History and Development of the Doctrine of Informed Consent

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Abstract

Informed consent is the practical application of autonomy, an ancient philosophical principle. The incremental development of the contemporary laws on informed consent in the United States developed in the 20th Century as a result of legal action brought by patients against their physicians. This paper will recount the development of the doctrine of informed consent as the standard of health care decision making, and outline the few exceptions to this requirement.

Introduction

Adult competent individuals have the right to make their own health care decisions under the United States constitutionally protected right of privacy. This right is grounded in the philosophical principle of autonomy. The practical application of this principle takes the form of informed consent. In addition to the protection afforded by the Constitution, the court system has upheld the right of individuals to make their own health care decisions. The landmark opinion of Judge Benjamin Cardozo (1914) in *Mary E. Schloendorff v. the Society of the New York Hospital* marked the first documented case upholding a patient's right to refuse medical treatment.

This paper outlines the philosophical and legal bases for requiring informed consent, which make up the morally valid medical decision-making paradigm (Faden & Beauchamp, 1986; Pellegrino, 1993). The selected cases from the clinical as well as the research literature are rooted in the principlist approach, and are cited to demonstrate the development of this paradigm.

Autonomy: A Philosophical Perspective

The term "autonomy" was first used by the Greeks to describe self rule, but has developed over time to include concepts such as "self-governance, liberty rights, privacy, individual choice, freedom of the will, causing one's own behavior and being one's own person" (Beauchamp & Childress, 1994, p.120). The practical application of this principle in modern medical practice is what is referred to as the doctrine of informed consent (Jonsen, Siegler & Winslade, 1998).

Informed consent epitomizes the current American medical decision-making model. Traditionally, physicians have had the upper hand over their patients. Because they are ill, patients may be vulnerable to physicians' manipulations, and physicians possess the knowledge that patients need to make appropriate decisions about their care. To protect patients from potential misuse of power by their physicians, they are empowered by their constitutionally protected right to privacy to accept or decline any medical intervention. While autonomy is the philosophical principle driving informed consent, the right to privacy as expressed in the United States constitution is the legal application of it (Pellegrino, 1993).

Constitutionally Guaranteed Right to Privacy: A Legal Perspective

Although the U.S. Constitution does not specifically address the doctrine of informed consent, the right of privacy has served to protect individuals from intrusion by the government in health care decision making. Contraception, abortion, treatment refusal cases and others were argued in the court system by citing the constitutionally protected right to privacy. The U.S. Constitution simply guarantees that people are protected from governmental interference when deciding private matters, such as when they make decisions about accepting or refusing medical care (Faden & Beauchamp, 1986). Patients exercise this right of privacy by participating in medical decision making and by signing informed consent forms.

Informed consent is a process which was developed to ensure that competent patients have adequate information about their medical conditions, and that they are informed about the benefits, burdens, and treatment alternatives. The patient's signature on the informed consent form is the legal documentation of having participated in the medical decision making process (Devettere, 1995). This documentation is but one of the five elements of informed consent. The five elements of the process of informed consent are outlined in a different segment of this paper.

The History of Informed Consent

There is little documentation in the literature about the conduct of physicians and the ethics of providing medical care in the 19th and early 20th centuries. Surgical records from the Massachusetts General Hospital in the 1840s, 1850s and 1860s, surgical records from the New York Hospital in the 1840s and 1850s, and the fracture books of the Pennsylvania Hospital in the 1850s and 1860s shed some light on conversations that took place between physicians and their patients. These records show that patients who objected to surgical procedures usually did not receive them. However, there is little evidence that physicians sought patient participation in

decisions that did not include surgery. However, there were some limitations to surgical consents as well. Faden and Beauchamp (1986) cite the case of a "very heavy" (p.84) female patient who so severely fractured her leg that it was thought to require amputation. Although the treating physician consulted with another physician and a decision was made not to amputate the leg, the patient was never consulted. There was evidence that the patient was competent to make her health care decisions, but she simply was not involved. At that time, "benevolent deception and nondisclosure" (p.76) was the standard of medical practice, and physicians frequently made decisions without involving the patient. This practice follows the Hippocratic tradition of not informing patients of their condition. This tradition is articulated in the following quote: "perform (these duties) calmly and adroitly, concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and sincerity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically and sometimes comfort with solicitude and attention, revealing nothing of the patient's future or present condition" (Jonsen, Veatch & Walters, 1998, p.466). Other published cases in medical journals documented conversations between physicians and their patients that indicated patients were given the opportunity to decide for themselves, and that treatment refusals were honored.

