COMMENTS

Genetic Test Results and the Duty to Disclose: Can Medical Researchers Control Liability?

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Increased knowledge of heredity means increased power of control over the living thing, and as we come to understand more and more the architecture of the plant or animal we realize what can and what cannot be done towards modification or improvement. . . .

It is not, however, in the economic field, important as this may be, that Mendel's discovery is likely to have most meaning for us: rather it is in the new light in which man will come to view himself and his fellow creatures. . . . The little that we know today offers the hope of a great extension in our knowledge at no very distant time. If this hope is borne out . . . and if also man decides that his life shall be ordered in the light of this knowledge, it is obvious that the social system will have to undergo considerable changes. 1

I. INTRODUCTION

Increasingly, medical clinicians and researchers use human genes to identify and predict specific traits that are inherited from parents and passed on to children. As ninety-nine percent of human beings’

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DNA molecules are identical, each person shares with every other more biological similarities than differences. Our individuality or personal genetic past and future resides in that one percent of our DNA molecules that is unique. Thus, a genetic test is a way to learn about oneself. Reliable genetic tests for inherited diseases have made the early detection and treatment of inherited diseases possible. For example, prenatal and perinatal genetic screening aids parents in making reproductive decisions. Today, physicians routinely screen fetuses and nearly four million newborns for known genetic defects. Prenatal genetic screening also gives parents an opportunity to choose the characteristics of their child. Collecting and storing blood from the umbilical cord allows doctors to establish the health of the newborn, to perform autologous blood transfusions in premature infants, and, most recently, to perform hematopoietic stem cell transplants in newborns with abnormal bone marrow stem cells.

Yet, not all genetic test results bring good news. Although your physician may have the means to diagnose your genetic conditions, he or she may not be able to offer an effective treatment. As a result, many people at risk for a genetic disorder choose not to undergo genetic testing.

2. Id.
3. Law enforcement officials have also benefited from the development of reliable genetic tests. “The DNA Proficiency Act of 1995 authorized the Federal Bureau of Investigation (FBI) to establish a national index of DNA . . . profiles.” This project, known as the Combined DNA Index System (CODIS), was completed in September 1998 and consists of four files of DNA records: a population file, a forensic file, a convicted offender file, and a missing persons file. John W. Hicks, The Use and Development of DNA Databanks in Law Enforcement, in STORED TISSUE SAMPLES: ETHICAL, LEGAL, AND PUBLIC POLICY IMPLICATIONS 305 (Robert F. Weir ed., 1998). Recently, the New York City police commissioner proposed to help solve crimes and reduce the number of repeat offenders by collecting DNA samples along with fingerprints on every person arrested. DNA Tests Sought with Every Arrest, SEATTLE POST-INTELLIGENCE, Dec. 15, 1998, at A13.
7. For example, less than 14% of the people at risk for Huntington’s disease choose to be tested for the disease. “As medical research unlocks the secrets of genetics, the battle over who can have access to your personal life story is just getting under way in courts and legislatures.”
The value of genetic information in predicting the present and future health of specific individuals has not gone unnoticed by third parties. Today, insurers, employers, schools, the military, courts, and families often request access to an individual's genetic test results. The debate over who should have access to genetic information intensifies as the list of genetically identifiable and potentially harmful diseases and traits continues to grow. Courts and legislatures are now in the center of this controversy.

This Comment examines research on the human genome and explores the existence of a duty to disclose genetic test results in clinical and research settings. Part II begins with a hypothetical describing how such a duty to disclose can arise. Part III (A-C) describes advances in the sequencing of the human genome, the development of reliable tests for genetic disorders, and issues regarding access and control of genetic test samples and results. Part III (D) looks at the tort law basis for a general duty of physicians to disclose medical information, the specific duty of clinical physicians to disclose the presence of genetic disease, and the specific duty of the nonphysician medical researcher to disclose genetic test results. Part III (E) explores justification based on a tort-contract hybrid for an expectation interest, on the part of a research subject and a third party, in the disclosure of genetic test results, as defined by informed consent. Part III (F) examines a tort-contract-property hybrid basis for invoking an affirmative duty to disclose genetic test results that combines a negligence standard of tort law with a tort-contract based duty of informed consent to form an individual property interest in genetic information.

This Comment concludes that whether a duty to disclose genetic test results exists depends on whether the court recognizes the plaintiff's claim as based in tort, contract, or property. If the court recognizes the claim as based in tort, then the status of the researcher will determine whether a special relationship exists. If the court recognizes the claim as based in tort-contract, then the status of the sample, informed consent, and the subject's expectation interest will determine the existence and scope of a duty to disclose. If the court bases the claim on the property right of the research subject in his or her genetic information, the court's analysis will be a hybrid of negligence and contract law that emphasizes the recognized property interest in informed consent. As a result, medical researchers may best protect themselves from liability surrounding the duty to disclose genetic test results by making the principal investigator a nonphysician and care-


8. FURROW ET AL., supra note 4, at 180-82.
fully drafting the informed consent document. The following hypothetrical is useful in illustrating these issues.

II. HYPOTHETICAL

Physician Doe routinely conducts breast biopsies on suspicious masses found in the breasts of her patients. Before each surgery, Dr. Doe explains the procedure and the attendant risks and obtains informed consent from her patients. A pathology lab examines the breast biopsies collected by Dr. Doe and catalogues and stores the samples. After reviewing the pathology report, Dr. Doe contacts her patients with the biopsy test results.

Geneticist Roe develops a genetic test designed to predict an increased risk of breast cancer in women. Geneticist Roe and a team of epidemiologists hope to confirm the validity and reliability of the new genetic breast cancer test. Their proposed research protocol requires the analysis of breast tissue samples. The researchers expect to reduce their data collection costs by analyzing previously collected breast tissue samples. Geneticist Roe realizes that pathology labs throughout the country routinely store tissue samples sent to them for analysis. The Roe research team contacts the pathology lab used by Dr. Doe and requests access to the repository of breast tissue samples stored in their freezers.

Attorney Black is retained by Ms. Jones, a patient of Dr. Doe, after she learns that her breast tissue, removed by Dr. Doe during a breast biopsy procedure, is being used for research purposes. Attorney Black reviews the informed consent document signed by Ms. Jones prior to surgery and fails to find a clause stating that tissue samples removed from Ms. Jones would be used in current or future research projects. Furthermore, the informed consent document did not notify Ms. Jones of the existence of a genetic test that could determine whether she was at an increased risk for breast cancer or the fact that this genetic test would be performed on her tissue sample. Attorney Black files a claim against Dr. Doe and the Roe research team asserting the following ten causes of action: (1) conversion, (2) lack of informed consent, (3) breach of fiduciary duty, (4) fraud and deceit, (5) quasi-contract, (6) bad faith breach of the implied covenant of good faith and fair dealing, (7) intentional infliction of emotional distress, (8) negligent misrepresentation, (9) slander of title, and (10) declaratory relief.

Attorney White is retained as defense counsel by the Roe research team and Dr. Doe. Attorney White's defense centers on
whether the Roe research team or Dr. Doe had an affirmative duty to disclose genetic test results to Ms. Jones.

The issues raised by this hypothetical fact pattern will be the subject matter of the background and analysis sections that follow.

III. BACKGROUND

A. The Human Genome

The human genome\(^9\) consists of approximately 70,000 to 100,000 pairs of genes\(^10\) found in twenty-three equivalent pairs of chromosomes.\(^11\) All nucleated somatic cells\(^12\) in the human body contain two sets of chromosomes.\(^13\) The individual genes within each chromosome are strung together in a double helix\(^14\) form of deoxyribonucleic acid (DNA). The DNA in each nucleated cell of the same body is identical.\(^15\) Each DNA molecule contains about three billion nucleotides.\(^16\) Nucleotides combine with one another in one of four possible base pairs.\(^17\) A useful visual analogy describes the nucleotide combination as a spiral staircase.

DNA is composed of a long double helix, which looks like a spiral staircase. The backbone of this molecule (i.e., the handrails and balustrade of the staircase) consists of repeated sequences of phosphate and deoxyribose sugar. Attached to the sugar links in the backbone are four types of organic bases: Adenine . . . , Guanine . . . , Cytosine . . . , and Thymine . . . . The steps of the staircase are formed by pairs of these bases . . . .  

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9. The human genome is the complement of genetic material in a set of chromosomes. DAVID T. SUZUKI ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 579 (3d ed. 1986).
10. A gene is the fundamental unit of heredity and is responsible for carrying information from one generation to the next. Id. at 578.
11. A chromosome is “a linear end-to-end arrangement of genes.” Id. at 575.
12. A somatic cell does not fuse with a cell of an opposite mating type to form a unique diploid cell or zygote. As such, the genes of a somatic cell are not passed on to future generations. Id. at 586.
13. Id. at 34-35.
14. The double helix form was first introduced by Watson and Crick and describes two interlocking chains of nucleotides that are joined by hydrogen bonds between paired bases. ARTHUR P. MANGE & ELAINE JOHANSEN MANGE, GENETICS: HUMAN ASPECTS 296-97 (1980).
15. SUZUKI, supra note 9, at 34.
16. A nucleotide is the basic building block of nucleic acids. Id. at 582. Each nucleotide molecule contains one of four nitrogen bases, a sugar and a phosphate group. Id.
17. Id. at 188.
DNA molecules encode a person's genes with a blueprint for the human organism. With the exception of identical twins, no two people have identical DNA.  

