threats to public health. A requirement of patient authorization might well have prevented critical research in two recent studies

70. Id. at 309-10. For a discussion of the "embarrassing" disclosures considered by the Privacy Commission, see infra notes 94-96 and accompanying text.

71. PRIVACY COMMISSION REPORT, supra note 4, at 306 (recommendation (10)(c)(i)-(v)). Specifically, the Commission's recommendation provides:

That each medical-care provider be considered to owe a duty of confidentiality to any individual who is the subject of a medical record it maintains, and that, therefore, no medical care provider should disclose, or be required to disclose, in individually identifiable form, any information about any such individual without the individual's explicit authorization, unless the disclosures would be: ... for use in conducting a biomedical or epidemiological research project, provided that the medical-care provider maintaining the medical record:

(i) determines that such use or disclosure does not violate any limitations under which the record or information was collected;

(ii) ascertains that use or disclosure in individually identifiable form is necessary to accomplish the research or statistical purpose for which use or disclosure is to be made;

(iii) determines that the importance of the research or statistical purpose for which any use or disclosure is to be made is such as to warrant the risk to the individual from additional exposure of the record or information contained therein;

(iv) requires that adequate safeguards to protect the record or information from unauthorized disclosure be established and maintained by the user or recipient, including a program for removal or destruction of identifiers; and

(v) consents in writing before any further use or redisclosure of the record or information in individually identifiable form is permitted. Id. at 306-07.

72. AMA MODEL STATE BILL ON CONFIDENTIALITY OF HEALTH CARE INFORMATION § 4(b)(4), reprinted in A. WESTIN, supra note 4, at 351. The term "confidential health care information" relates to a person's health care history, diagnosis, condition, treatment or evaluation. Id. § 3(c), reprinted in A. WESTIN, supra note 4, at 350.

73. Id. at 309.
involving Legionnaire’s Disease and DES (diethylstilbestrol). Thus, neither present nor proposed standards adequately address the release of confidential patient data to qualified researchers; and under existing case law, most such releases probably would not be considered a breach of confidentiality. Moreover, because the many legal theories on which the duty of confidentiality has been based do not provide clear guidance for proper conduct, this is an area ripe for litigation. The issue requires a comprehensive approach that would clarify existing law and provide a workable set of standards.

B. The Right to Privacy

Both ethical and moral principles incorporate a regard for the individual’s right to be left alone. The law, however, was slow to grant redress for the dissemination of the intimate details of one’s personal life. Like the patient’s privilege of nondisclosure, the rights of an individual to make decisions in private and to prevent public knowledge of those decisions have emerged only in sporadic bursts of judicial or legislative energy.

There was no per se right to privacy at common law. In 1890, however, Samuel Warren and Louis Brandeis argued in a landmark law review article that a “right of privacy” had always existed, its tenets implicit in the laws of property, defamation, and the patient’s privilege of nondisclosure. In each of these research situations, time was of the essence in order to identify and locate infected or affected individuals. In the Legionnaire’s Disease example, researchers were compelled to isolate the cause of the disease by utilizing broad patient data with the hope of diminishing the number of fatalities. In the DES (diethylstilbestrol) example, it was learned that there is a statistically significant association between prenatal ingestion of certain stilbene derivatives and the subsequent occurrence of adenocarcinoma (a malignant tumor) and clear cell adenosis in female offspring sometime after puberty. Access to appropriate medical records of mothers was essential to efficacious treatment and monitoring of daughters. A number of potentially affected DES daughters, however, later brought forth their medical records as a concomitant to a products liability/medical malpractice lawsuit. For a discussion of the Legionnaire’s Disease and DES incidents, see Privacy Commission Report, supra note 4, at 309. See also Deitchman v. E.R. Squibb & Sons, Inc., 740 F.2d 556 (7th Cir. 1984) (DES products liability action allowing limited discovery of plaintiff’s medical records, balancing defendant drug company’s need for information against privacy interests of medical records registry established to study DES).


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Shortly after publication of this piece the courts in New York and Georgia were faced with cases involving privacy questions. In *Roberson v. Rochester Folding Box Co.*, the plaintiff claimed that her privacy had been invaded by the defendant’s use of her photograph to advertise flour without her consent. The New York Court of Appeals, viewing the recognition of a right to privacy as improper judicial lawmaking, rejected her claims. Public outrage at the decision, however, led the New York Legislature to enact a limited privacy statute designed to prevent the type of commercial expropriation that occurred in *Roberson*. In 1905, in *Pavesich v. New England Life Insurance Co.*, the Georgia Supreme Court acknowledged a right to privacy. The plaintiff's name and picture, along with a fictitious testimonial, had been used to advertise the defendant's insurance. In allowing recovery of damages in tort, the court expressly rejected the majority view in *Roberson*. These two cases mark the beginnings of a judicially and legislatively recognized right to privacy that would be the focus of considerable subsequent attention.

Although it has since received fairly widespread judicial ac-

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77. Warren & Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 193-213 (1890). Because the common law in these four areas had developed to the stage of permitting causes of action where the only discernible wrong was an intangible one, it was reasonable to label such actions “merely an instance of the enforcement of the more general right of the individual to be left alone.” *Id.* at 205. The authors argued that existing theories of implied contract, trust, or breach of confidence could be other forms of a right to be free from prying publicity. *Id.* at 210-12. Warren and Brandeis urged the courts to call this already-protected interest the “right to privacy” and argued that it should apply in future cases of unwarranted invasion of a person’s private affairs. *Id.* at 209-213. The authors hastened to add, however, that they were not advocating “judicial legislation”; because privacy already existed as a principle they were merely urging judicial application. *Id.* at 213 n.1.


79. 171 N.Y. at 545, 64 N.E. at 443.

80. *See Act* of Apr. 6, 1903, ch. 132, §§ 1-2, 1903 N.Y. Laws 308 (codified at N.Y. CIV. RIGHTS LAW §§ 50-51 (McKinney 1976 & Supp. 1984)). The act essentially provides that the use of another’s name, picture, or portrait without such person’s written consent is a misdemeanor, and may be remedied by an action for damages or injunction. *Id.* *See also* Shields v. Gross, 58 N.Y.2d 358, 448 N.E.2d 108, 461 N.Y.S.2d 254 (1983) (reviewing the *Roberson* decision in light of the statutory right to privacy; recognizing the right to privacy where photographs are used for advertising purposes).

81. 122 Ga. 190, 50 S.E. 68 (1905).

82. *Id.* at 211-17, 50 S.E. at 77-79. Justice Cobb took the view that the common law maxim *ubi jus ubi remedium* (for every right there shall be a remedy) should apply. *Id.* at 194, 50 S.E. at 69.
ceptance by the state courts, the right to privacy has not experienced uniform development among jurisdictions. As a result, it has evolved into a multifaceted right, three aspects of which are particularly relevant to a consideration of the use of patient data for medical research. These three developments involve the acceptance of the right to privacy as a branch of tort law, constitutional interpretations of the right to privacy, and recent statutes or constitutional amendments aimed at protecting privacy, including the Federal Privacy Act of 1974. Each of these will be discussed below.

1. Development of Privacy in Tort Law

The Second Restatement of Torts formulates a cause of action for "unreasonable interference with privacy" and divides violations of the right of privacy into four categories: (1) unreasonable intrusion upon the seclusion of another; (2) appropriation of another's name or likeness; (3) unreasonable publicity given to or disclosure of another's private life; and (4) publicity that unreasonably places another in a false light before the public. With respect to research involving medical records, the right to privacy implicates two of these categories: freedom from "unreasonable intrusion" and freedom from "disclosure of private facts."

Because it requires no publicity, the tort of unreasonable intrusion easily could include unreasonable investigation of medical information. Intentional and unreasonable investigation of an individual's mail, bank account, or other personal documents constitutes an actionable invasion of privacy. Only public records

83. In 1956, the Iowa Supreme Court noted that only twenty states had a judicially recognized right to privacy. Bremmer v. Journal-Tribune Publishing Co., 247 Iowa 817, 821, 76 N.W.2d 762, 765 (1956). At present, however, only Rhode Island continues to reject a right to privacy. See PROSSER & KEETON, supra note 76, § 117, at 851 & n.18 (citing Note, Tort Recovery for Invasion of Privacy, 59 Neb. L. Rev. 808 (1980)).

84. For a discussion of this tort aspect, see infra notes 88-96 and accompanying text.

85. For a discussion of this constitutional aspect, see infra notes 97-143 and accompanying text.

86. For a discussion of this statutory aspect, see infra notes 148-83 and accompanying text. These statutes are aimed at fair information practices by government entities and other organizations.