To reduce the incidence of medical malpractice suits, physicians were encouraged in 1934 to seek consent from patients before medical examinations or surgeries were performed. There were no standards for consent, and *informed* consent did not seem to be contemplated. In fact, according to Faden and Beauchamp (1986), physicians strived to gain their patients' trust by concealing unpleasant medical information. What is known in contemporary medical practice as the standard of disclosure would not have been compatible with medical standards in the early 20th century. The practice of "benevolent lying" (Faden & Beauchamp, 1986, p.84) appears to have been prevalent among physicians. The term "informed consent" (Faden & Beauchamp, 1986, p.86) did not appear in the literature until the second half of the 20th century.

Documenting the process of informed consent is necessary under current laws for conducting research as well as for providing medical treatment. The Nuremberg Code (1947) was developed subsequent to the exposure of unethical activities and atrocities which occurred in Nazi Germany during the Second World War. When the Nazi trials ended, the Nuremberg Code was designed to ensure that future research subjects were not exposed to the inhumane research activities attributed to the Nazi regime.

In the United States there were several research projects that also attracted public attention and pointed to the necessity of developing ethical standards for research. The following section reviews some cases from the clinical as well as the research literature to demonstrate how the doctrine of informed consent became the accepted standard in the provision of medical care and in conducting research on human subjects.

Cases from the Literature

Health Care Decision Making Cases

Among the many informed consent cases resulting in court decisions that helped to shape current methods of medical decision making, Devettere (1995) cites the following four landmark cases: Schloendorff, 1914; Salgo, 1957; Canterbury, 1972; and Candura, 1978. Faden and Beauchamp (1986) cite a fifth case, that of Natanson, 1960. Each of the five cases are described below to illustrate unique contributions to the contemporary doctrine of informed consent.

Schloendorff (1914):

Mrs. Mary E. Schloendorff (Devettere, 1995) agreed to have her physician examine her under anesthesia to determine if a diagnosed fibroid tumor was malignant. She specified that she was not consenting to the removal of the tumor. While she was anesthetized, the surgeon removed the tumor without her consent. Mrs. Schloendorff sued the hospital because the surgeon operated on her against her repeatedly expressed wishes. This case generated the following quote by Judge Benjamin Cardozo, an eloquent and well respected justice: "Every human being of adult years and sound mind has the 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, for which he is liable in damages, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained" (Schloendorff v. New York Hospital (1914), 149 App. Div. 915, affirmed). This surgery was not an emergency, and the surgeon was found guilty of committing assault. Justice Cardozo's opinion is widely cited as the basis for seeking consent from patients before medical intervention is provided, thus upholding a patient's right to autonomous decision making.

Salgo (1957):

Devettere (1995) asserts that the Salgo decision marks the birth of the doctrine of informed consent as it is now known. The term "informed consent" was first used in this case. Mr. Salgo consented to undergo a diagnostic procedure to locate the source of chronic pain that he had in his leg. A dye, that caused paralysis, was injected in his leg. He sued his doctor, and claimed that he was not informed about paralysis being a risk or possible complication of the dye injection. In the doctor's defense, it was argued that if patients were informed of all the possible complications they would become frightened and would not consent to treatment. The court did not

accept this defense and ruled that simple consent is not sufficient for medical procedures. Sufficient disclosure of possible risks and complications, i.e. "informed consent" was necessary for patients to be making autonomous decisions.

Natanson (1960):

Mrs. Natanson (Faden & Beauchamp, 1986) suffered severe burns resulting from radiation, subsequent to a mastectomy. Although Mrs. Natanson had consented to the radiation, she sued her physician because he did not disclose to her its possible harm or the alternatives to the treatment. This case confirms the need for full disclosure and emphasizes the need for offering patients alternatives to the treatments proposed by their physicians.