B. Genetic Disease and Testing

In 1988 Congress initiated the Human Genome Project (HGP), a fifteen-year, three billion dollar research project designed to map and sequence the human genome. One goal of the HGP is to develop diagnostic tests and treatments for the more than five thousand diseases with a genetic basis. The need for reliable diagnostic tests and treatments is extraordinary, as more than fifteen million Americans suffer from inherited diseases. Studies estimate that fifty-three out of one thousand individuals will suffer from an inherited disease by the time they reach the age of twenty-five.

Technological advances of the 1980s made it possible to cut DNA molecules into segments in order to isolate and analyze the function of a specific gene. By studying large families affected with a specific genetic disease, researchers are now able to identify DNA markers that are always present in people who have or will develop the disease. The DNA marker guides the researcher to the region of the chromosome on which the mutated gene is found. Today, scientists expect the Human Genome project to have ninety percent of the eighty thousand genes in human DNA identified by the year 2000, nearly five years ahead of schedule.

19. Identical twins have the same genotype. However, somatic mutation is possible due to environmental factors. MANGE, supra note 1, at 531. See generally SUZUKI, note 9, at 2.


23. Id.

24. The mutated genes responsible for fragile x syndrome, Marfan syndrome, cystic fibrosis, Duchenne muscular dystrophy, sickle cell anemia, myotonic dystrophy, some forms of inheritable cancer, heart disease, and rare forms of Alzheimer's disease are examples of the types of disorders that have been isolated recently. See generally C. Thomas Caskey, Molecular Medicine a Spin-Off from the Helix, 269 JAMA 1986 (1993).

C. Bioethical Implications of Genetic Research with Human Subjects

Today, scientists, doctors, religious organizations, courts, and legislative bodies are beginning to grapple with the possible consequences of genetic research. Chief Justice Burger outlined a number of the Supreme Court's concerns regarding genetic research in his majority opinion in *Diamond v. Chakrabarty.*

To buttress his argument, the petitioner, with the support of amicus, points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better to "bear those ills we have than fly to others that we know not of."

As a result, the majority concluded that policies regarding genetic research should be left to the legislature.

[W]e are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

Reliable genetic tests and treatments for inherited diseases should reduce health care costs and result in profits for clinical physicians, medical researchers, research institutes, and pharmaceutical and biotechnology companies. In addition, improved reliability of genetic

27. Id. at 316.
28. Id. at 317.
29. Id.
tests should lead to an increase in the use of these tests in the clinical medical setting and forensics.

Because genetic tests are easily done on routinely collected blood and tissue samples, patient privacy advocates voice concerns over the access and control of DNA samples and other genetic information. Furthermore, the increased use of genetic tests encourages patient privacy advocates to seek restrictions on the collection, storage, and oversight of blood and tissue samples.

In 1993, in response to concerns of privacy advocates, the U.S. Department of Energy's Ethical, Legal, and Social Issues Working Group (ELSI) of the Human Genome Project developed guidelines for DNA banking designed to protect the privacy of individuals whose DNA was stored. ELSI determined that, in order to protect the privacy of individuals whose DNA was stored, any proposed genetic privacy act must also regulate the acquisition and analysis of the DNA samples. The ELSI working group prepared a model Genetic Privacy Act for federal legislation. The workgroup identified six core provisions of the proposed Genetic Privacy Act: (1) the collection of DNA for analysis is impermissible without an informed voluntary consent; (2) DNA analysis cannot be undertaken without the verification of the execution of written authorization; (3) the scope of DNA analysis cannot exceed that specified in the written authorization; (4) DNA is the property of the individual from whom it was collected; (5) DNA samples must be destroyed once the authorized DNA analysis is completed; and (6) persons who store private genetic information in the course of their everyday business must keep the information confidential and cannot disclose it unless authorized in writing by the individual from whom it was collected.

The fundamental premise of the proposed act was that no stranger should have or control identifiable DNA samples or private genetic information about an individual, unless that individual has specifically authorized the collection of DNA samples for the purpose of genetic analysis, has authorized the creation of that private information, and has access to and con-
trol over the dissemination of that information.\textsuperscript{36}

ELSI's proposed Genetic Privacy Act pertains solely to issues of privacy and confidentiality of already collected genetic information and, as such, does not address other policy issues surrounding the creation or collection of genetic information.\textsuperscript{37}

More recently, the Human Genome Organization (HUGO)\textsuperscript{38} asked a group of ethicists to consider whether close relatives of patients should have access to stored genetic information and under what circumstances researchers might use tissue and blood samples collected during routine medical care.\textsuperscript{39} In December 1997, after reviewing eighty official policy statements on the control of blood and tissue samples and the control of genetic information, the ethicists released a draft of six recommended guidelines.\textsuperscript{40}

First, genetic information is personal and familial. If a condition is serious and inheritable, then the patient should be encouraged to inform his or her relatives of their increased risk.\textsuperscript{41} Second, blood and tissue samples collected during routine medical care can be used for research, given the following: the patient is notified of the use, the patient did not object to the use, and the blood or tissue samples have been anonymized.\textsuperscript{42} Third, samples collected during routine medical care and stored by the researcher prior to the institution of a policy of notification can be used in research provided that the blood or tissue samples have been anonymized.\textsuperscript{43} Fourth, research samples can be used for other research provided that the patient is notified of the potential other use, the patient did not object to the other use, and the blood or tissue samples have been anonymized.\textsuperscript{44} Fifth, the researcher must institute security mechanisms in order to ensure confidentiality.\textsuperscript{45} Finally, "unless authorized by law, research results should [not]

\begin{itemize}
\item \textsuperscript{36} Id.
\item \textsuperscript{37} Id.
\item \textsuperscript{38} HUGO is an international group of scientists and others working on the Human Genome Project. HUGO supports the collection of data used in efforts to sequence the human genome and organizes workshops to encourage researchers to think about ethical, social, and legal issues relating to the Human Genome Project. See Joan Stephenson, Ethics Group Drafts Guidelines for Control of Genetic Material and Information, 279 JAMA 184 (1998).
\item \textsuperscript{39} Id.
\item \textsuperscript{40} The ethicists did not address issues regarding the ownership of research samples.
\item \textsuperscript{41} Stephenson, supra note 38, at 185.
\item \textsuperscript{42} Id. Although originally collected with identifying information, anonymized research samples have been irreversibly stripped of all identifiers. Karen K. Steinberg et al., Use of Stored Tissue Samples for Genetic Research in Epidemiologic Studies, in STORED TISSUE SAMPLES: ETHICAL, LEGAL, AND PUBLIC POLICY IMPLICATIONS 82, 84 (Robert F. Weir ed., 1998).
\item \textsuperscript{43} Stephenson, supra note 38, at 185.
\item \textsuperscript{44} Id.
\item \textsuperscript{45} Id.
\end{itemize}
be disclosed to institutional third parties . . . even with patient consent.'\textsuperscript{46}

The HUGO recommendations, however, are not internally consistent. The HUGO ethicists begin with the proposition that genetic information is personal and familial. As a result, they recommend that a person with a serious genetic disorder should inform his blood relatives of his condition. However, if HUGO's second, third, and fourth propositions are adhered to, then the person could never learn the results of his genetic tests, because the medical researcher would be required to anonymize the blood or tissue samples.

Although the recommendations of the ELSI workgroup and the HUGO ethicists address some of the issues surrounding the disclosure of genetic information, additional risks are posed by the collection and analysis of genetic material. Consider the risk posed by groups who control resources and may use genetic information to ration an individual's access to these resources.\textsuperscript{47} However, a more subtle risk concerns how the disclosure of genetic information threatens the contract and property interests of the individual from whom the genetic information was collected. Challenges to disclosure of genetic information can be based in three areas of law: tort, contract, and property. The facts relevant to deciding whether an affirmative duty to disclose genetic test results exists will vary depending on the area of law from which the court recognizes the claim to arise.

\textit{D. Tort Law and the Disclosure of Medical Information}

1. A Physician's General Duty to Disclose Medical Information

Under common law, a person owes no duty to control the conduct of another or to warn others of anticipated conduct.\textsuperscript{48} As a result, courts have found that patients have limited privileges against disclo-
sures of personal medical information by their physicians. An exception to the common law rule exists when the defendant has some special relationship with the person whose conduct needs to be controlled or is in a relationship with a foreseeable victim of the conduct.

Section 314A of the Restatement (Second) of Torts enumerates four relationships in which an actor is under a duty to another:

(1) A common carrier is under a duty to its passenger to take reasonable action . . . . (2) An innkeeper is under a similar duty to his guests. (3) A possessor of land who holds it open to the public is under a similar duty to members of the public who enter in response to his invitation. (4) One who is required by law to take or who voluntarily takes custody of another under circumstances such as to deprive the other of his normal oppor-

49. See generally Derrick v. Ontario Community Hosp., 120 Cal. Rptr. 566, 571 (Cal. Ct. App. 1975) (concluding that while a hospital had no common law duty to warn the plaintiffs, a mother and her daughter, that the daughter had contracted a contagious disease, a reporting statute did impose a duty on the attending physician to advise the mother and daughter of the contagious disease); Tooley v. Provident Life and Accident Ins. Co., 154 So. 2d 617, 618 (La. Ct. App. 1963) (upholding a physician's disclosure of his female patient's medical records to her husband on the grounds that the plaintiff's husband had a right to his wife's medical records and possessed the right to disclose the records to others because the husband "is head and master of the community"); Hague v. Williams, 181 A.2d 345, 345 (N.J. 1962) (holding that a physician can disclose information about an infant's congenital heart condition to an insurer because a patient's right of nondisclosure can be superseded by the interest of society in an honest and just result or a legitimate interest in the patient's health); Curry v. Corn, 277 N.Y.S.2d 470, 471 (N.Y. Sup. Ct. 1966) (holding that a physician can disclose information pertaining to his female patient to her husband because the information may have a bearing on the marital relation); Berry v. Moench, 331 P.2d 814, 817-18 (Utah 1958) (finding that medical information is conditionally privileged due to the rule of good sense and customary conduct of good will, but the happiness and well-being of the young lady courting the plaintiff were interests sufficient to justify disclosure of the plaintiff's mental status by his physician).