87. For a discussion of the Federal Privacy Act of 1974, see infra notes 165-73 and accompanying text. There are also other federal laws containing privacy guarantees such as those governing drug abuse surveillance, public health, juveniles, and banking.


89. Id. § 652B comment b.
are exempt from the purview of this tort. Because medical records are not public records as defined by the *Second Restatement,* a patient whose record is viewed by non-health care providers without proper authorization could bring suit for tortious intrusion. However, this tort is limited by the requirement that the intrusion be "unreasonable." Disclosure of medical information to a researcher may be deemed wholly "reasonable" in many circumstances, thereby defeating a viable cause of action for the intrusion tort.

The tort of disclosure of private facts is defined by the *Second Restatement* as publicity given to private matters that would be "highly offensive to a reasonable person" and "not of legitimate concern to the public." Although it easily may apply to certain types of medical information, this tort, because it deals with offensive or embarrassing information, requires communication to a large group of persons, not a mere few. The limiting effect of this broad publicity requirement can be illustrated by a typical disclosure situation noted by the Privacy Commission. A witness from the National Institute of Mental Health told the Commission of a member of a research team doing a follow-up study of people who had been enrolled in a methadone maintenance

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90. *Id.* § 652B comment c. Comment c to § 652B provides that "[t]he defendant is subject to liability . . . only when he has intruded into a private place, or has otherwise invaded a private seclusion that the plaintiff has thrown about his person or affairs." *Id.* The comment continues by noting that "there is no liability for the examination of a public record concerning the plaintiff, or of documents that the plaintiff is required to keep and make available for public inspection." *Id.* Thus, disclosure of public records does not give rise to a privacy action. See *Cox Broadcasting Corp. v. Cohn,* 420 U.S. 469 (1975).

91. *Restatement (Second) of Torts,* § 652B comment c (1976). At common law, a "public record" is defined as a record that must be kept in the discharge of a duty imposed by law. *Nero v. Hyland,* 76 N.J. 213, 221-22, 386 A.2d 846, 851 (1978). A public record must constitute a written memorial that is made by a public official who is authorized by law to make the record. *Id.* at 222, 386 A.2d at 851.

Some state statutes expressly exclude medical records from the definition of public documents, making disclosure an invasion of privacy. *See, e.g., Ga. Code Ann.* § 50-18-72 (Supp. 1984). However, other state statutes, such as public disclosure acts, may bring medical records within the ambit of public records. *See Oliver v. Harborview Medical Center,* 94 Wash. 2d 559, 618 P.2d 76 (1984) (medical records of patient at public hospital are public records subject to disclosure under state public disclosure act).


93. *Id.* § 652D comment a. Comment a suggests that the crucial inquiry is whether the communication was public or private. *Id.*

94. See *Privacy Commission Report,* supra note 4, at 309 (quoting *Medical Records Hearings* 83 (July 20, 1976) (testimony of National Institute of Mental Health)).
program. These people had gone to another former enrollee's residence to attend a party on a Saturday night. Upon his arrival at the party the visitor proceeded to introduce himself as a researcher conducting a follow-up study of patients who had been enrolled in the methadone maintenance program.95 Despite the blatant offensiveness of such a disclosure of private information, it is unlikely that it would satisfy the broad publicity requirement for tort recovery under the Second Restatement.96

Thus, although the torts of disclosure and intrusion may be applicable to medical records research in extreme situations, the scope of their protection is inadequate to assure informational privacy in the ordinary situations in which medical records are used. Other legal doctrines are needed to carry out this task.

2. Development of Privacy in Constitutional Law

Although there is doubt as to the precise source of the doctrine, invasion of personal privacy has taken on constitutional dimensions. Constitutional protection has been applied to informational privacy, and could therefore be a source of control on the use of medical records by researchers.

As long ago as 1928, Justice Brandeis, dissenting in a government wiretap case, insisted that the "right to be left alone—the most comprehensive of rights and the right most valued by civilized men," was protected from unjustifiable governmental intrusion by the fourth amendment.97 In another dissent in the same case, Justice Holmes proposed that the fourth amendment might have a "penumbra" within which privacy was protected.98

Later, Justice Douglas raised the notion of penumbral zones of protection to the level of accepted constitutional doctrine. In Griswold v. Connecticut,99 a state ban on contraceptives was held to

95. Id.
96. Compare Vogel v. W.T. Grant Co., 458 Pa. 124, 327 A.2d 133 (1974) (defendant's notifying four persons of plaintiff's debt was not unreasonable publicity) with Brents v. Morgan, 221 Ky. 765, 299 S.W. 967 (1927) (publicizing a customer's overdue account by posting a large sign in a window for public view was beyond reason and thus an invasion of privacy).
97. Olmstead v. United States, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting). Justice Brandeis argued that any unjustified intrusion into an individual's privacy is a violation of the fourth amendment, regardless of the means employed. Id.
98. Id. at 469 (Holmes, J., dissenting). Justice Holmes' dissent was narrower than that of Justice Brandeis. Holmes limited the scope of unjustified privacy intrusions to instances in which officers of the law committed crimes to obtain evidence. Id. at 469-71 (Holmes, J., dissenting).
99. 381 U.S. 479 (1965). For a discussion of the Griswold decision, see Ka
be an unconstitutional intrusion on the privacy of married
couples. The majority found that the first amendment “has a pe-
numbra where privacy is protected from governmental
intrusion.”

Given the amorphous nature of penumbral rights, other jus-
tices have looked instead to the concept of “ordered liberty” as
the framework for privacy protection. In *Rochin v. California*, 101 a
case involving involuntary stomach pumping, Justice Frankfurter

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100. 381 U.S. at 483. The *Griswold* majority took notice of a broad range of protections that, although not expressly addressed in the Constitution, have been enforced judicially as within the spirit of the first amendment. *Id.* at 482. Specifically, the Court characterized the rights to freedom of association and privacy in one's associations as peripheral first amendment rights. *Id.* at 485. Specific guarantees in the third, fourth, fifth, and ninth amendments likewise were held to be sources of the penumbral protections of privacy in relation to one's home or person, because without specific practical applications the express guarantees would be meaningless. *Id.* at 484-86. The Court concluded that the right of married couples to use contraceptives encompassed several fundamental constitutional rights of privacy, and therefore merited protection. *Id.* at 485-86.

Although he agreed with the majority’s aversion to Connecticut’s anti-con-
traceptive law, Justice Black objected strenuously to the *Griswold* majority’s crea-
tion of a constitutional right of privacy. *Id.* at 508-10 (Black, J., dissenting). He feared that the ambiguity inherent in a term such as “privacy” would be ex-
tended to cover any and all imagined offenses against personal dignity. *Id.*

In spite of Justice Black’s objection, this concept is now generally accepted, although his fear of imprecision and expansion of the right has been borne out to a certain extent. A constitutional privacy right has been found to embrace broadly disparate interests, resulting in far-reaching privacy protections. See, e.g., *Moore v. City of East Cleveland*, 431 U.S. 494 (1977) (right to choose to live with non-immediate members of one’s family notwithstanding zoning ordinance to the contrary); *Roe v. Wade*, 410 U.S. 113 (1973) (right to procure an abortion); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (right to buy contraceptives); *Stanley v. Georgia*, 394 U.S. 557 (1969) (right to possess obscene materials in one’s own home); *Nader v. General Motors Corp.*, 57 Misc. 2d 301, 292 N.Y.S.2d 514 (1968) (unauthorized wiretapping and eavesdropping by mechanical means constitute cause of action for invasion of privacy), aff’d, 25 N.Y.2d 560, 255 N.E.2d 765, 307 N.Y.S.2d 647 (1969). While imprecision as to the exact source and scope of the right continues, a right to privacy under the aegis of at least one amendment to the Constitution is firmly established.

Early versions of a constitutional right of privacy were recognized by the
Supreme Court even before *Griswold*. See *Rochin v. California*, 342 U.S. 165
(1952) (right not to have one’s stomach forcibly pumped by police looking for
criminal evidence); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (avoidance of
state-mandated sterilization of certain felons); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (parental right to direct children’s upbringing prevents state from mandating attendance at public school); *Meyer v. Nebraska*, 262 U.S. 390
(1923) (right to have children taught foreign language that was challenged as
inimical to national interest).