Canterbury (1972):

Mr. Canterbury developed paralysis after he fell off his hospital bed while urinating, subsequent to having surgery on his back. The court held that Mr. Canterbury should have been told of the risk of paralysis even though it was not clear whether the paralysis was caused by the surgery or as a result of the fall. Faden and Beauchamp (1986) hail this case as the most influential of all the informed consent cases. The physicians had the knowledge of the possibility that paralysis could result from the procedure that Mr. Canterbury received, but this information was not disclosed to him. He consented to the surgery without being sufficiently informed of all the possible consequences of that surgery. Although his consent was an expression of his right to self-determination, he made his decisions without the benefit of full disclosure.

This case makes the distinction between the different standards, or levels, of disclosure. The court decided that the "professional standard" (Faden & Beauchamp, 1986, p.135) of disclosure was not sufficient for Mr. Canterbury to make an informed decision. In this case, the court advocated the use of the "reasonable person standard" (p.135). These standards are outlined in more detail in the disclosure section of this paper under the elements of informed consent.

Candura (1978):

After initially consenting to the amputation of her gangrenous leg, Mrs. Candura changed her mind. Her daughter filed a petition with the court to become her legal guardian so she could sign the informed consent form for her mother and have the surgery performed, against her mother's wishes. The court decided that Mrs. Candura was not incompetent, that she had capacity to make her own health care decisions, even though her decision may have seemed irrational to others. Mrs. Candura's decision prevailed (Devettere, 1995). The significance of this case is in its illustration that the court system will uphold the right of adult competent patients to make health care decisions, even when viewed by others not to be in their best interest.

The clinical landmark cases discussed above paved the way for the development of a legal mechanism to ensure that physicians obtain informed consent from their patients before they provide medical treatments. To protect patients' right to privacy, the doctrine of informed consent, with its five elements, was developed and is used as the standard in the United States.

Informed consent also applies to subjects participating in clinical studies, and to social research subjects. Several cases in the history of research in the United States reflect the absence of obtaining informed consent from research subjects. Some of these landmark cases are now discussed.

Research Cases

The Tuskegee Syphilis Study (1932-1972):

The most infamous American research project which violated informed consent and other ethical rules was the Tuskegee Study, which was conducted over a period of approximately forty years. Holmes-Farley and Grodin (1998) give the following account of the study which was conducted by the U. S. Public Health Service. One of the objectives of the study was to observe the natural progression of syphilis in African-American men. Although penicillin was proven to be an efficacious therapy, treatment with this available and affordable medication was purposely withheld from them. One of the major criticisms of this study is that the subjects were led to believe that their syphilis was being treated. Therefore, their consent to have the treatment withheld was never sought. The researchers justified their omissions by stating that because of the subjects' poverty level and lack of access to regular medical care, they would not have received treatment, even if they were not participating in the research study. Although penicillin was discovered in 1947 to be effective in the treatment of syphilis, these men were "expressly and regularly discouraged" from seeking or receiving the readily available and affordable treatment (Furrow, et al., 1997, p.381). Another major criticism of the Tuskegee Study was that the entire sample of subjects was comprised of poor, uneducated African-American men. The researchers responded to this criticism by stating that African-Americans, who were thought to be more sexually active than whites, and physically and mentally weaker, would be the most likely beneficiaries of the results of the research study (Furrow, et al., 1997).

The Tuskegee Study was already made public during the Nazi trials and was continued even after the international community adopted the Nuremberg Code in 1947. Although the United States was condemning the Nazi experiments, and participating in prosecuting war criminals, an unethical and inhumane experiment was going on in Tuskegee, Alabama. The Nazis

accused the United States of applying a double standard, and they used that argument as part of their own defense (Furrow, et al., 1997).

The research continued until 1972 when an article in the *New York Times* reported on the study. There was public outrage that such a study would be sponsored by the U. S. Public Health Service. Curiously, several articles were previously published in medical journals with no reference to the immorality of the study. There is no justification for studying the natural course of an illness without providing treatment to its victims, when the efficacy of existing treatment is proven, available, and affordable (Devettere, 1995). In addition, the subjects were never fully informed of the alternatives available to them, and they never consented to having the treatment withheld from them.

The scientific merits of the Tuskegee Study were criticized, as reported by Jonsen, Veatch and Walters (1998). Criticisms focused on the lack of written research protocols, the absence of informed consent, the immorality of withholding proven therapy from illiterate black men, the racial overtones, and the validity and reliability of the research not being able to be confirmed for lack of standard evaluation procedures. In 1972, an advisory panel appointed to evaluate the Tuskegee Study recommended that the study be terminated, and that survivors be treated for any disabilities that resulted from their participation in the study.