50. Tarasoff, 551 P.2d at 343 (citations omitted). See also Olson v. Children's Home Soc'y of Cal., 252 Cal. Rptr. 11, 13 (Cal. Ct. App. 1988) (having knowledge of a genetic condition in a child given up for adoption fails to create a duty to disclose such information to blood relatives who may have an interest in the information, because no special relationship existed between the biological mother of the child given up for adoption and the Children's Home Society of California); Vause v. Bay Medical Center, 687 So. 2d 258, 264 (Fla. Dist. Ct. App. 1996) (holding that an action for medical negligence could not be filed absent privity between the patient and the physician); Calwell v. Hassan, 925 P.2d 422, 431-32 (Kan. 1996) (refusing to find a physician-outpatient relationship to be a special relationship because the relationship did not create a situation where the physician could control the conduct of the patient); Ellis v. Peter, 627 N.Y.S.2d 707, 709 (N.Y. App. Div. 1995) (ruling that a physician treating a patient for tuberculosis had no duty to warn the patient's wife of the risks of her contracting tuberculosis from her husband, because the physician and the wife did not have a physician-patient relationship, the doctor did not breach a statutory duty to the wife, and the doctor did not owe the wife a duty of reasonable care); Bradshaw v. Daniel, 854 S.W.2d 865, 872 (Tenn. 1993) (holding that the existence of the physician-patient relationship is sufficient to impose upon the physician a duty to warn identifiable third parties in the patient's family of foreseeable risks of the patient's illness).
tunities for protection is under a similar duty to the other.\textsuperscript{51}

Yet, the duty arising out of a special relationship is only "to exercise reasonable care under the circumstances."\textsuperscript{52} At least one court has looked beyond the special relationship between the psychotherapist defendant and his patient and held that the foreseeability of harm to the plaintiff, the moral blame of the defendant, and the prevention of future harm were additional considerations in finding an affirmative duty.\textsuperscript{53}

2. The Specific Duty of a Physician to Disclose Genetic Test Results

The duty of a physician to disclose the presence of genetic disease is rarely addressed in case law. Typically, courts have only addressed issues surrounding the impact and use of genetic tests in causes of action claiming wrongful birth, wrongful life, questions of paternity, failure to warn third parties of genetic transferability of a disease, and sufficiency of forensic evidence.

For example, in \textit{Schroeder v. Perkel},\textsuperscript{54} the New Jersey Supreme Court considered whether a defendant physician owed a duty to the plaintiff parents to diagnose their daughter's illness and inform them that she had cystic fibrosis.\textsuperscript{55} The court reasoned that "the scope of duty in negligence . . . is coextensive with the reasonable . . . conse-

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\item \textsuperscript{51} \textit{Restatement (Second) of Torts} § 314A (1965).
\item \textsuperscript{52} \textit{Restatement (Second) of Torts} § 314A cmt. e (1965).
\item \textsuperscript{53} See L.J. Deftos, \textit{Genomic Torts: The Law of the Future—The Duty of Physicians to Disclose the Presence of a Genetic Disease to the Relatives of Their Patients}, 32 U.S.F. L. Rev. 105, 132 (1997). \textit{See also} Jablonski v. United States, 712 F.2d 391, 398 (9th Cir. 1983) (finding a psychiatrist's failure to warn the patient's girlfriend of the patient's violent tendencies was the proximate cause of the girlfriend's death); Reisner v. Regents of the Univ. of Cal., 37 Cal. Rptr. 2d 518, 521 (Cal. Ct. App. 1995) (holding that a physician had a duty to warn the patient or her parents of the danger of her HIV diagnosis in order to protect unknown third parties from harm); Werner v. Varner, Stafford, & Seaman, 659 So. 2d 1308, 1310 (Fla. Dist. Ct. App. 1995) (ruling a physician owed no duty to a motorist for failing to warn a patient not to drive while taking an antiepileptic medication because a duty is only owed to identifiable parties not the public at large); Ranier v. Frieman, 682 A.2d 1220, 1223 (N.J. Super. Ct. App. Div. 1996) (citations omitted) (concluding that an ophthalmologist, as a professional, owes a duty to the patient and to third parties who will foreseeably rely on his skill or care because, "existence of a duty is a question of law to be determined by the court as a matter of fairness and policy by 'weighing the relationship of the parties, the nature of the risk, and the public interest in the proposed solution'"); Estate of Morgan v. Fairfield Family Counseling Ctr., 673 N.E.2d 1311, 1324 (Ohio 1997) (holding that a psychotherapist treating a patient in an outpatient setting did have a special relationship with the patient because (1) a physician can have a duty to others with whom he has no relationship, (2) a duty can result from the public's interest in containing risks, and (3) a physician has a duty to protect others from a danger of which he is aware or should be aware).
\item \textsuperscript{54} 432 A.2d 834 (N.J. 1981).
\item \textsuperscript{55} \textit{Id.} at 838
\end{itemize}
quences of the negligent act in question." Because a family is bound together with the fibers of life, when one member of the family is damaged by a negligent act, the whole family suffers the consequences. Therefore, the court concluded that a physician's duty might extend beyond the interests of the patient to the immediate family members of the patient who might be adversely affected by the breach of the physician's duty.

Similarly, in *Pate v. Threlkel*, the Florida Supreme Court adopted the approach of the New Jersey Supreme Court when it considered whether a physician has a duty to warn his or her patient of a genetically transferable disease and to whom a duty to warn of the nature of a disease run. A Florida medical malpractice statute imposes a statutory standard of care that requires a reasonably prudent health care provider to warn a patient of the genetically transferable character of the patient's condition. Because the case went to the supreme court on appeal from an order granting the physician's motion to dismiss, the record was not developed with regard to expert testimony on the issue of standard of care. As a result, the court accepted the plaintiff's allegations that, pursuant to the standard of care, the defendant physician was under a duty. While past decisions required privity between the physician and the patient to maintain a cause of action against a physician, the court noted that in other professional relationships the privity requirement had been relaxed to extend the rights of identified third parties to recover from a professional because that party was the intended beneficiary of the standard of care. Accordingly, the *Threlkel* court concluded that because the prevailing standard of care created a duty to warn that plainly benefited identified third parties, the physician's duty must run to those third parties.

In *Safer v. Estate of Pack*, the New Jersey Supreme Court again found itself faced with the issue of whether a physician has a duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition that extends beyond the patient to identified members of the patient's family who may be affected by the physi-
cian's breach. There, the plaintiff sued her father's physician for failing to warn her of the risks that passed to her from her father's inheritable form of colon cancer. Although the court ruled that the physician owed a duty to his patient and his patient's immediate identifiable family, much like the Florida court in Pate, the court's ruling was narrower than the Pate court's in defining the scope of the circumstances in which the duty to warn would be satisfied by informing the patient.

The Safer court posited that it may be possible for a conflict to arise between the duty to warn and a patient's expressed preference that nothing be revealed to family members about the patient's condition. In such a conflict, a court would be faced with determining, as a matter of law, whether there are or should be limits to physician-patient confidentiality. While these decisions addressed a physician's duty of care, many nonphysicians are also involved in genetic research. Whether a nonphysician genetic researcher owes a duty of care to his or her research subject is explored in the following section.

3. The Specific Duty of a Nonphysician Medical Researcher to Disclose Genetic Test Results

No court has yet been faced with deciding whether a nonphysician medical researcher has an affirmative duty to disclose genetic test results to a research subject or other third party. Under the common law of tort, the nonphysician medical researcher owes no duty to disclose unless a special relationship exists between the researcher and the research subject or third party that imposes a duty upon the researcher. However, although a researcher-research subject relationship is not enumerated in section 314A of the Restatement of Torts, those relationships enumerated in section 314A were not intended to be exclusive. The duties associated with section 314A arise from the special relationship between the parties, and the special relationship creates a special responsibility. In general, the law recognizes a duty to aid or protect in any relationship of dependence or of mutual dependence.

66. Id. at 1190.
67. Id. at 1192.
68. Id.
69. Id. at 1193.
71. See RESTATEMENT (SECOND) OF TORTS § 314A cmt. b (1965).
72. Id.
73. Id.
74. Id.
Like a physician-patient relationship, a nonphysician medical researcher-research subject relationship generally arises through contract. Because a nonphysician medical researcher possesses specialized knowledge, that knowledge may serve to make the research subject dependent on the researcher. Furthermore, the researcher’s specialized knowledge may serve to make the researcher a fiduciary of the research subject.

A fiduciary relationship could also be supported under a theory of the nonphysician medical researcher acting as an agent. Agency is a fiduciary relationship created by the manifestation of consent by one person to another that the first person will act on the second’s behalf and subject to the second’s control and consent to act. Consequently, a nonphysician medical researcher acting as an agent of the research subject would owe a duty of loyalty to his or her research subject. Thus, recognizing the specialized knowledge of the researcher and accepting the agency argument, a court, under tort law, could view the nonphysician medical researcher-research subject relationship to be a special relationship that supports an affirmative duty.