101. 342 U.S. 165 (1953). For a discussion of the *Rochin* decision, see
invoked the ordered liberty theory developed in an earlier procedu-
dural due process case. 102 He found that some personal rights—
in *Rochin*, the right not to have one’s bodily integrity violated in a
manner that “shocked the conscience”—are so fundamental that
they are “implicit in the concept of ordered liberty.” 103 These
rights are thus entitled to constitutional protection even without
explicit supportive language in the Constitution. 104 Not surpris-
ingly, courts and commentators have had difficulty finding a satis-
factory construct to explain “privacy” jurisprudence. One
commentator called “privacy” interests an “unrelated bag of
goodies.” 105 Other writers have organized privacy decisions into
taxonomies of interests such as “repose, sanctuary, and intimate
decision”; 106 “self-fulfillment, non-conformity, and dignified
treatment by government agencies”; 107 and “autonomy and inti-
macy.” 108 The Supreme Court itself has attempted to categorize
personal privacy into discrete subject areas that include marital
intimacies, home, family, child-rearing, and procreation. 109 This

102. See *Palko v. Connecticut*, 302 U.S. 319 (1937). In *Palko*, Justice Car-
dozo found the prohibition against double jeopardy to be not so fundamental as
to warrant protection against state action. *Id.* at 328. While this specific holding
has since been overturned, the notion of ordered liberty has survived. See *Bent-
103. 342 U.S. at 169, 172.
104. Justice Black, in an opinion anticipating his *Griswold* dissent, decried
the notions of “ordered liberty” and “fundamental rights” as judicial subjectiv-
ism. *Id.* at 174-77 (Black, J., concurring). Although he concurred in the result in
*Rochin*, Justice Black observed that derivation of rights from judicial predictions
not only would produce disparate results but also could lead to an eventual dilu-
tion of the federal guarantees themselves. *Id.* at 177 (Black, J., concurring).
In *Moore v. City of East Cleveland*, 431 U.S. 494 (1977), a decision made 25
years after *Rochin*, the notion of “ordered liberty” appeared again as the pre-
ferred theory for dissenting Justices Stewart, Rehnquist, and White. There, Jus-
tice White stated:

> There are various “liberties” . . . which require that infringing leg-
islation [here, a restrictive zoning ordinance] be given closer judicial
scrutiny . . . [Interests such as] the right of association, the right to
vote, and various claims sometimes referred to under the general rubric
of the right to privacy . . . weigh very heavily against state claims of
authority to regulate. It is this category of interests which Mr. Justice
STEWART refers to as “implicit in the concept of ordered liberty.”

*Id.* at 548-49 (White, J., dissenting).
106. Note, *A Taxonomy of Privacy: Repose, Sanctuary and Intimate Decision*, 64
City of East Cleveland*, 431 U.S. 494 (1977) (family); *Roe v. Wade*, 410 U.S. 113
(1973) (procreation).
reduction of privacy to a common denominator of home life or intimate family choices may be a reflection of the predilections of the Justice who is writing, or of the particular subject matter of the case, rather than a true characterization of privacy jurisprudence. Because privacy continues to be an umbrella term for a variety of interests, attempts to categorize it generally do not contribute to a substantive understanding of the constitutional parameters of the right to privacy. However, Justice Stevens’ delineation of the informational privacy interest in *Whalen v. Roe* is helpful in analyzing the scope of the right of privacy in the context of medical research.

In *Whalen*, physicians and patients challenged the constitutionality of a New York statute requiring the registration of the names of all patients who had prescriptions for certain legal but potentially abusable drugs. The plaintiffs claimed that a patient identification program of this sort would both infringe upon their personal privacy and have a chilling effect on their pursuit of needed medical assistance.

The Court began its discussion by identifying two sets of interests. The first set, represented by the *Griswold* line of cases, centered around autonomy in intimate, personal, or familial decision-making. These cases are the source of commentators’ categorization of privacy into areas labeled intimate decision-making autonomy, human dignity, and the like. The second set of identifiable interests, labeled “informational privacy,” focused upon disclosure of personal matters, in particular, disclosure that might adversely affect one’s reputation or relations in the community.

The *Whalen* Court determined that the plaintiffs’ claims were based on informational privacy, but found such claims unwarranted because of the sheer number of prescriptions filled each


111. *Id.* at 591. These drugs included opium, cocaine, methadone, amphetamines, and methaqualones, drugs prescribed for conditions varying from heroin addiction to migraine headaches. *Id.* at 593 n.8.

112. For a discussion of *Griswold*, see *supra* notes 99-100 and accompanying text.

113. For a discussion of commentators’ categorization of privacy, see *supra* notes 106-08 and accompanying text.

month among the general state population. 115 In addition, the Court reasoned that no one had been deprived completely of the choice to use the needed medication because the drugs were not prohibited and because patients did not have to face any additional bureaucracy to obtain them. 116 As a result, the Court concluded that the plaintiffs' interest in freedom from disclosure was insufficient to override the state's interest in the control of drug abuse.

The Court dealt with the plaintiffs' informational privacy interest in Whalen in the context of concern for disclosure of information in the drug records. It found that the mere collection of patients' names did not constitute "disclosure" because the information was accessible only to proper persons. 117 Noting that public disclosure could have occurred in Whalen had state employees violated the statute's security provisions, the Court regarded disclosures to state employees administering the program, hospital personnel, insurance companies, and public health agencies as unpleasant but essential intrusions on privacy. The Court concluded that as long as a statute or regulation that mandates these "normal" disclosures as part of modern medical practice contains appropriate safeguards against unwarranted disclosure, a state need go no further in protecting individual privacy. 118

The factual setting of the case undoubtedly played a role in the Whalen Court's evaluation of the freedom from disclosure. Drug abuse is a major social problem requiring stringent measures of control. As a result, states have a strong and legitimate

115. 429 U.S. at 598. This reasoning is something of a non sequitur in constitutional privacy jurisprudence. That other people fill their prescriptions does not mean that the complaining parties are not deprived of their constitutional right to make personal decisions free of the state's shadow. Perhaps the Court regarded this claim as makeweight or at least as insufficient to outweigh a state interest in data collection for prevention of drug abuse.

116. Id. at 603. Again, its reasoning suggests that the Court may not have regarded the privacy claim in Whalen as a serious one. The Court noted that the state has broad policy power to regulate the administration of drugs by the medical profession, within which choices may be exercised by patients in consultation with a physician. Id. at 603 n.30. The Court refused to place much weight on the evidence in the record that a chilling effect had in fact occurred and that some patients were forgoing medication due to fear of the data collection program. The Court's reference to the absence of additional bureaucracy impeding patient access to drugs suggests that the state's relatively passive system of patient data collection would not trigger strict judicial scrutiny of the statute. See Doe v. Bolton, 410 U.S. 179 (1973) (Court held additional bureaucracy to be unconstitutional impediment to women's abortion choice).

117. 429 U.S. at 600-02.

118. Id. at 605-06.
interest in controlling illicit drug traffic. The Court determined that New York’s law was reasonable in light of its purpose. The Court left open, however, the possibility that in other situations a higher standard might be applied. It emphasized that it had

119. Id. at 605. In Whalen, the Court used a different standard from the one generally used to evaluate the propriety of the challenged conduct. The Court evaluated the state interest using the reasonableness standard rather than strict scrutiny. Id. at 597-98. Reasonableness is not the standard ordinarily invoked to evaluate state laws when a “fundamental right” such as privacy is implicated; rather, the strict scrutiny standard is employed. See Moore v. City of East Cleveland, 431 U.S. 494 (1977) (zoning ordinance); Roe v. Wade, 410 U.S. 113 (1973) (abortion law); Griswold v. Connecticut, 381 U.S. 479 (1965) (state contraceptive ban). For a discussion of these cases, see supra notes 99-100 and accompanying text. The Court’s application of the less stringent standard in Whalen may have been due to the specific factual setting, including both the relative remoteness of the threat of damaging disclosures and the state’s interest in an area of enormous social concern. Alternatively, the Court may have rejected the strict scrutiny standard because it did not consider informational privacy to be a fundamental right.

Justices Brennan and Stewart, in separate concurring opinions, articulated two possible interpretations of the Court’s view of whether the right to freedom from disclosure was a fundamental right. Although both justices agreed with the Court’s basic holding, Justice Brennan believed that the Court had recognized an individual’s interest in avoiding sensitive disclosure as an aspect of the right of privacy. 429 U.S. at 606 (Brennan, J., concurring). Justice Stewart, on the other hand, felt that the Court had not recognized such a right. Id. at 608 (Stewart, J., concurring). Justice Brennan stated that he would require the state to demonstrate a compelling interest if it deprived persons of their right to avoid public disclosure of private information. Id. at 607 (Brennan, J., concurring). Justice Stewart, finding that no such right existed, implicitly presumed any reasonable state interest would be sufficient. Id. at 609 (Stewart, J., concurring). Although Justice Brennan’s approach is more consistent with the majority’s own reasoning, Justice Stewart’s view demonstrates the possibility that informational privacy is not a fundamental constitutional right at all.