Tearoom Trade Study (1975):

This social research study generated public debate and controversy because of including human subjects in research without their informed consent. Laud Humphreys, a sociologist, studied homosexual men performing sexual acts in public restrooms. He participated by serving as "watch-queen" (i.e., a voyeur and lookout). He revealed his true identity to only a few participants to gain their confidence and to engage them in conversations about their lifestyle. However, he also followed unsuspecting participants in the sex acts and noted their license plates, and was able to identify the participants through the drivers' license bureau. After the observation phase of his study was completed, Humphreys visited the subjects in their homes and misrepresented himself as a "health service interviewer," to inquire about their private lives. The subjects of this study were not informed of Humphreys' true study, and they never consented to participate. This unethical research study was condemned by the public and by Humphreys' colleagues at the University of Washington (Faden & Beauchamp, 1986, p.177).

The doctrine of informed consent may not eradicate all unethical treatment and research misconduct, but it provides ethical guidelines for practitioners to use. The following elements of informed consent summarize the requirements stipulated in the Nuremberg Code (1947), the Declaration of Helsinki (1964), and in the Belmont Report (1979). These three documents provide ethical guidance in the conduct of medical care and in research that involves human subjects.

Elements of Informed Consent

According to Beauchamp and Childress (1994), the literature agrees that the five fundamental elements of informed consent are: i) disclosure; ii) understanding; iii) voluntariness; iv) competence; and v) consent. Each of the elements is described below.

(i) *Disclosure*

Disclosure of information to patients and research subjects is a necessary component of consent. There are three standards of disclosure according to Beauchamp and Childress (1994). These standards are the professional practice standard, the reasonable person standard and the subjective standard.

The professional practice standard is determined by the medical community and it emphasizes the patient's best medical interest. Expert witnesses are in the best position to determine whether this standard has been upheld or violated. This standard is frequently criticized because it assumes that the physician is capable of determining what is in the patient's best interest. This standard is cited by the physicians in their defense in the Canterbury case discussed above. The court expressed preference for the use of the reasonable person standard.

The standard supposes a "hypothetical reasonable person" (Beauchamp & Childress, 1994, p.148). It takes into consideration the *patient's* need for information, rather than the *physician's* opinion of the patient's needs. Respecting the patient's autonomy and his right to self-determination is central to this standard. The difficulty with this standard is that it is difficult to determine what is a reasonable person.

The most preferred standard of disclosure is referred to as the subjective standard. This standard indicates that for the principle of autonomy to be maximized, the level of disclosure of relevant information should be tailored to the person based on his/her individual needs. Information should be presented at a level that the person understands, based on intellectual ability, and taking into consideration cultural differences, functional limitations and language barriers.

(ii) *Understanding*

Related to the concept of disclosure, but even more important, is the concept of understanding. Physicians and researchers need to ensure that an atmosphere that encourages patients or subjects to ask questions and clarify ambiguous information exists. Understanding clearly implies that if the patient has difficulty understanding the English language, an interpreter needs to be provided. If the patient has difficulty hearing or seeing, assistive devices need to be made available to ensure that thorough understanding is

occurring, and that the communication between the physician and the patient is optimized.

(iii) *Voluntariness*

Voluntary participation in treatment and research is essential to the concept of autonomy and self-determination. Patients can make reasoned choices when they are not manipulated or coerced to undergo procedures they are resisting (Pellegrino, 1993). Physicians who persuade their patients to undergo medical treatment may have some influence on the patient's final decision, but they may not be coercive.

(iv) *Competence*

The concept of competence is elusive because individuals may have the competence to perform some functions at the same time they may not be able to perform others. In 1978, the case of Mr. Robert Quackenbush was decided in his favor based on the Judge's decision that Mr. Quackenbush was competent, albeit lacking decisional capacity at times (In re Quackenbush, 156 N.J.Super.282, 383 A.2d 785, 788). Mr. Quackenbush was a 72-year-old patient who needed amputation of his gangrenous leg. His capacity to make health care decisions fluctuated, and there was no consensus of medical opinion between the psychiatrists who evaluated his ability to make health care decisions. The court decided that although Mr. Quackenbush did not maintain decisional capacity at all times, that his competence is not in question. It concluded that the decisions Mr. Quackenbush made during times of capacity were valid, and needed to be followed by his physicians (Furrow, et al., 1997).