However, circumstances exist where a nonphysician medical researcher’s broad duty to disclose genetic test results would conflict with prevailing medical, social, and legal policies. For example, a duty to disclose anonymized research samples would be impossible for the researcher to fulfill. Similarly, the researcher’s duty of disclosure could be precluded by a statute, or by a research subject’s express wish for nondisclosure, informed consent.

An Illinois appellate court was recently faced with such a situation. The Illinois Masonic Medical Center operates a research pro-

75. However, if the research subject’s samples are anonymized, then the possibility that the researcher-research subject relation is based on unilateral dependence or mutual dependence seems to be greatly reduced, if not impossible.

76. See Richard Delgado & Helen Leskovac, Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice, 34 UCLA L. Rev. 67, 108 (1986); Theodore R. Lebang & Jane L. King, Tort Liability for Nondisclosure: The Physician’s Legal Obligations to Disclose Patient Illness and Injury, 89 DICK. L. Rev. 1, 5 (1984) (theorizing that as courts expand the doctrine of informed consent and broaden the physician’s fiduciary disclosure obligation, the personal rights of a patient are emphasized so as to grant the patient control over his or her body); Marjorie Maguire Shultz, From Informed Consent to Patient Choice: A New Protected Interest, 95 YALE L.J. 219, 259 (1985) (theorizing that a physician’s specialized knowledge makes her a fiduciary to those who depend on her, thereby requiring the physician to justify her competence in the transaction through disclosure and seeking the agreement of the patient).

77. See RESTATEMENT (SECOND) OF AGENCY § 1(1) (1958).

78. See id. § 387 (“Unless otherwise agreed, an agent is subject to a duty to his principal to act solely for the benefit of the principal in all matters connected with his agency”).


gram designed to reduce the incidence of cystic fibrosis. The research protocol involves the removal of several ova from a female research subject to be tested for the presence of the cystic fibrosis gene. Healthy ova, not containing the diseased gene, are then fertilized and implanted into the female research subject.

The plaintiffs in Doe v. Illinois Masonic Medical Center were the parents of a baby girl born with cystic fibrosis after her mother underwent the preimplantation procedure described above. The Does had one older son with cystic fibrosis. Therefore, they decided to undergo the experimental procedure.

The issue before the Illinois appellate court was whether the Illinois Medical Studies Act precluded the production of all documents relevant to the preimplantation genetic testing procedure. Because the legislative intent of the Illinois Medical Studies Act was "to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease," the court concluded that the interests of the plaintiffs must yield to the interests of confidentiality, privacy, and peer review within medical institutions. As a result, all documents relating to the research protocol, including the hospital Internal Review Board (IRB) approvals of the research protocol, could not be produced under the Illinois Medical Studies Act.

The Doe decision is one example of a statute precluding a duty to disclose information surrounding medical research data collection and analysis. The facts available in the Doe opinion do not indicate the

81. If the preimplantation procedure had been successful, the Doe's daughter would have been the first baby born without cystic fibrosis as a result of the research protocol. Id. at 708.
82. Id.
83. Id.
84. Id. The Illinois Medical Studies Act provides that: "[a]ll information used in the course of . . . medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation, shall be privileged, strictly confidential and shall be used only for medical research." Id. at 709.
85. Id. at 710-11 (citing Niven v. Siqueira, 487 N.E. 2d 937, 942 (Ill. 1985)).
86. Id. at 711.
87. The court noted that this decision should not inhibit patients from maintaining causes of action for medical malpractice, because the Medical Studies Act does not prohibit access to a patient's own medical records, and the patient could depose all persons involved in his or her treatment and hire experts to define the quality of care received. Id.
88. In Washington, § 42.48.040 of the Revised Code of Washington defines four circumstances under which a research professional may disclose research records: (1) the research subject or the subject's personal representative has given informed written consent; (2) "the researcher reasonably believes that disclosure will prevent or minimize injury to [the subject] and the disclosure is limited to information necessary to protect the [subject]"; (3) the research data is disclosed for the purposes of auditing a research program; or (4) the research data is disclosed in response to a search warrant or court order. WASH. REV. CODE § 42.48.040 (1998).
professional status of the researchers involved in the research protocol at issue. Rather, the court noted that the Illinois Medical Studies Act extends to protect all medical research that advances hospital conditions and patient care, or reduces the prevalence of disease or mortality.\textsuperscript{89} As a result, in Illinois, both physician and nonphysician medical researchers are afforded the same protections under the Illinois Medical Studies Act.\textsuperscript{90}

In addition to its discussion of nonphysician disclosure, the \textit{Doe} decision implicates another tort-contract basis for supporting a finding of no duty to disclose for medical researchers: informed consent.

\textbf{E. Informed Consent and the Research Subject/ Third Party Expectation Interest}

1. General Theory of Informed Consent\textsuperscript{91}

Informed consent requires medical and behavioral professionals to inform their patients and human subjects of the risks and benefits of the procedures involved with their care and to obtain the patient’s or subject’s agreement to undergo the procedures.\textsuperscript{92} The doctrine of informed consent has its origins in the contemporary view of the collaborative nature of the physician-patient relationship.\textsuperscript{93} The doctrine accomplishes two primary objectives: to promote individual autonomy and to encourage rational decision making.\textsuperscript{94} The central premise of informed consent is that all decisions about the medical care of a patient will be carried out so that the patient’s authorization for the care is given intentionally, voluntarily, and with substantial understanding.\textsuperscript{95}

\begin{itemize}
\item \textsuperscript{89} \textit{Doe}, 696 N.E.2d at 710-11.
\item \textsuperscript{90} \textit{Id.} at 710.
\item \textsuperscript{92} \textit{See} Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972), \textit{cert. denied}, 409 U.S. 1064 (1972); Delgado \& Leskovic, supra note 76, at 69.
\item \textsuperscript{93} \textit{See} APPELBAUM, supra note 91, at 41.
\item \textsuperscript{94} GEORGE J. ANNAS ET AL., \textit{INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA} 34 (1977).
\item \textsuperscript{95} Gail Geller et al., \textit{Genetic Testing for Susceptibility to Adult-Onset Cancer: The Process and Content of Informed Consent}, 277 JAMA 1457, 1468 (1997) (footnotes omitted).
\end{itemize}
2. Informed Consent in the Clinical Medical Setting

Judge Cardozo effectively captured the values behind the doctrine of informed consent when he wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault...." A physician in a clinical setting owes his or her patient a duty to inform as part of his or her professional care. The physician must provide the patient

97. ANNAS, supra note 94, at 285. In 1966 the American Medical Association (AMA) adopted the ethical principles set forth in the 1964 Declaration of Helsinki of the World Medical Association concerning human experimentation. Id. The AMA drafted four guidelines to aid physicians in meeting their ethical responsibilities while performing clinical investigation:
1. A physician may participate in clinical investigation only to the extent that his activities are part of a systematic program competently designed, under accepted standards of scientific research, to produce data which is scientifically valid and significant.
2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.
3. In clinical investigation primarily for treatment-
   A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.
   B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: (a) [sic] disclosure that the physician intends to use an investigational drug or experimental procedure, (b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits, (c) an offer to answer any inquiries concerning the drug or procedure, and (d) a disclosure of alternative drugs and procedures that may be available.
4. In clinical investigation primarily for the accumulation of scientific knowledge-
   A. Adequate safeguards must be provided for the welfare, safety and comfort of the subject.
   B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.
   C. Minors or mentally incompetent persons may be used as subjects only if:
      i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.
      ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.
   D. No person may be used as a subject against his will.

Id. at 285-87 (emphasis in original)
with sufficient information to allow the patient to make an intelligently informed decision as to his or her care. However, a number of exceptions to a physician’s duty to disclose have been identified by the courts: (1) when the disclosure relates to minor or remote risks, (2) when the patient was aware of the risk, (3) when the existence of the risk was common knowledge, (4) when the risk was not known to the medical community, (5) when the risk exists only if the medical procedure is improperly performed, (6) when the patient expressly requests not to be informed, (7) when the medical treatment is being performed during a medical emergency, and (8) when disclosure would cause the patient’s condition to deteriorate.

To recover for a failure to disclose under the rules of professional malpractice, the plaintiff must show that the physician violated his or her duty to inform. In addition, the plaintiff must show that the physician’s nondisclosure caused a recognizable harm under the law of negligence. Most jurisdictions use an objective standard of causation in medical malpractice informed consent cases. This standard requires the plaintiff to show that the undisclosed information would have induced not just the plaintiff, but also a reasonable patient, to withhold consent to the treatment.

3. Informed Consent in the Research Setting

Early case law held that a duty of informed consent for physicians in a research setting equals the duty of informed consent for physicians in a clinical setting. Informed consent increases the general fund of knowledge surrounding the research project and genetic tests. A physician researcher must disclose any information that might somehow influence a research subject’s decision to participate in the study. In fact, the scope of information a physician is required to

98. See id.
105. Spence, 464 F.2d at 788.
106. Wilkinson, 295 A.2d at 689 (citations omitted).
107. Shultz, supra note 76, at 227.
108. Id.
disclose includes the physician's economic and research interests.\textsuperscript{111} Furthermore, a physician is liable under breach of informed consent for a procedure or protocol performed on a subject who did not give informed consent.\textsuperscript{112}

From the perspective of the research subject, disclosure informs the subject about the nature of the project. The subject learns the risks and benefits associated with participation in the research protocol. As a result, research subjects can better avail themselves of the benefits and avoid the risks associated with the research.\textsuperscript{113}

Additionally, obtaining informed consent serves the interests of researchers. Disclosure reduces the researcher's risk that the research subject will pursue legal action if his or her expectations concerning the outcomes of the research project are not fulfilled.\textsuperscript{114} Furthermore, disclosure reinforces a general societal interest in respecting the autonomy of human subjects and avoiding harm to human subjects involved in research programs.\textsuperscript{115} Thus, disclosure reduces the costs associated with placating an unhappy research subject or any resultant litigation.