120. 429 U.S. at 605-06. Justice Stewart’s reasonableness approach, however, was favored in several subsequent lower court decisions. See Barry v. City of New York, 712 F.2d 1554 (2d Cir.), cert. denied, 464 U.S. 1017 (1983); Fadjo v. Coon, 633 F.2d 1172 (5th Cir. 1981); United States v. Westinghouse Elec. Corp., 638 F.2d 570 (3d Cir. 1980); Plante v. Gonzalez, 575 F.2d 1119 (5th Cir. 1978), cert. denied, 439 U.S. 1129 (1979). Notably, in Plante, the Fifth Circuit indicated that the disclosure requirements of Florida’s Sunshine Amendment did not necessarily implicate fundamental rights, and it declined to use a strict scrutiny standard. 575 F.2d at 1134. See Fla. Const. art. 2, § 8 (requiring certain elected officials to make public details of their personal finances). Instead, the court chose a variation of the reasonableness test, cautioning that the test required more than a showing of mere rationality. 575 F.2d at 1134. Furthermore, the court noted the Supreme Court’s warning “against giving heightened attention to cases involving new ‘fundamental interests.’ ” Id. (citing San Antonio Indep. School Dist. v. Rodriguez, 411 U.S. 1 (1973)).

An even more cautious posture was adopted in a 1981 Sixth Circuit decision, where the court contended that the Supreme Court recognized no general right to nondisclosure of private information. J.P. v. DeSanti, 653 F.2d 1080 (6th Cir. 1981). Adopting the language of a 1976 Supreme Court decision, the DeSanti court maintained that the only constitutionally protected privacy interests were those that were “implicit in the concept of ordered liberty,” or “funda-
not reached the question of "unwarranted disclosure of accumulated private data . . . by a system that did not contain [a security provision]." As a result, similar statutes reflecting strong state interests could be subjected to strict scrutiny and possible invalidation under the fourteenth amendment in the event of public revelation of sensitive private data and in the absence of a mechanism for screening the data's dissemination.

Two other cases, Paul v. Davis and California Bankers Association v. Schultz, suggest that a state's interest in law enforcement is a strong factor in the Supreme Court's balancing of personal against societal interests. In Paul, plaintiff Davis was a newspaper photographer who had been arrested but never convicted for shoplifting in Louisville. Davis' name and photograph appeared on an "active shoplifters" flier that the city police chief's office had circulated to shopkeepers. Davis sued the police chief under 42 U.S.C. § 1983 for defamation and deprivation of his constitutional right to privacy. Writing for the majority, Justice Rehnquist found that mere damage to reputation without injury...
to one's employment or other economic interest was insufficient to sustain a claim of deprivation of a due process "liberty" interest. This rather harsh result appears to have hinged on the Court's fear that any other outcome would open the Civil Rights Act to abusive and frivolous claims against state authority. The holding was also supported by the Court's determination that a mere reputational interest was insufficient to trigger due process "liberty" guarantees. Rejecting Davis' claim that his right to privacy had been violated, the Court asserted that "disclosure of the fact of his arrest on a shoplifting charge" did not implicate the type of fundamental right that had been recognized in the Roe v. Wade line of decisions that had begun with Griswold. With this stance, the Court essentially discounted its previous recognition of informational privacy interests.

In his dissent in Paul, Justice Brennan focused on the majority's discussion of the Civil Rights Act, asserting that the Court's privacy holding was not necessary. He chastized the majority for introducing the right of privacy into consideration only to re-

126. 424 U.S. at 698-99, 706-10. Justice Rehnquist cited several cases involving the stigmatization of government employees who had lost their jobs in the 1950s because government officials had branded them "subversives." Id. at 705 (citing Peters v. Hobby, 349 U.S. 331 (1955) (Civil Service Commission's Loyalty Review Board, acting on its own motion in removing and barring employee from federal service, went beyond its jurisdiction); Weiman v. Updegraff, 344 U.S. 183 (1952) (Oklahoma law denying employment solely on basis of organizational membership violated due process clause since it classified innocent with knowing association); Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123 (1951) (suit for declaratory and injunctive relief filed by organizations designated as communist on Loyalty Review Board list should not have been dismissed for failure to state claim)). These cases do not stand for the general proposition that the due process clause may not be expanded to protect federal employees from the loss of their jobs. While the result in the cases appears somewhat heavy-handed when applied to the facts of Paul, it is difficult to match the federal government's interest in non-communist employees with Louisville's campaign against shoplifting.


128. 424 U.S. at 712-13. The Court apparently disregarded the dissent's point that the flier asserted Davis was an active criminal, thus confusing arrest with proven guilt. Justice Brennan, for himself and two other dissenters, wrote a stinging rebuke of the Court's cavalier treatment of the American criminal justice system's presumption of innocence. Id. at 714-24 (Brennan, J., dissenting).

129. In Whalen, the majority had characterized the reputational interest in Paul as only one of "at least two" sets of privacy interests, the other being an interest in avoiding the disclosure of intimate personal data. 429 U.S. at 599, 600 n.26. For a discussion of these characterizations in Whalen, see supra notes 110-14 and accompanying text.

ject it without ever offering any real analysis of the right.131

Justice Brennan also expressed his fear that, as a result of the majorities holding in Paul, the doctrines cited in a series of recent state and federal decisions based on privacy notions and involving circumstances favoring limits on the power of government to disseminate unresolved arrest records would "never have the opportunity for full growth and analysis."132

Another Supreme Court case, California Bankers Association v. Schultz133 undercuts Justice Stevens' recognition in Whalen of a privacy right based on disclosure of embarrassing information. In California Bankers, banks and their clients challenged the constitutionality of record-keeping provisions of the Bank Secrecy Act of 1970134 as violating depositors' right to privacy. The Act requires banks to maintain records of customers' identities and photocopies of customers' checks for any domestic transactions over $10,000, which in turn can be utilized in criminal, tax, and regulatory proceedings.135 Taking a balancing approach and relying heavily on the state's interest, Justice Rehnquist, writing for the majority, found the law enforcement objectives of the Act to be a proper exercise of congressional power that did not impinge on a protected interest.136 The Court found that the plaintiffs, including depositors and the American Civil Liberties Union, had brought the suit prematurely because no disclosures that might threaten their privacy interests had occurred. The banks themselves were found not to have an unrestricted right to keep transactions confidential, and thus their privacy claim failed on the merits.137 Once again, state interests were deemed to outweigh the right to privacy from disclosure.

California Bankers, like Whalen and Paul, included dissentss supporting the privacy claims. Justice Douglas questioned the "big

131. 424 U.S. at 735 (Brennan, J., dissenting).
137. Id. at 66.
brother's quality of the Act and found a serious threat to bank customers' legitimate expectations of privacy, especially because one's financial transactions reflect one's protected beliefs, ideas, and associations. The Douglas dissent, along with those by Justices Brennan and Marshall, expressed concern that the majority's blanket approval of broad record-keeping reflected an illogical assumption that all bank depositors are imminent lawbreakers. The dissenters deplored the seizure of personal data occasioned by the record-keeping requirement as a sweeping violation of the fourth amendment. These dissents reflect the dilemma of the Court as it attempts to achieve a workable balance between individual rights of privacy and the state interest in maintaining personally identifiable data.

When the Court attempts to evaluate the constitutionality of the disclosure of intimate data regarding an individual, it evaluates three interrelated factors: the importance of the state's interest, the strength of the plaintiff's claims, and the degree of protection the privacy right should be afforded against the disclosure of intimate data.

In the extreme situation, an individual's interests in protecting his or her reputation from ruin, in maintaining the secrecy of financial records and all of the personal information that they contain, and in keeping the use of strong medication confidential, are no match for the state's interest in prevention and detection of crime. However, in less extreme cases, there remains a large area in which differing results might be reached. For example, were it not the state but a research team that wanted access to sensitive patient data, the state interest might be viewed as less significant, although deference to the exigencies of "modern medical practice" mentioned in Whalen could allow a court to reject any claim of privacy invasion. At the present time, the cases give no clear indication of whether a state's interest in the advancement of medical knowledge is as strong as its interest in law enforcement.