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (Jonsen, Veatch & Walters, 1998) also makes the distinction between decisional incapacity, a medical determination that can fluctuate, and incompetence, which is a more durable legal determination. Decisional capacity means that the individual has values and goals, has the ability to communicate and to understand information, and has the ability to reason (Jonsen, Veatch & Walters, 1998).

Research subjects whose decisional capacity appears to be impaired due to the use of drugs and/or alcohol should be temporarily excluded from participating in the research, and from giving informed consent. Consent obtained under conditions of impairment is not legally "informed" because the subject lacks the capacity to understand relevant information (President's Commission, 1982). Understanding basic information relevant to participating in research such as the consequences of participating and the ability to assess the burdens and benefits of participating may not be possible while impaired by the use of drugs and alcohol.

In the provision of medical care, when there is question about the individual's ability to comprehend the given information, an assessment of that individual's ability to make decisions is necessary before consent forms are signed. Patients who have never had competence, such as minors, or adults who have had developmental disabilities precluding competence, also have the right to autonomy, but it is exercised through a legal proxy decision maker. Never-competent individuals' parents or their legally appointed guardians are the appropriate decision makers.

Making health care decisions for those who lack competence is done by following legal standards. According to Jonsen, Veatch and Walters (1998), the President's Commission recognizes best interest, substituted judgment, and reasonable judgment as the acceptable standards for decision making by proxies. Substituted judgment is based on the proxy's knowledge of what the patient's wishes would have been; best interest is simply based on promoting what is good for the patient; and both standards are guided by what is considered reasonable by medical standards.

(v) *Consent*

The final step in the process of informed consent is the signed form to indicate that the individual agrees to participate in a procedure or therapeutic intervention. Although the patient's signature is the standard indication that the patient has consented, it is not an essential component of the consent process. The law requires that the process of being informed by the physician has occurred. The physician may document such a process in the patient's medical record. Devettere (1995) emphasizes the need for proper documentation of the informed consent process as a reminder of its importance, and its symbolic portrayal of patient participation in decision making.

Informed consent is provided by competent adult patients to ensure that their right to self-determination is respected. However, this doctrine also applies to others who do not possess competence, through their legal decision maker. Periodically, the established guardian for a minor is not capable of making health care decisions and providing informed consent in the minor's best interest. In these cases, the courts can be petitioned to replace the appointed decision maker. Obtaining informed consent for medical intervention is the standard practice in the United States. There are some exceptions to this standard, as outlined below.

Exceptions to the Doctrine of Informed Consent

Informed Consent and Cultural Differences

Some elements of the informed consent doctrine may conflict with the beliefs and habits of subcultures in the United States. For example, full disclosure of medical information and seeking consent from the individual patient are two ways that members of certain subcultures are not in agreement with the majority culture. Cultures that emphasize hope, such as the Navajo tribe, opt to receive limited information. Disclosure of the risks of medical treatment and

discussion related to delivering bad news is not acceptable to members of the Navajo tribe. It is their belief that thought and language have the power to shape reality and to control events (Carrese & Rhodes, 1995), and that discussing potential complications may in fact precipitate their occurrence. Discussing negative information with members of the Navajo tribe may be viewed as potentially harmful, and therefore, needs to be reexamined within the context of informed consent.

Members of other cultures may find the strict application of individual autonomy unsuitable, and they may prefer a family-centered approach to medical decision making. However, in 1982, the President's Commission "found a universal desire for information, choice, and respectful communication about decisions" (Jonsen, Veatch & Walters, 1998, p.464). The form in which communication occurs should be tailored to the individual patient based on his/her cultural preferences.

Competing Claims

Competing claims may override the doctrine of informed consent when the best interest of society or of the individual is at stake. Faden and Beauchamp (1986) outline five recognized exceptions to the informed consent requirement: the public health emergency, the medical emergency, the incompetent patient, the therapeutic privilege, and the patient waiver (Faden & Beauchamp, 1986 p.35). Each of these exceptions is detailed below.