4. Federal Law and Informed Consent

The general requirements for informed consent appear in Title 45 of the Code of Federal Regulations.\textsuperscript{116} Under Title 45, Section 46.116 of the C.F.R., the researcher is required to provide the research subject with the following information:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

\textsuperscript{111} Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 484 (Cal. 1990).
\textsuperscript{113} Ellen Wright Clayton et al., Informed Consent for Genetic Research on Stored Tissue Samples, 274 JAMA 1786, 1787 (1995).
\textsuperscript{114} Id. at 1788.
\textsuperscript{115} Id.
\textsuperscript{116} 45 C.F.R. § 46.116 (1998).
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.\textsuperscript{117}

Federal law prohibits research on human subjects unless the investigator has obtained legally effective informed consent. Federal law applies to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency.\textsuperscript{118} The federal regulations represent an effort by Congress to balance society's needs for increased knowledge with the protection of individual interests, while reflecting the post-World War II concern for the rights and welfare of human research subjects.\textsuperscript{119}

\textsuperscript{117} 45 C.F.R. § 46.116(a) (1998).
\textsuperscript{119} The Nuremberg War Crimes Tribunal formulated the first code designed to protect the rights of human subjects. The Nuremberg Code explained the principle behind the doctrine of informed consent as follows:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by
5. Research Using Anonymized Samples

Federal regulations exempt anonymized samples from the requirements of informed consent in three situations: (1) where the research protocol uses existing specimens or data, (2) where the research data is publicly available, and (3) where the subjects cannot be identified.120 As a result, researchers can remove identifiers from existing samples without seeking consent for their use in data analysis.121

Typically, researchers use their currently funded data collection protocols as an opportunity to collect additional samples for future research projects.122 However, researchers collecting anonymous research samples for future tests should obtain informed consent. Ethicists believe that if the purpose of the future test is known at the time of collection, then the researcher should obtain informed consent.123

Interestingly, there might be an exception to obtaining informed consent on the collection of samples for future research if the sample is collected in a clinical setting where the subject seeks medical treatment. Federal regulations define a human subject as a person about whom the researcher obtains data through interventions with the person.124 "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 (emphasis added)."125 Thus, it may be argued that an individual whose interventions occur in a clinical setting, and, thus, not for research purposes, is not a human subject by definition.

Of course, legally, if the sample involves private information, the person is a human subject regardless of where the sample is collected.126 Thus, the clinician faces an ethical problem in that it would

which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

121. Some ethicists find this practice to be problematic, as the researcher had an opportunity to obtain consent and chose not to do so. See Clayton et al., supra note 113, at 1787-88.
122. See id.
123. Id. at 1791.
125. Id.
be deceptive to collect samples in a clinical setting knowing they will probably be used for research.

Federally mandated institutional review boards (IRBs)\(^{127}\) could offer a solution to these ethical problems.\(^{128}\) An IRB is established by the institution where the research is being conducted and is composed of a cross-section of the scientific and lay community.\(^{129}\) IRBs are intended to protect the rights and welfare of research subjects from abuses by research investigators.\(^{130}\) An IRB contains at least five persons with varied backgrounds.\(^{131}\) For instance, there must be at least one member who is not a scientist and at least one member who is not affiliated with the institution.\(^{132}\) The varied backgrounds are intended to promote the complete and adequate review of research proposals.\(^{133}\)

IRBs approve and monitor research proposals to ensure informed consent.\(^{134}\) While the content of the written report submitted to an IRB may vary by institution, in general, the report contains the following information:

(1) the purpose of the study; (2) the past experimental and clinical findings leading to the proposed protocol; (3) the names of the organizations contributing funds for the research program; (4) an estimate of the number of subjects and controls to be included in the research protocol and a statement describing the population from which they are derived; (5) the specific location where the research subjects will be contacted; (6) an estimate of the duration of the entire study; (7) a description of the intended research methodology to be used; (8) a description of all potential risks to the research subject, including an estimate of their frequency severity, and reversibility; (9) a description of any precautions the researcher will take to avoid harm to the research subjects, how the researcher will monitor and detect these harms, and the point at which the study will be terminated if these harms occur; (10) the procedures to be used to ensure con-

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127. In addition, some health care institutions have organized institutional ethics committees (IECs) as a means by which to address ethical dilemmas by educating the hospital administration or staff, assisting in the development of health care institution policy, and providing a forum for the resolution of cases involving appropriate patient care. FURROW ET AL., supra note 4 at 391-2. Typically, the structure of an IEC varies considerably from one institution to another, as it is not federally regulated. Id.


129. FURROW ET AL., supra note 4, at 387.


131. Id.

132. Id.

133. Id.

134. HERSHEY, supra note 130, at 24-31.
fidentiality of the data and the identity of the research subjects; (11) the scientific qualifications of the researcher; (12) prior IRB determinations; and (13) a written consent form.¹³⁵

Although federal regulations do not give specific guidelines as to how the IRB should make its findings, the IRB must make the following four findings in order to approve a research proposal in which a research subject's consent is limited or not obtained: (1) the risks to the subjects must be minimized, (2) the waiver or alteration of informed consent must not affect the rights of the subjects, (3) the research program could not practicably be carried out absent the waiver or alteration of informed consent, and (4) the subjects will be provided with additional information after participating, whenever appropriate.¹³⁶

Thus, the task of an IRB is to evaluate whether the risks faced by the research subject are reasonable when compared with the benefits to be realized by the research subject and the importance of the scientific knowledge gained by following the research protocol.¹³⁷ In this way, federal regulations place the duty on the research institution to protect the rights of the research subjects.¹³⁸

6. Research with Identifiable Samples

Some people want to know their personal genetic information. For others, the prospect of knowing personal genetic information elicits feelings of anxiety and can even cause family ties to become strained when family members do not want to know the information.¹³⁹ However, no matter what one's position is, in contrast to anonymous samples, subject consent is generally required for research using linkable or identifiable samples.¹⁴⁰

One unique issue pertaining to linkable samples is "look-back" liability. "Look-back" liability is particularly important when a researcher fails to recontact current or past subjects when new diagnostic or treatment protocols are developed. Thus, using linkable samples would increase the researcher's liability risk.

¹³⁵  Id.
¹³⁷  FURROW ET AL., supra note 4, at 387-88.
¹³⁸  Failure to comply with the federal regulations would result in the research institute losing its federal funds.
¹³⁹  Experiences of anxiety are probably amplified when no effective treatment for a given genetic condition exists, when issues surrounding access to reproductive planning are highlighted, or when the availability of genetic information to employers and insurers may result in barriers to receiving jobs or insurance.
¹⁴⁰  Clayton, supra note 113, at 1789.
However, if the findings are unclear or no effective interventions exist, then the researcher would have no liability. To compound the problems surrounding disclosure, federal regulations governing research with human subjects may not apply when the subject has died.141

7. Research Using Samples of the Deceased

Some ethicists argue that if the genetic information might impact the health of a living blood relative, the federal restrictions imposed on the samples of living subjects should be extended to the samples of subjects who are deceased.142 Of course, the researcher should respect the deceased subject’s express wishes as to whether the subject wanted samples of his or her remains to be used in research. In addition, the researcher should respect recognized property rights that are held by heirs and assigns in the bodies of deceased research subjects.143 As the Brotherton court stated,

The importance of establishing rights in a dead body has been, and will continue to be, magnified by scientific advancements. The recent explosion of research and information concerning biotechnology has created a market place in which human tissues are routinely sold to and by scientists, physicians and others. [After all], the human body is a valuable resource. As biotechnology continues to develop, so will the capacity to cultivate the resources in a dead body. A future in which hearts, kidneys, and other valuable organs could be maintained for expanded periods outside a live body is far from inconceivable.144

As this discussion demonstrates, the need for clarifying the scope of property rights in biological samples has never been greater.

F. Property and a Duty to Disclose

1. General Theory of Property

In the early United States, the legal concept of property was expansive in scope, encompassing land, faculties, and conscience.145 Property interests were viewed as the best means for protecting the life

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143. See Brotherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991).
144. Id.
145. See James Madison, Property, 6 THE WRITINGS OF JAMES MADISON 101, 102 (Gaillard Hunt ed., 1906).
and liberty of individuals. American courts have recognized that property consists of a collection of interests that are incident to ownership and protected by the state: "rights, duties, claims, exemptions, and immunities." The Restatement of Property considers property to be the legal relations between parties with respect to the subject of property. The first chapter of the Restatement of Property defines four legal concepts that describe the legal relations between parties with respect to property: right, privilege, power, and immunity. To have complete property ownership in a given object, a person must possess all of the rights, privileges, powers, and immunities that are legally possible.

2. Genetic Information as Property

Both the Hohfeldian and Restatement of Property concepts of property support the notion that an individual owns his or her genetic information. First, an individual possesses the DNA encoded in his or her genes. Second, an individual has the exclusive right to use the genetic information in his or her body. Third, an individual's genetic information can be wasted, modified, destroyed, or alienated only by the person in whom it resides. Fourth, an individual can control who has access to his or her genetic information. Lastly, only the individual can give his or her genetic information away.