138. Id. at 82-86 (Douglas, J., dissenting). In his concurrence, Justice Powell warned that if the Bank Secrecy Act had provided for stringent record-keeping for the whole banking population, and not just for those with transactions in amounts greater than $10,000, he would have recognized a constitutional privacy interest. Id. at 78-79 (Powell, J., concurring).

139. Id. at 82-97 (Douglas, Brennan, Marshall, J.J., dissenting).

140. 429 U.S. at 602.

141. In a 1980 decision, the Sixth Circuit did enforce a subpoena issued by the National Institute for Occupational Safety and Health to obtain medical records of a company's employees on file in the plant physician's office in order
With respect to the importance of the privacy interest involved, there are strong similarities between the plaintiffs’ interests in *Whalen* and *Paul* and the interest of patients in the nondisclosure of their medical histories. As has been documented in the Privacy Commission Report and at least one other government-funded study, individuals whose medical records have reached potential employers, insurance companies, or other third parties have suffered losses of employment opportunities, setbacks in medical treatment, and other detrimental effects because of the revelation of erroneous, misunderstood, or embarrassing information contained in their files. Similarly, the aggrieved parties in *Whalen* and *Paul* feared social opprobrium and job insecurity; in *Whalen* some even avoided medical treatment for fear of disclosure or stigmatization. The Supreme Court has indicated that such interests are not protected so long as there is a sufficient countervailing state interest and adequate security provisions regulating data collection and use.

A dictum in *Whalen*, however, modifies this conclusion. The Court stated that as long as informational privacy, that is, an expectation of freedom from unwarranted disclosure of personal data, remains an accepted and viable aspect of the constitutional right to privacy, a plaintiff may have a cause of action for unwarranted revelation of personal information. In the medical research context, such a claim could arise where medical records are left unsecured in such a way that nonresearch personnel can peruse them, or where records are deliberately disclosed to persons outside of the research team. A patient’s cause of action also could arise either where the hospital or doctor neglects to establish proper security or where the users of the medical data violated the existing security procedures. A patient would first have to demonstrate that compensable injury, such as economic or job...
loss, resulted from the revelation. General damages for loss of reputation or other personal embarrassment, as well as punitive damages for intentional acts causing harm, could then be asserted.

Taken together, Whalen, Paul, and California Bankers suggest that although private data can be collected for a legitimate purpose, its dissemination must be safeguarded so as to prevent broad public revelation or exposure to casual outsiders. Such protection for data collection no doubt applies to medical records as well. Patients’ medical histories, after all, are at least as sensitive as their financial transactions. It remains unclear, however, exactly how significant a role the need for such protection will play in the Court’s balancing process.

Constitutional support for a right to privacy has been asserted in Supreme Court decisions for half a century. However, the issue has been ensnared in a philosophical debate in which both the existence and scope of the right have been questioned. Because of this, the Court has employed an after-the-fact balancing of interests, making it difficult to predict the strength of privacy protection in a given situation. While this balancing approach may provide for flexibility in judicial opinions, it does not assure individuals any consistent personal privacy protection. The analysis offered by Justice Stevens in Whalen is helpful, but in view of the decisions in Paul and California Bankers, hardly determinative. In sum, although constitutional doctrine does provide some insight into the problem of privacy protection, it offers few solutions to the issues raised by the use of medical records in scientific research.

3. Statutory Protections

Because issues involving intrusions of privacy are currently receiving a great deal of legislative attention, recently enacted statutes dealing with the subject provide useful guidelines for understanding the current state of privacy law in the area of medical research. However, although a number of state statutes recognize the right of privacy, most apply only to the commercial exploitation of one’s name or image. For example, the New York Civil Rights Law provides only minimum protection for the indi-

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146. See infra note 177 and accompanying text.
147. For example, the Whalen Court acknowledged the potential damage that could occur from a security breach revealing legitimate drug use by patients. 429 U.S. at 600-01.
individually, merely prohibiting the exploitation by a commercial enterprise of an individual's name or visage for profit without his or her consent.148 Other privacy statutes are modeled after the New York statute,149 suggesting that they are likely to be interpreted in a similarly narrow manner. More recently, federal and state privacy statutes have been extended in order to control consumer credit reporting agencies150 and financial institutions.151 State legislation that would apply to institutions such as hospitals, whether or not they receive public funding, or to practicing medical personnel, remains almost entirely in the proposal stage.152

148. N.Y. Civ. Rights Law § 50 (McKinney 1976). Section 50 provides:

A person, firm or corporation that uses for advertising purposes, or for the purposes of trade, the name, portrait or picture of any living person without having first obtained the written consent of such person, or if a minor of his or her parent or guardian, is guilty of a misdemeanor.

Id. This statute afforded no protection to the plaintiff in Doe v. Roe because the psychiatrist had not commercialized the plaintiff's likeness. 93 Misc. 2d 201, 211-12, 400 N.Y.S.2d 668, 675 (Sup. Ct. 1977). The court, however, did find a cause of action for privacy invasion, derived from public policy and statutes. Id.


152. See PRIVACY COMMISSION REPORT, supra note 4, at 491-92. The report notes that while various states have statutes granting patients a right of access to their medical records, or regulating disclosure of medical data, there is little comprehensive state legislation in existence. Id. In response, the Privacy Commission advised that states enact their own statutes incorporating the protection for medical records recommended by the Commission so that individuals would not have to rely on the federal government to enforce the rights established by the Commission's recommended measures and so that the recommended rights and obligations could be extended to public and private medical care providers who do not need to qualify for Medicare or Medicaid participation. Id. at 493.

Two states, Montana and Rhode Island, recently have enacted legislation
Among the various state legislative efforts, California's Information Practices Act of 1977 comes closest to approximating the spirit of what the Privacy Commission contemplated. Typical of such state legislation, this statute affirms a right of privacy as a "personal and fundamental right protected by . . . the Constitution of California and by the United States Constitution." The California statute recognizes that an individual's right of privacy is directly affected by the kind of disclosure and use made of identifiable information about him in a record. In particular, the law acknowledges the danger that data misuse poses to the data subject's employment, insurance, and credit opportunities; and to preservation of his or her due process rights. Where it applies, the statute requires written consent of the data subject as a prerequisite to disclosure of pertinent record information.

California's law could be applied easily to medical research data. "Personal information" as defined in the statute explicitly includes records of medical treatment among the protectable data. Furthermore, California's law would appear to apply to a hospital and its institutional review board. In this respect, the bill differs from other legislation because its application is not limited to "agencies" but applies broadly both to organizations, however organized, and to natural persons.

The general purpose of the California statute is to prohibit nonconsensual disclosure of personal information. There are, however, several troublesome exceptions to the prohibition that substantially could prevent the law's application to medical record research and could render patient data vulnerable to an end-governing the confidentiality of medical records. See Mont. Code Ann. §§ 50-16-301 to -314 (1983); R.I. Gen. Laws §§ 5-37.3-1 to -11 (Supp. 1984). The Montana statute governs: when consent is required to release or transfer confidential health care information; when a third party such as an insurance company may transfer confidential health care information to the physician of an affected person; and when an affected person may expunge any part of medical information that he believes is in error, or request the addition of relevant information. Mont. Code Ann. §§ 50-16-312 to -314 (1983). The Rhode Island statute is very similar.

154. For a discussion of the Privacy Commission Report, see supra note 4.
156. See Privacy, A Public Concern, supra note 160, at 42-60 (presenting sample legislation from California, Michigan, and Minnesota and a model bill from the National Association of State Information Systems).
158. Id. § 1798.24(b).
159. Id. § 1798.3(b).
160. Id. § 1798.3(d).
One such exception is the apparent automatic availability of information to a recipient who has given advance written assurance that the subject of the information will not be identified and that the information will be used solely in research. In accordance with the Privacy Commission's recommendations on medical records, California exempted disclosure "to a person who has provided the agency with advance adequate written assurance that the information will be used solely for statistical research or reporting purposes, but only if the information to be disclosed is in a form that will not identify any individual." A second exception to the disclosure prohibition operates when there is a showing of compelling circumstances affecting the health or safety of a data subject.