148. See RESTATEMENT OF PROPERTY § 1-4, ch. 1, introductory note (1936).
149. Barrad, supra, note 147, at 1056. The concepts of right, privilege, power, and immunity were originally developed by Wesley Hohfeld and adopted by the American Law Institute in 1936 in the Restatement of Property. The Restatement of Property defines the four legal concepts as follows:

A right . . . is a legally enforceable claim of one person against another, that the other shall do a given act or shall not do a given act. . . . A privilege . . . is a legal freedom on the part of one person as against another to do a given act or a legal freedom not to do a given act. . . . A power . . . is an ability on the part of a person to produce a change in a given legal relation by doing or not doing a given act . . . . An immunity . . . is a freedom on the part of one person against having a given legal relation altered by a given act or omission to act on the part of another person.

RESTATEMENT OF PROPERTY § 1-4 (1936).

150. See id. § 5 cmt. e. Thus, the Restatement of Property makes a distinction between a person who owns one or more interests in an object, a partial owner, and a person who owns all the interests in an object, a complete owner. Id. See generally Brotherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991) (holding that the aggregate of rights that constitute a wife's property interest in her deceased spouse's body are sufficient to rise to the level of a legitimate claim of entitlement protected by the Due Process Clause of the Fourteenth Amendment); Fuller v. Marx, 724 F.2d 717, 719 (8th Cir. 1984) (plaintiff's interest in the decedent's remains is only a limited property interest); Ravellette v. Smith, 300 F.2d 854 (7th Cir. 1962).

151. The most common means by which a person can give his or her genetic information
However, a person is not a complete owner in his or her genetic property. For example, a person does not retain a property interest in skin cells that are shed as he or she walks down the road because these cells are no longer in the exclusive control of the person.

Yet, courts have found property rights in a variety of human biological samples including dead bodies,\textsuperscript{152} feces,\textsuperscript{153} preembryos,\textsuperscript{154} and sperm.\textsuperscript{155} One exception is the landmark case of Moore v. Regents of the University of California,\textsuperscript{156} that refused to recognize a property right in spleen cells removed for therapeutic reasons and later used in medical research.

In Moore, the plaintiff, John Moore, "allege[d] that his physician failed to disclose [his] preexisting research and economic interests in [Mr. Moore's] cells [prior] to obtaining [informed] consent to the medical procedures by which [the cells] were extracted."\textsuperscript{157} Moore sought treatment at the Medical Center of the University of California, at Los Angeles for hairy-cell leukemia.\textsuperscript{158} Dr. David Golde, one of five defendants and the attending physician, confirmed Mr. Moore's diagnosis and recommended that Mr. Moore's spleen be removed.\textsuperscript{159} Moore consented to the splenectomy and the surgery was performed.\textsuperscript{160} For the next seven years, Moore traveled from his home in Seattle to UCLA Medical Center at Dr. Golde's request in order to ensure his health and well-being.\textsuperscript{161} During these visits, Dr. Golde collected samples of Moore's blood, skin, bone marrow, and sperm.\textsuperscript{162}

\footnotesize{152. Many courts faced with the issue of whether a property interest exists in a dead body have found that a quasi-property right exists. \textit{Brotherton}, 923 F.2d at 481; Arnaud v. Odom, 870 F.2d 304, 308 (5th Cir. 1989), \textit{cert. denied sub nom.} Tolliver v. Odom, 493 U.S. 855 (1989); \textit{In re Estate of Moyer}, 577 P.2d 108, 110 (Utah 1978).
154. York v. Jones, 717 F. Supp. 421, 425 (E.D. Va. 1989) (finding that the wording of defendant's cryopreservation agreement with the plaintiffs clearly recognized the plaintiff's property rights in the preembryo); Del Zio v. Presbyterian Hospital, No. 74 Civ. 3588, 1978 U.S. Dist. LEXIS 14450, at 92, 11 (S.D.N.Y. November 9, 1978) (instructing a jury that the contents of a test tube used in an in vitro fertilization procedure were personal property able to be converted).
155. Hecht v. Super. Ct. of Los Angeles (KANE), 20 Cal. Repr. 2d 275, 283 (Cal. Ct. App. 1993) (finding that fifteen vials of sperm deposited in a sperm bank were part of the decedent's estate because Kane, the depositor, had an intent to control the sperm after deposit).
156. 793 P.2d 479 (Cal. 1989).
157. Id. at 480.
158. Id.
159. Id. at 481.
160. Id.
161. Id.
162. Id.}
However, at Dr. Golde’s first appointment with Moore, he realized that Moore’s body was overproducing usually rare lymphokines, important parts of the human immune system.\textsuperscript{163} Dr. Golde hoped to use Moore’s cells to produce large quantities of lymphokines.\textsuperscript{164} Toward this end, before Moore’s surgery, Dr. Golde and another defendant, Shirley Quan, a researcher employed by the Regents, made arrangements to have portions of Moore’s spleen retained for research purposes.\textsuperscript{165}

Dr. Golde used the spleen tissue and the samples collected at Moore’s subsequent medical visits to produce a culture of lymphokine cells that were enabled to reproduce themselves indefinitely.\textsuperscript{166} Dr. Golde and Quan, hoping to capitalize on the commercial potential of the cell line, entered into a number of contracts with several pharmaceutical companies and the University of California to commercially develop the cell line.\textsuperscript{167} These contracts resulted in Dr. Golde receiving a large number of shares of one of the companies and both Dr. Golde and the university were paid large sums of money. Finally, Dr. Golde and Quan were issued a patent on the cell line.\textsuperscript{168} They assigned the patent to the university.\textsuperscript{169}

Upon learning of the activities of Dr. Golde, Moore brought suit\textsuperscript{170} claiming that Dr. Gold, Quan, the University, and the pharmaceutical companies had converted his cell line and that he was entitled to the profits.\textsuperscript{171} The superior court rejected Moore’s claim on a preliminary motion.\textsuperscript{172} The court of appeal reversed, finding that Moore retained a proprietary interest in his cells and was thus entitled to monetary compensation for conversion if he could prove his claims at trial.\textsuperscript{173} The California Supreme Court found that Moore did not have a proprietary interest in his cells but that he was entitled to compensation only if he could prove that Dr. Golde had breached his fiduciary

\textsuperscript{163} \textit{Id.}
\textsuperscript{164} \textit{Id.}
\textsuperscript{165} \textit{Id.}
\textsuperscript{166} \textit{Id.} at 482 n.3.
\textsuperscript{167} \textit{Id.} at 482.
\textsuperscript{168} \textit{Id.}
\textsuperscript{169} \textit{Id.}
\textsuperscript{170} Moore stated thirteen causes of action: (1) conversion, (2) lack of informed consent, (3) breach of fiduciary duty, (4) fraud and deceit, (5) unjust enrichment, (6) quasi-contract, (7) bad faith breach of the implied covenant of good faith and fair dealing, (8) intentional infliction of emotional distress, (9) negligent misrepresentation, (10) intentional interference with prospective advantageous economic relationships, (11) slander of title, (12) accounting, and (13) declaratory relief. \textit{Id.} at 482 n.4.
\textsuperscript{171} \textit{Id.} at 482.
\textsuperscript{172} \textit{Id.}
\textsuperscript{173} \textit{See id.} at 483.
obligations by failing to inform Moore of his commercial interest in Moore’s cells.\textsuperscript{174}

The \textit{Moore} court expressed four separate understandings of the relationship between the human body and property law in its majority and dissenting opinions. The majority feared that granting Moore a property right in his own tissues would impede future research and development by pharmaceutical companies using human cells.\textsuperscript{175} Medical researchers would be hesitant to use previously collected tissue samples because of uncertainty over whether the donor properly gave consent to the use of the sample for research and commercial development.

The court relied on a 1987 report of the U.S. Congress Office of Technology Assessment asserting that biotechnology and pharmaceutical companies would be unlikely to invest in new products without certainty that title to the human material was clear.\textsuperscript{176} The court reasoned that a decision to recognize Moore’s property right in his own tissues would thwart the commercial trade in these tissues.\textsuperscript{177}

Conversely, the court concluded that trade would benefit by granting property rights in human tissues to researchers and pharmaceutical companies who are developing new drugs for the community.\textsuperscript{178} However, although the majority rejected Moore’s property claims, it did reinforce Moore’s right to be autonomous in making medical decisions by extending the law of informed consent to require Dr. Golde to inform his other patients of any commercial interest he had in Moore’s tissues.\textsuperscript{179}

Justice Arabian’s concurrence emphasized that Moore’s claim involved moral values as well as market effects.\textsuperscript{180} Moore asked the court to recognize his right to sell his tissues for profit.\textsuperscript{181} However, for Justice Arabian, equating the human body with commercial commodities involved a complex balancing of moral and economic values that lay beyond property law, tort law, and the abilities of the court.\textsuperscript{182} Like the majority, Justice Arabian believed that the proper forum for deciding mixed issues of morals and economics was the legislature.\textsuperscript{183}

\begin{itemize}
  \item \textsuperscript{174} See \textit{id.} at 497.
  \item \textsuperscript{175} \textit{Id.} at 495-96.
  \item \textsuperscript{176} \textit{Id.} at 496.
  \item \textsuperscript{177} \textit{Id.} at 495-96.
  \item \textsuperscript{178} See \textit{id.}
  \item \textsuperscript{179} \textit{Id.} at 485-86.
  \item \textsuperscript{180} \textit{Id.} at 497.
  \item \textsuperscript{181} \textit{Id.}
  \item \textsuperscript{182} See \textit{id.} at 498.
  \item \textsuperscript{183} \textit{Id.}
\end{itemize}
Justice Broussard’s minority opinion argued that the Court could recognize Moore’s property right in his own bodily tissue without negatively impacting the research and development of new pharmaceutical products. Broussard reasoned that a patient possesses a property right in his or her tissue prior to removal. As a result, a physician who removes tissues knowing of their commercial value but neglects to inform the patient of the value must turn over any realized profits to the patient.