These blanket exceptions for two broadly defined categories of research are not sufficiently sensitive to individualized problems. When individual contact with selected patients is proposed, a researcher may require patient identification; the burdens imposed by the California statute may hinder seriously the researcher's ability to conduct that research. Similarly, the exemption requiring "compelling" circumstances opens a wide range of issues. Although "compelling" is not defined in the law, the exception could be interpreted to include all research intended to render further medical treatment to the data subject. Arguably, most research falls within this exception. Once a researcher has demonstrated a "compelling" need to contact a subject, he or she will be afforded ready access to records. The researcher's only obligation is to notify the patient once there has been disclosure. As such disclosure can now be made with legislative sanction, records actually may become more readily available to researchers than before passage of the law.

On the federal level, the Federal Privacy Act of 1974 (Privacy Act) recognizes a constitutional right to personal privacy, but applies only to agencies within the executive branch of the government. The reason for this limitation is that the Privacy Act was designed primarily to inhibit federal agencies from abusing their legitimate duties of collection, maintenance, use, and dis-
semination of individually identifiable data.\textsuperscript{167} The Privacy Act was an afterthought to the Freedom of Information Act.\textsuperscript{168} After enacting a law that was to open government operations to public view, Congress became concerned that a great deal of personal information regarding citizens that was collected by federal agencies would become available for public scrutiny. Congress responded with the Privacy Act in order to give individuals some control over the government's data.\textsuperscript{169}

Most of the provisions of the Privacy Act address concerns that are dealt with elsewhere in privacy law. For example, non-consensual disclosure is prohibited in the Privacy Act by the same language that appears in California's statute, with identical exemptions for statistical research and compelling health circumstances.\textsuperscript{170} Additional sections of the Privacy Act deal with agency requirements and rules peculiar to government-related matters.\textsuperscript{171} An agency head, for example, has the power to promulgate exemptions to certain subsections of the Privacy Act. These discretionary exemptions relate to keeping an accounting of disclosures, granting individuals access to their own records, and seeking only information relevant to the statutory purposes of research projects. While such exemptions would seem to dilute the Privacy Act's original goal, the agency-promulgated exemptions apply only if the records will be used in law enforcement investigations or investigations for employment eligibility.\textsuperscript{172} As a result, a hospital or federally funded research

\textsuperscript{167} The Privacy Commission, created by the Privacy Act, recommended in its mid-1977 report that the Privacy Act be revised to clarify ambiguities but that it "not be extended in its present form to organizations outside the Federal government," recognizing that states, in conjunction with input from the private sector, should initiate further privacy legislation. \textit{Privacy Commission Report, supra} note 4, at 497 (emphasis in original).


\textsuperscript{169} \textit{See Privacy Commission Report, supra} note 4, at 504-05, 520.

\textsuperscript{170} For a discussion of California's privacy statute, see \textit{supra} notes 153-64 and accompanying text.

\textsuperscript{171} 5 U.S.C. § 552a(c). (f) (1982).

\textsuperscript{172} \textit{Id.} § 552a(k).
team could not take advantage of the exemptions unless its research were to be used for those purposes.

Although ostensibly the Privacy Act applies only to governmental agencies, its application could extend to a vast amount of medical research in the private sector. First, the Privacy Act includes a provision concerning federal contractors that potentially covers medical research conducted in hospitals. Section 552a(m)(1) specifies:

When an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of this section to be applied to such system. For purposes of subsection (i) of this section [regarding criminal penalties] any such contractor . . . shall be considered to be an employee of an agency.173

Assuming that HHS funding for a medical research project renders the contracting hospital an “employee” of HHS, then the research would become an “agency function” and would trigger the Privacy Act, rendering the research and the system of information it generates subject to the Privacy Act’s protections.

Moreover, the Privacy Commission has explicitly stated that recipients of discretionary federal grants for research projects, who were originally not thought to be “federal contractors,” should have been included in the Privacy Act.174 Thus, whether the explicit language of the Privacy Act or the Privacy Commission’s interpretation of it is used, hospitals and their IRB’s are apparently within its ambit.

California’s Information Practices Act and the Federal Privacy Act share several premises.175 The first is that there should be no information system the very existence of which is secret. Under the Privacy Act, each agency to which the Act applies must publish an annual notice in the Federal Register detailing what information systems are being kept, categorizing the types of persons included, and listing the “routine uses” to be made of the

173. Id. § 552a(m)(1).

174. See id. § 552a(a)(1) (defining agency as in 5 U.S.C. § 552(e)). See also Parsons, A Comment on the Privacy Act of 1974, in Privacy, A Public Concern, supra note 151, at 180 (Appendix XVII).

records. California has a similar requirement of annual notice to its Secretary of State. This “notice” then becomes a matter of public record.

In practice, however, these openness requirements are of limited utility to the average citizen. A system of information generated by a medical records research project must contain data retrievable by the patient’s name or to her patient identification if it is to be subject to a state notice requirement. If patient-identifying information has been removed before a research team obtains the records for research, the system of information its project generates presumably would not come under the legislative requirements for notice. Moreover, even when formal notice is given, actual disclosure depends entirely on the potential subject’s individual initiative. He must discover on his own whether a system of information of which he would be a likely subject has been established.

Furthermore, increased patient access is important to ensure accuracy of records. While it is the recordkeeper’s duty—as the statutes examined here explicitly require—to see to it that records are accurate for their intended use, the records may contain errors or may be incomplete. Complete accuracy in large record systems may be impossible.

Closely related to this concern over patient access is an awareness that a patient should be in a position to exert some control over third-party access to intimate data. This is a potential source of antagonism between patient and researcher. The data’s accuracy, after all, may not make the information any less embarrassing or threatening to one’s privacy. If a patient absolutely controls the access to his or her record, he or she may

176. 5 U.S.C. § 552a(e)(4)(A)-(D) (1982). Subsection (j), however, provides that notice need not be published if the data is being maintained for law enforcement purposes or for federal employment screening. Thus, health data used to determine eligibility for a federal job may not be accessible to the data subject.

177. CAL. CIV. CODE § 1798.9 (West 1985). Section 1798.9 provides in pertinent part:
Each agency maintaining a system of records containing personal or confidential information shall file with the Office of Information Practices the notice specified in Section 1798.10. Such notices shall be filed with that office by such agencies on the first day of July of each year. Such notices shall be permanent public records.

Id.


179. See CAL. CIV. CODE § 1798.41 (West 1985) (disclosure of personal data relating to others).
forbid its use in research. A patient may refuse to permit access because of a strongly held principle, the satisfaction of a whim, or the fear of exposure of the record's information beyond the research team. The grant to an individual of the right to control the access to intimate data implicates basic policy considerations along with one's degree of commitment to independent medical research.

Although the statutes provide for civil damages and other remedies for failure to comply with access and disclosure provisions, the patient's control of access remains extremely limited. Under both state and federal legislation, in order to recover, a patient has to have suffered an "adverse effect." This term is not defined, but the Supreme Court, in Whalen, Paul, and California Bankers, has indicated that such injury would have to take some tangible, pecuniary form. Fear of social opprobrium or speculation as to loss of credit or employment opportunities probably would not constitute an "adverse effect," nor would a claim that the patient had foregone further medical treatment because of embarrassment from the disclosure. Furthermore, as previously noted, no written consent of the patient will be required when a patient's identity has been expunged from a record or when a research team has demonstrated a compelling reason related to the patient's health or safety for using identifiable information. In such cases, a patient will have no power to refuse access to his or her record.

Statutory attempts to protect privacy are far from complete. Even if medical records are within the general scope of the federal and state legislation described above, the statutes contain exemptions that could allow research to go forward without full protection. In addition, the damage provisions do not seem to be strong enough to deter wrongful disclosure.

C. Conclusion

Privacy rights of subjects of biomedical research are not adequately protected by existing statutory and case law. In its pres-

181. 5 U.S.C. § 552a(g)(1)(D) (1982); CAL. CIV. CODE § 1798.45(c) (West 1985).
182. For a discussion of these cases, see supra notes 110-39 and accompanying text.
183. For a discussion of these exceptions to patient protections, see supra notes 162-64 and accompanying text.
ent state, the law lacks the uniformity and certainty required to protect individuals' expectations of privacy and confidential communications. Constitutional theory, another potential source of protection, has also failed to respond to these needs, perhaps because a court is not the proper forum in which to balance the need for individual protection against the needs of medical research. Accordingly, existing standards provide neither adequate guidance for, nor sufficient protection to patients and researchers. A strong and comprehensive position is needed. This position should create a clear right to privacy in this context and at the same time recognize that there may be situations in which privacy protection has to yield to other needs of society.