Furthermore, Justice Broussard stated that the economically valuable part of a pharmaceutical product was derived from the work of the researcher and not the material itself. Therefore, pharmaceutical companies are unlikely to face large damage awards and the development of new pharmaceutical lines is unlikely to be thwarted.

Finally, Justice Mosk’s dissent rejected the majority’s contention that courts should grant property rights based solely on market considerations. Rather, Justice Mosk posited that courts should base their decisions on a system of values that are without a market price. If the court’s property analysis neglects to consider noneconomic values, then the court’s decision will be devoid of equity and morality. As a result, Justice Mosk argued that a patient should be granted a property right in his or her bodily tissues in order to allow the patient to maintain control over his or her body and preserve human dignity.

3. Natural Rights Theory and Informed Consent Property Justifications

Courts justify property rights by employing a number of theories. Under a natural rights theory of property justification, a person’s property interest in his or her genetic information is necessary to experience a sense of personal identity. Furthermore, a person’s

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184. Id. at 504.
185. Id. at 501.
186. Id. at 502.
187. Id. at 505.
188. Id.
189. Id. at 516.
190. Id. at 516-17.
191. Id. at 517.
192. Discussion in this Comment is limited to three prominent theories of justification: natural rights theory, labor theory, and social utility theory.
193. Recall that in Moore, Justice Mosk believed that every person has a legally protectable property interest in his own body because society respected the body as an expression of an individual’s unique human persona. 793 P.2d at 515 (Mosk, J., dissenting). See Vanborne’s Lessee v. Dorrance, 2 U.S. 304, 310 (1795) (property expresses the desires of man; the security of property induces men to unite in society).
individuality requires that the person be in control of his or her self-expression.

The doctrine of informed consent is based on a person's right of self-determination. Because a person has a property right in his or her person, a person seeking medical care or taking part in a medical research project owns the right to determine how his or her body will be used. 194 The clinical physician or the researcher has the correlative duty to not act in a manner contrary to the person's informed decision. 195 The clinical physician or the researcher protects the person's right in his or her genetic property by disclosing the risks and benefits associated with the procedures in question and obtaining the person's consent before acting. 196

4. Natural Rights Theory and the Right to Privacy
   Property Justifications

The right to privacy theory also justifies a person's property interest in his or her genetic information. 197 A right of privacy protects against intrusions against a person's property. Courts have protected an individual's identity interest when a party appropriated the individual's voice without permission. 198 Thus, a court should recognize a right of privacy against unwelcome intrusions into a person's genetic material because attributes, like a person's voice, are expressions of the person's identity. 199

5. Labor Theory and Property Justification

The labor theory of property holds that a person owns that which he or she creates or earns through his or her own labor. 200 However, genetic material is not the result of the efforts of the body. Rather, genetic material predates the body and, in fact, makes the body what it is. 201 But labor theory is more than just the efforts of the body in labor. Labor theory is based on the natural rights notion of individuality. 202 Thus, property is an extension of a person's individuality to

194. Barrad, supra note 147, at 1063.
195. Id.
196. Id. at 1063-64.
197. A right to privacy theory may also be referred to as a "right to be left alone" theory.
199. Barrad, supra note 147, at 1070.
200. Id.
201. Id. at 1071.
202. Id.
the products of his or her labor. Hence, under labor theory, genetic material is justified as property of the body.

Interestingly, courts may employ a labor theory of property when considering issues surrounding the patenting of living organisms. Consider that a discovery can be patented if it is useful, novel, and nonobvious. In general, courts also value inventions in terms of their economic value. However, one line of analysis that courts use to evaluate whether to grant patent rights to biological organisms, known as phenomenon of nature analysis, is not based on economic grounds.

The United States Supreme Court defined phenomena of nature goods as those with qualities that "are the work of nature." The Funk Brothers Court found that the qualities of six individual strains of bacteria were the product of nature. Furthermore, the Court ruled that when the six strains of bacteria were mixed together to inoculate a crop of leguminous plants, none of the individual bacteria acquired a new or different use. Because the uses of the bacteria did not change from their original natural use, the Court concluded that the mixture of bacteria was nothing more than a phenomenon of nature, and no invention existed.

However, the noneconomic foundation of the phenomena of nature analysis in Funk Brothers was discarded thirty-two years later in Diamond v. Chakrabarty. The Chakrabarty decision involved the genetic engineering of a new form of bacteria that digests oil spills. No naturally occurring bacteria possessed this capability. The Court held that Chakrabarty, the microbiologist who engineered the new bacteria, was entitled to a patent. The Court's holding represents a reformulation of the phenomena of nature argument set forth in Funk Brothers. In Chakrabarty, the Court distinguished patentable goods from phenomena of nature by the fact that patentable goods are the product of human intervention.

203. Id.
206. Id. at 68.
208. Id. at 131.
209. Id.
210. Id.
211. 447 U.S. 303 (1980).
212. Id. at 305.
213. Id.
214. Id. at 310.
In the context of the *Chakrabarty* decision, the California Supreme Court's decision in *Moore* to not extend a property right to Moore in the tissue of his removed spleen is more easily understood. Under *Chakrabarty*, a person would have a property right in his or her biological material only if the material is the product of human intervention. Thus, Moore would have a recognizable property right in the tissue of his spleen only. He would not have a recognized property right in the cell line based on the tissue of his spleen because the cell line was not the product of his human ingenuity.

6. Social Utility Theory and Property Justification

Social utility theory justifies the protection of property because society benefits from putting underutilized resources to an efficient use.\(^{215}\) Traditional utility theory balances intrusions according to elements of free will so as to maximize social welfare.\(^{216}\) However, the freedom of the balancing test of social utility makes predicting outcomes difficult.

For example, one type of utilitarian theory would embrace an individual's interests in controlling his or her genetic material and privacy interests in guarding against release of genetic information to third parties. Another utilitarian theory would emphasize the interests of employers and insurers in accessing genetic information on inheritable diseases and the interests of society in maintaining public health. Without knowing the particular utilitarian bent of the court, it is impossible to predict the extent to which a property interest in genetic material will be protected under social utility theory. Depending on a court's specific property rights justification, a person may or may not have recognized property rights in their own genetic material. This ultimately affects whether there is a duty to disclose.

### IV. Analysis of Disclosure Claims Based in Tort, Contract, and Property

Courts have not addressed whether medical researchers have a duty to disclose the results of genetic tests conducted during their research protocols to either research subjects or a third party. Whether a court finds a medical researcher has an affirmative duty to disclose will depend on whether the claim is based in tort, contract, or property.

\(^{215}\) See Barrad, *supra* note 147, at 1072.

It is likely that a court will find an affirmative duty to disclose genetic test results when the medical researcher is a physician and the test results are directly related to the condition being studied. Because the medical researcher is a physician, a court would probably find that the relationship between physician, medical researcher, and research subject is special, and is an exception to the general common law rule of that no duty is owed to another. A plaintiff research subject asserting a claim for breach of duty to disclose in tort should emphasize his or her dependence on the researcher based on the researcher's specialized knowledge. The fiduciary duties associated with this dependence would further support a court's finding of an affirmative duty to disclose. However, this duty may be limited when the test results are inconclusive, no reliable treatment for the condition exists, or if the research samples tested were anonymized, because each of these situations weakens the plaintiff's assertion that the researcher has superior knowledge and the subject is dependent on the researcher's superior knowledge.

Looking back to the original hypothetical, for example, suppose Geneticist Roe and the team of epidemiologists approach Dr. Doe to join their research team. The research protocol proposes to have Dr. Doe administer the genetic breast cancer test to each of her patients prior to any surgical intervention. Because Dr. Doe is a physician and responsible for the clinical care of each of her patients, Dr. Doe is excepted from the common law rule of no duty owed to another. Each of Dr. Doe's patients is dependent on Dr. Doe's skill and knowledge as a physician. As a result, Dr. Doe would owe her patients a fiduciary duty that requires her to fully disclose the benefits and risks of the care she proposes to undertake as well as the results of all tests she performs. However, Dr. Doe's duty may be limited by the court if the genetic test results and the biopsy pathology results are inconclusive.

The analysis is different for the nonphysician medical researcher despite the fact that nonphysician medical researchers possess a specialized knowledge far different from their research subjects. Although the trend in court rulings is to expand the list of recognized special relationships to include relationships of either unilateral or mutual dependence, the research protocol for a nonphysician medical researcher rarely involves a relationship of dependence, because the structure of medical research is very different from medical care received in the clinical setting.

Often medical researchers are not physicians. Thus, no physician-patient relationship exists between the researchers and the research subject. Also, federal informed consent guidelines designed
to protect the privacy and welfare of research subjects often are applicable and contract around any disclosure duty that may be present from the relationship of care between the researcher and the research subject. Lastly, the samples used in research studies are often anonymized, making it impossible for the researcher to offer the subject any follow-up disclosure.

Neither Geneticist Roe nor any member of the team of epidemiologists is a physician. In contrast to Dr. Doe, neither Geneticist Roe nor any member of the team of epidemiologists has a fiduciary relationship with the research subject or a duty to obtain the research subject's informed consent to the medical procedure. If the Roe research team is to be liable for a breach of fiduciary duty or for performing medical procedures without informed consent, it could only be on the basis of Dr. Doe's acts and a theory of secondary liability, like respondeat superior.\(^{217}\) Additionally, the Roe research team may be liable under a contract-based claim of performing research without informed consent. Finally, because the proposed research protocol does not anonymize the tissue samples, the Roe research team would not be excepted from providing the research subjects follow-up disclosure.