IV. RECOMMENDATIONS FOR PRIVACY PROTECTION

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission), directed to study the privacy interest of patients,\textsuperscript{184} heard extensive testimony from witnesses on current and proposed mechanisms for ensuring the confidentiality of patient medical records.\textsuperscript{185} In its final report, the President's Commission acknowledged the tension between the law and ethics of medical privacy and the need for detailed empirical exploration. The President's Commission recognized patients' need for privacy in their medical records, but it also acknowledged the importance of these records in medical research and the continuing needs of scientists to have access to them.\textsuperscript{186} In the end, however, the President's Commission provided no set of recommended statutory or administrative rules to resolve these

\textsuperscript{184.} President's Commission Report, supra note 7, at 34-35. The enacting legislation directed the President's Commission to study "the ethical and legal implications of current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained in such records." Id. For a further discussion of the work of the President's Commission, see supra note 7 and accompanying text.

\textsuperscript{185.} A consultant, Professor William Winslade, was commissioned to prepare a report on the philosophical aspect of privacy and confidentiality of medical records. See W. Winslade, A Report on Privacy and Confidentiality in Health Care (1982)(unpublished report). The report was presented to the President's Commission in a hearing in March, 1982. See President's Comm'n for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Transcript of Proceeding: Meeting No. 18 (March 13, 1982) [hereinafter cited as Proceeding Transcript].

\textsuperscript{186.} President's Commission Report, supra note 7, at 37.
conflicts. Instead, the report merely encouraged health care providers to give greater heed to privacy concerns.

In spite of the report’s rather lenient approach, the need for a regulatory construct in this area is of continuing urgency. The following discussion proposes a model that attempts to balance the conflicting interests in light of the principles and problems set forth above.

As a necessary first step in protecting biomedical research subjects from invasion of their privacy, a statute must clearly and explicitly state that there is a right of privacy in medical information. Such a statement should acknowledge expressly the patient’s right to privacy with respect to information in his or her medical records and the concomitant obligation of the doctor and institution to protect such information from disclosure. This would give the patient or subject—not the physician or institution—control over medical records, and make disclosure the exception rather than the rule. In the absence of such a statutory expression, the clear enunciation of that right by the President’s Commission, the Department of Health and Human Services (HHS), or some other federal body could be an interim step. The need for protection has been stated clearly by these bodies but the full scope of the right has not been delineated.

Once this definitive principle has been established, a mechanism that would serve privacy interests and yet accommodate medical research should be developed, either in a legislative or regulatory format. Regulatory modification is an appropriate method because it is flexible and builds on the model that already has been established to balance a researcher’s need for data

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187. Professor Winslade’s report recognizes the desirability of uniform and comprehensive regulations, but stops short of proposing a federal statutory minimum. It suggests that the individual states may be “politically, pragmatically and logically” best suited to implement regulations, guided by a national policy. W. WINSLADE, supra note 185, at 7.

188. It has been argued that the inadequacy of standards governing the disclosure of medical records is due to the patient’s lack of collective representation. Physicians and researchers are represented by active lobbying groups; patients “lack knowledge and power in this area.” PROCEEDING TRANSCRIPT, supra note 185, at 13. This conclusion may not be entirely fair to the medical community. The American Medical Association, the American Psychiatric Association, and especially the American Medical Record Association do support measures to protect patients’ confidentiality, recognizing that if privacy concerns are protected, the patient-physician relationship will be strengthened. W. WINSLADE, supra note 185, at 41.

against the potential for physical harm to the research subject. The balancing function that has been used to evaluate issues involving physical harm could be used in a substantially similar form to weigh and protect privacy interests.

Institutional review boards (IRBs) are ideally suited to perform this balancing function because they are set up to screen all research proposals. Although current regulations emphasize that the IRB's primary role is to balance the risk of physical harm to a patient against society's need, a recognition of the patient's right to privacy protection simply would add another dimension to the IRB's analysis. This added dimension would not require an IRB to change its function or its general practice. Regulations could be issued to amend and supplement the existing HHS model used to control all biomedical and behavioral research approval today. The IRB would continue to apply a risk-benefit analysis in determining whether an individual research protocol should proceed, and the present focus would be expanded to include privacy factors in deciding whether to approve specific research requests. The imposition of this additional criterion will not overburden the IRB because the information needed to analyze the privacy question is included in the information that the IRB already receives. This proposal creates an additional standard—patient privacy—and requires the IRB to apply that standard in the same manner as the IRB applies the standard protecting the patient's physical welfare. Statutory or regulatory authority should thus require the IRB, created under HHS authority, to assure a review of privacy rights and sufficient privacy protection in all research. The IRB will then become the primary enforcement device for the protection of a patient's privacy.

Once this new standard is imposed on the IRB, changes in the current standard for informed consent should be made.


193. For a discussion of the IRB and the information it receives, see supra notes 15-27 and accompanying text.

Typically, before an individual participates in a study, his or her prior informed consent must be obtained. To obtain informed consent, the researcher must first disclose to the patient or subject the potential risks to physical well-being and the potential benefits accruing to the individual or to society, and then allow the individual to make an independent decision. As noted above, however, informed consent becomes problematic where research involving medical records is concerned because researchers often use records created long before the research design had been developed. In this type of research, appropriately known as retrospective research, it may be difficult to locate the individuals involved. Similar problems exist with respect to prospective research projects where the record is created during the study. There, even though the subject is easily located, prior consent is not really meaningful since the subject would not be in a position to evaluate the potential risks to his or her well-being at the time consent is given. There may be, however, a lesser need to obtain informed consent to the release of information in the context of medical records than in the context of physical experiments, inasmuch as a threat to privacy is usually less severe than a threat to physical harm.

The IRB, therefore, should be required to approve research access in all cases, but it should screen the cases to distinguish between those in which individual consent is necessary and those in which it is not. When consent is not required, the IRB should then act to assure protection of the privacy interest of the patient and set the terms and conditions of researcher access to patient records. In this way, personal privacy will be protected, but the degree of protection will be responsive to the circumstances. In those cases in which IRB protection alone would be sufficient, necessary research will not be hindered by the need to obtain personal informed consent. Assuming, therefore, that the IRB can utilize a screening device to distinguish between those cases in which informed consent is needed and those in which it is not, the essential task is to develop standards for the IRB to apply in making that distinction. This involves a balancing of the potential

196. PROCEEDING TRANSCRIPT, supra note 185, at 101.
197. Id.
198. For a discussion of the criteria for IRB approval, see supra notes 20-27 and accompanying text.
199. See PROCEEDING TRANSCRIPT, supra note 185, at 107-09 (discussing standards that should be applied and the situations in which they are needed).
degree of harm to the individual endangered by the invasion of his privacy against the benefits to society accruing from the anticipated medical research.\footnote{200}

A. Retrospective Review of Record

The initial question when addressing the review of records created in the past is whether the subject can be located.\footnote{201} Often, even if it is theoretically possible, the cost of a large-scale location effort will make the effort prohibitively expensive, and its scale will make it unduly difficult.\footnote{202} Accordingly, it is usually assumed that individual consent is not necessary in this circumstance and that IRB review alone will suffice. This assumption, however, should not be applied in all cases; the requisite degree of review will depend on the specifics of the studies. Individual subjects can be divided into three distinct categories: (1) those persons who will be identified in the study or who will be contacted by the researchers on a follow-up basis; (2) those who, while not identified in the study, will have potentially damaging information revealed about themselves; and (3) those who will not be identified in the study or contacted and as to whom only nondamaging or benign information will be revealed.

Situations in which the individual will be identified in the study or will be the subject of a follow-up interview present a relatively clear case. If the research involves a follow-up study in which researchers will not only know the subject’s identity, but also will be dealing with him or her on a personal basis, there exists a substantial risk to the individual’s personal privacy, or at least a substantial threat to the expectation of privacy that was created when the original record was developed.\footnote{203} In this situation, the initial cost justification for doing away with consent in the retrospective review situation does not apply because the project design contemplates actual contact between the researcher...

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\footnote{200. President’s Commission Report, supra note 7, at 37.}

\footnote{201. Proceeding Transcript, supra note 185, at 101.}

\footnote{202. An analogous balancing test was performed in Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306 (1950). The Court in Mullane recognized the cost of notifying multiple beneficiaries of a common trust fund whose interests or addresses were unknown to the trustee. Id. at 319.}

\footnote{203. Professor Winslade indicates that the majority of patients may not realize the extent to which access to medical records can be legitimately gained by third parties. W. Winslade, supra note 194, at 2. This may be increasingly true as medical information is computerized and made available to a wide variety of users. See generally Boyer, Computerized Medical Records and the Right to Privacy: The Emerging Federal Response, 25 Buffalo L. Rev. 37 (1975).}
and the subject. Thus, informed consent should not be circumvented; there is a significant threat to privacy and the subject can be located easily. The researcher should be required to obtain informed consent in all cases of this type.

In obtaining this consent, the investigator, whether in person or by proxy, must explain to the subject the nature of the study and the potential threat to the individual's expectation of confidentiality or protection of privacy before the subject's medical records are perused or before he or she is contacted on a follow-up basis. Only such an informed consent will protect the identified subject from violations of privacy.

The second category of individuals who might be involved in a retrospective study are those who will not be identified or contacted, but about whom potentially damaging information can be obtained. For example, research into whether individuals with certain types of diseases abuse certain types of drugs, or whether child abuse coincides with certain types of educational and familial background, falls into this category. Consent should be obtained for studies involving such "sensitive" information. Although the individual in these instances may not be identifiable, potentially embarrassing and sensitive information will be disseminated to researchers with whom the individual has not dealt and over whom he or she has no control. Only the individual involved can measure the effects of the disclosure on his or her well-being. The only adequate protection, therefore, is to require informed consent. Although this requirement may impede research, the nature of the material in the record requires some control on the part of the individual. Thus, in this situation the researcher should fully inform the subject and obtain the subject's informed consent before access is had to the subject's medical records.

In the third situation, the patient is neither identified by the study nor contacted during it. In addition, the information in the file is benign and will cause no adverse consequences if released. This type of material might refer to basic physical characteristics and health information. Here, research should proceed without individual consent, but only after IRB approval. The IRB should


205. See Committee on Federal Legislation, Privacy of Medical Records, 35 REC. A.B. CRY N.Y. 488, 500 (1980) (supporting the Privacy Commission's recommendation to require a patient's consent in writing before any further use of information about the patient is permitted).
review the research protocol and require the investigator to provide procedural safeguards adequate to protect the subject’s privacy interests. These safeguards should include removal of names or identifying characteristics from research reports. Additionally, the IRB should require security measures to prevent unauthorized access. In this regard, the IRB would be performing functions similar to those required of the state agency in *Whalen v. Roe*. The IRB, therefore, would function both as a patient consent surrogate and an experimental control mechanism.

While this proposal removes primary control of privacy from the individual subject and places it upon the IRB, it adequately protects the needs of the individual. The proposal permits medical research to proceed, but recognizes that each individual has a right to privacy which the investigator must protect. The researcher’s access without the subject’s consent should be limited to those situations in which either there is a very low risk of privacy invasion or it is practically impossible to contact large numbers of persons within reasonable time and cost constraints. With respect to benign information about nonidentified subjects, this approach incorporates a recognition of both the right of privacy and the need for medical research to go forward where there is little risk to the individual.

B. Prospective Review of Record

Consent should be required routinely with respect to prospective record review because the practical impossibility argument for removing consent in the retrospective situation does not apply. In these cases, the subject is in a position to give an authorization to the record custodian to release his or her records for specific types of medical research. Requiring informed consent in these cases also allows those people with a general aversion to research to exclude themselves from the potential re-


207. The standard for surrogate consent was set out in *Mitchell v. W.T. Grant*, 416 U.S. 600 (1974). There the Court held that a Louisiana sequestration statute that did not require the defendant to be notified prior to seizure of property was constitutional. *Id.* at 619. The Court reasoned that because the statute directed a judge to issue the order, required the filing of an affidavit reciting details of the plaintiff’s claimed right, and provided opportunity for a post-trial hearing and for damages for wrongful sequestration, the defendant’s rights had not been abridged. *Id.* at 618.

208. This procedure would merely require a modification of the existing practice of obtaining informed consent for physical risks.
While a consent form in prospective research cases will warn the subject of the potential disclosure and use of his or her medical record, it may not be sufficient to ensure that the consent is fully informed. At the time the record is being compiled, the subject may not know what information will be ultimately included in the record or the content of the research plan in which that information eventually will be used. In order to ensure that the individual granting consent is fully aware of the content of the record, a separate consent form should be used at the end of each treatment segment in the hospital or office. The individual who is the subject of the record should be presented with his or her record, allowed to review it, and then permitted to sign a form authorizing access to information included in the record. The individual also should have the opportunity to decline to participate altogether or to exclude some particular bit of information. However, because an individual who grants a prospective consent may not be fully aware in advance of the use to which the information will be put, the IRB should play an active role both to assess the need for informed consent and to serve as a surrogate in those circumstances in which actual informed consent prior to each use of the information is not required.

In situations in which the research subject will be identified or in which potentially sensitive or damaging information will be revealed by the research process, there is no substitute for informed consent. A blanket authorization simply would be inadequate. The subject should consent specifically to the actual research protocol on an individualized preresearch consent form.

209. Rosen, supra note 204, at 58. The President’s Commission notes that the patient’s expectation of confidentiality is critical to the success of the physician-patient relationship. In many instances, the physician can obtain information necessary to effect treatment only if the patient believes that the information will remain confidential. President’s Commission Report, supra note 7, at 36. Winslade suggests that in addition to stricter disclosure standards, patients ought to receive access to their records. Access to records would permit patients to ensure that the information contained in the records is accurate and would foster the patient’s sense of trust in the physician. See W. Winslade, supra note 185, at 94 (discussing developments in the physician-patient relationship and in the content of medical records).

210. The researcher may be equally unable to predict the ultimate content of a patient’s records. Were this not the case, a patient theoretically could be fully informed and could give a sufficient and comprehensive consent at the outset of the research.

211. This function is essentially the same as that performed for retrospective research review. For a discussion of the IRB’s function in retrospective research review, see supra notes 201-07 and accompanying text.
The IRB should also require maximal protection in terms of research methodology. Thus, in cases of identified subject users and sensitive information, the researcher should not be permitted to hide behind a blanket authorization or a prior record consent form.

With respect to situations in which the individual is not going to be identified and will be the subject of benign disclosure, a prior consent in the record should be sufficient, so long as the IRB is convinced that the disclosure in the consent form adequately apprises the subject of the potentiality for inclusion in future research. If the IRB is so persuaded, consent in the record will substitute for further IRB review of privacy interests. The IRB, however, must still ensure that the records are subject to controls and that the investigator meets his or her burden of protecting the confidentiality and the privacy of the research subject.

Thus, with respect to prospective record review, informed consent will lessen the IRB's task because each potential research subject will have the opportunity to make his or her own authorization. Because this authorization takes place before the research does, however, it will still be necessary for the IRB to review and classify research proposals. Finally, while research with records to be created presents fewer difficulties for the IRB, there are still sufficient problems to justify this proposal. A requirement for consent review at intervals may produce some additional work for the IRB, but it will ensure that individual confidentiality will receive maximal protection without hindering the progress of needed medical research.

V. Conclusion

Today there is a strong and growing belief that an individual's personal history and private life should be subject to his or her own disposition and control. While the doctrinal label and the degree of protection may vary, there is a clear recognition that unauthorized disclosure should be prevented. The use of personal information contained in medical files in connection with bio-medical and behavioral research is an important but inadequately protected facet of this more general problem of privacy. Although totally prohibiting the use of personal

212. A legal precedent for this consent requirement was established in United States v. Westinghouse Elec. Co., 638 F.2d 570 (3d Cir. 1981). There the court required that employees be notified of, and given an opportunity to object to disclosure of their medical records.
information contained in medical records would frustrate the advance of scientific research in many areas of important social concern, more can be done to protect the individual from potential abuses. A mechanism that would protect an individual's privacy and at the same time facilitate necessary bio-medical and behavioral research is needed.\textsuperscript{213} The utilization of the institutional review board as a control and screening device would achieve this end. The creation of this right to privacy, in unison with control mechanisms whereby the individual can consent to invasions of his or her privacy, would afford privacy of medical records the same status accorded other personal rights protected originally by the Helsinki Accords and today by the HHS guidelines. As absolute strictures may prevent and frustrate needed societal gains, there may be situations where, with appropriate safeguards proposed by the experimenter and implemented by the IRB, medical research may proceed without express consent. The foregoing model is specific enough to provide guidelines yet general enough to be easily and efficiently administered within the existing medical research framework, thereby accommodating the conflicting needs of personal privacy and medical science.

\textsuperscript{213} It should be noted that the success of any new regulatory scheme will depend in part on the sanctions set out in the regulations. \textit{See generally} W. Winslade, \textit{supra} note 185, at 71 (discussing sanctions).