Thus, to limit liability for failure to disclose research genetic test results, the Roe research team must inform research subjects as to what type of information the subject can expect to receive from the researcher. In addition, the informed consent should delineate the circumstances in which the researcher will or will not disclose research findings to research subjects. The research subject must also be given an opportunity to refuse to be recontacted by the research team. However, if the Roe research protocol involves the use of anonymous samples, recontacting the research subject after participation in the study is impossible, and the informed consent document should clearly state that, because the samples are anonymous, the researchers are unable to link the test results to the individual study participants.

The informed consent document should also recognize that some research subjects may want to limit the use of their tissue samples to studies of breast cancer or some other disease. In this case, the research team must clarify in the informed consent document whether the subject's tissue samples or genetic test results will be shared with other researchers.

If a court recognizes property as the basis of the plaintiff's claim, then whether the court finds an affirmative duty to disclose test results in the medical research setting will depend on which theory of justifi-

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\(^{217}\) Cf. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 486 (Cal. 1989).
cation the court adopts to protect the property interests. Under a natural rights theory of property justification, a researcher protects a research subject’s ability to control how his or her body will be used by ensuring informed consent prior to undertaking the research protocol. By disclosing the risks and benefits associated with the research protocol, the researcher protects the research subject’s property right in his or her genetic material.

However, typically the informed consent document is prepared by the researcher prior to contacting the research subject. Thus, Dr. Doe and the Roe research team have the ability to contract around the duty to disclose prior to the research subject participating in the research protocol. By including a provision in the informed consent document that expressly waives the researcher’s duty to disclose, Dr. Doe and the Roe research team have the ability to control their exposure to liability.

Alternatively, Dr. Doe and the Roe research team could include a clause in the informed consent document that makes the transfer of the tissue sample an inter vivos gift. When a research subject deliv-

218. An inter vivos gift is an absolute transfer of property between the living without consideration. BLACK’S LAW DICTIONARY 619 (5th ed. 1979). See Karen Gottleib, Human Biological Samples and the Laws of Property: The Trust as a Model for Biological Repositories, in STORED TISSUE SAMPLES: ETHICAL, LEGAL, AND PUBLIC POLICY IMPLICATIONS 182 (Robert F. Weir ed., 1998), for a comparison of four types of property transfer of biological samples: abandonment, bailment, gifting, and the trust. Gottleib contends that a charitable trust is an ideal form of property transfer of biological samples, because the researcher trustee’s fiduciary duty requires the researcher to act in the best interest of the beneficiary, the general population. Id. at 195-6. Thus, the structure of a charitable trust operates to protect the donor research subject’s tissue sample as property in the trust, and ensures that the tissue samples, or trust res, is available for researchers to manipulate for the benefit of the beneficiary. Id. at 192-96. However, a charitable trust model is only a useful model for nonprofit entities. Id. at 192-93. As a result, a trust model of property transfer is not an option for medical researchers conducting their research while under the employ of a for-profit hospital, pharmaceutical company, or research organization. In contrast, an inter vivos gift model of property transfer for tissue samples is a viable model for medical researchers operating in all types of research settings. Cf. UNIFORM ANATOMICAL GIFT ACT (1987) (laying out the procedures necessary for making anatomical gifts and requiring that the intentions of the donor be followed, the Act has been adopted by all fifty states and the District of Columbia); see also CHARLOTTE L. LEVY, THE HUMAN BODY AND THE LAW: LEGAL & ETHICAL CONSIDERATIONS IN HUMAN EXPERIMENTATION 59-63 (1983). Here, the research subject interested in donating his or her tissue samples to a research protocol would complete a Tissue Donor Card. A sample Tissue Donor Card might look like the following:

Tissue Donor Card

Of __________________________

print or type name of donor

In the hope that I may help others and further medical knowledge, I hereby make this tissue gift, if medically acceptable, to take effect on ______ (date). The words and marks below indicate my desires.

I give:  (a) _____ any needed tissue sample
        (b) _____ only the following tissue sample
ers his or her tissue sample to a medical researcher as a gift, the research subject is divested of dominion and control of the tissue sample and, therefore, his or her property interest in that tissue sample. As a result, if Ms. Jones gifted her tissue sample to Dr. Doe and the Roe research team, no affirmative duty to disclose genetic test results incident to the research protocol would extend to the medical researchers, as the property right in Ms. Jones’ tissue sample would transfer from Ms. Jones to the researchers at the time the gift is made.

Under a labor theory of property justification, Dr. Doe, Geneticist Roe, and the epidemiologists would have a recognized property right in the tissue samples used in the research protocol only if the research protocol changes the nature of the tissue samples. However, in the current hypothetical, the proposed research protocol does nothing to change the nature of the sample being tested. Rather, part of the research sample is tested to see if the subject is at an increased risk for breast cancer. As a result, the tissue sample is nothing more than a phenomenon of nature. Thus, neither the research subject nor the medical researchers can assert a property right in the tissue sample, and whether the medical researchers had an affirmative duty to disclose genetic test results would depend on the nature of the relationship between the researchers and Ms. Jones and the content of the informed consent document relating to the collection of the tissue sample in question. However, if the research protocol were to alter the nature of the tissue sample removed from the research subject, then the court may recognize that medical researchers have a property right in the altered tissue sample and, thus, no duty to disclose genetic test results. The research subject would have no property right in the altered tissue sample, as it was not the research subject’s labor that changed the nature of the sample.

Specify the tissue sample(s) for the purposes of medical research or education.
Limitations or special wishes if any: ___________________________________________
Signed by the donor and the following two witnesses in the presence of each other:

______________________________
Signature of Donor

______________________________
Date of Birth of Donor

______________________________
Date Signed

______________________________
City and State

______________________________
Witness

______________________________
Witness
Under one type of social utility theory of property protection, society must benefit from putting under-utilized resources to an efficient use. Recall that the Moore Court reasoned that if it recognized a property interest for Mr. Moore in his own biological tissue, then the economic incentive to conduct medical research would be destroyed.\(^\text{219}\) In Moore, the medical researcher’s use of Mr. Moore’s cells was deemed to be more economically efficient than Mr. Moore’s own use of his cells. As a result, the court recognized that only medical researchers had a property interest in the cell line developed from Mr. Moore’s tissues.

The medical researchers in the proposed hypothetical are attempting to validate a newly developed genetic test for an increased risk of breast cancer. This research protocol is likely to positively impact the economic basis of the health care industry. Therefore, under this type of social utility theory of property justification, the use by the Roe research team and Dr. Doe of Ms. Jones’ tissue sample is more efficient than the use by Ms. Jones of the same sample, thereby giving the Roe research team and Dr. Doe, not Ms. Jones, a property right in Ms. Jones’ tissue sample and no affirmative duty to disclose genetic test results.

In contrast, an alternative type of social utility theory of property justification emphasizes noneconomic values inherent in an individual’s interest in controlling his or her genetic material. Under this theory, the privacy interests of the individual outweigh the economic interests of society and, therefore, justify guarding against the release of an individual’s genetic information to third parties. Thus, under this theory, Ms. Jones’ noneconomic privacy interests in relation to her own genetic information are of greater import than Dr. Doe’s and the Roe research team’s economic interest in her genetic information. As a result, Ms. Jones possesses a recognized property right in her own genetic information, and Dr. Doe and the Roe research team would be under an affirmative duty to disclose to Ms. Jones the results of all genetic tests.

V. CONCLUSION

This Comment explores the means by which medical researchers can reduce their liability associated with the disclosure of genetic test results to research subjects and third parties. Whether a medical researcher has a disclosure duty depends on whether the plaintiff bases his or her claim in tort, contract, or property.

\(^{219}\) Moore, 793 P.2d at 495.
Under tort, liability for breaching a duty to disclose will turn on whether the court recognizes the medical researcher-research subject relationship as a special relationship. The important elements for finding a special relationship include the status of the researcher and the level of dependence created by the relationship.

The plaintiff’s claim can also be based in a tort-contract hybrid of informed consent. Here, whether a medical researcher has an affirmative duty to disclose genetic test results will depend on the scope of the expectation interest of the research subject as defined by the content of the informed consent document.

A final basis for the plaintiff’s claim can be a tort-contract-property hybrid. In this instance, a medical researcher is liable for a breach of the duty to disclose if the court finds the research subject’s genetic information to be a protectable property interest. Whether genetic information is found to be a protectable property interest will depend on which theory of property justification the court adopts. If the court justifies a property interest in a research subject’s genetic information under a natural rights theory grounded in either informed consent or the right of privacy, then it is probable that the researcher will not be liable for failure to disclose genetic test results. Similarly, if the court justifies genetic information as property under a labor theory of property, the researcher should not have a duty to disclose. However, whether the researcher has a disclosure duty under a social utility theory of a genetic information property interest depends on whether the court chooses to recognize the individual interests of privacy and autonomy or the social interests in maintaining public health.

In conclusion, medical researchers can reduce their exposure to disclosure liability in at least five ways: (1) by carefully defining the nature of the researcher-research subject relationship; (2) by carefully stating informed consent to fully apprise the research subject of all risks and benefits of the protocol and the means by which confidentiality will be protected and ensured; (3) by recognizing that the genetic samples of their research subjects are the property of the research subject, and including a statement to this effect in the informed consent document; (4) by structuring the informed consent document to make the transfer of tissue samples from research subject to researcher a gift inter vivos; and (5) by limiting their use of identifiable samples so as to make it impossible to have identifiable test result information that can be disclosed to either the subject or a curious third party.