(i) *Public Health Emergencies*

To protect the interests of the public and of society, such as in the case of epidemic disease, the government may infringe the rights of individuals. The case of tuberculosis is in point. To this day, patients who are diagnosed with tuberculosis are coerced into receiving treatment. The disease is airborne and is easily transmitted by casual contact. Quarantine and forced treatment are two strategies that have been successfully used, and can be enforced through the court system. Mass, compulsory immunizations at times of epidemics are another example of this public health exception to informed consent (Faden & Beauchamp, 1986).

There are limits to the State's intervention when the contagion is not likely, such as in the case of the spread of AIDS. AIDS cannot be transmitted by casual contact, thus, the public is not at immediate risk of infection. Involuntary confinement and treatment of AIDS patients is, therefore, not excepted from informed consent.

(ii) *Medical Emergencies*

In matters of life and death, or for purposes of relieving pain and suffering, obtaining consent is not necessary. Also, when the patient is not able to consent due to incapacity that resulted from the medical emergency, the physician is relieved from the responsibility of obtaining informed consent. In cases where preservation of life is not at stake, the physician is obligated to seek consent from an appropriate proxy (Faden & Beauchamp, 1986).

(iii) *Incompetence*

The concept of incompetence is illusive. As a rule, incompetence is a legal determination. Adult individuals are presumed competent unless determined otherwise by a judge. Minors are not capable of giving informed consent except when they have engaged in activities which presumes their competence, such as by marriage, or engaging in sexual activity and requesting medical treatment for venereal disease. A legal guardian is required to make health care decisions for minors (Faden & Beauchamp, 1986).

iv) *Therapeutic privilege*

This concept is controversial because it borders on the practice of paternalism and should, therefore, be used sparingly. Physicians may use this privilege of limited disclosure when complete disclosure can be proven to be harmful to the patient. The courts have struggled with this concept and its interpretation varies between jurisdictions. The courts caution that this privilege should not be widely used because it interferes with the patient's right to self-determination (Faden & Beauchamp, 1986).

v) *Waiver*

Waiving the right to make decisions is an informed choice made by the individual in question. When a patient exercises this decision, the physician may not be required to obtain informed consent from the patient. The patient has the right to defer his decision making to anyone he wishes. This is the patient's constitutionally protected right to privacy. Although this right is guaranteed by the U.S. Constitution, it can potentially be abused by physicians. The potential for paternalism abounds (Faden & Beauchamp, 1986).

Practical Application of the Principles of Informed Consent:

Obtaining written informed consent can protect researchers and their sponsoring institutions from litigation, although written consent may not always be necessary. Consent forms can be used as a tool to enhance subjects' understanding of the research and its consequences, and it ensures that researchers have addressed certain basic requirements with their subjects. McDermott and Sarvela (1999) summarize the essential components of an informed consent as follows:

explain the purpose of the research;
avoid technical jargon;
match reading level with subjects' literacy level;
list risks and consequences;
assure subjects of confidentiality;
respect subjects' autonomy and right to privacy;
report results of the research anonymously;
avoid unnecessary risk;

alert subjects to possible consequences (benefits and burdens) of participating;
disclose alternatives to participation;
ensure that subjects understand participation to be voluntary;
assure participants of their right to withdraw at any point; and finally
facilitate communication between the subject and the researcher to respond to subjects' inquiries.

Consequences of Violating Research Ethical Principles

The purpose of conducting research in an ethical manner is to ensure that human subjects are protected from harm. Absent this protection, institutions that sponsor the research may be subjected to litigation and to disruption of their research activities.

Violating the ethical principles of research may result in harmful consequences to the subject such as loss of employment, or interference with relationships. Vulnerable subjects, such as the institutionalized elderly, may also be harmed by giving consent to participate in research when they do not possess the competence to make informed decisions, or when they become too fatigued from participation (Kayser-Jones & Koenig, 1994).

The research sponsoring institutions may also suffer grave consequences of violating informed consent protocols. For example, in January 2000, the Food and Drug Administration placed the human gene therapy research conducted at the University of Pennsylvania on an indefinite clinical hold when a subject, Mr. Jesse Gelsinger, died and the process of his informed consent was not well-documented (Ciment, 2000).

Researchers who engage in unethical research may also suffer personal negative consequences, such as taking the risk being dismissed from their employment, loss of tenure, inability to publish research results and loss of grant sponsorship. Conducting research in an ethical manner protects research institutions, human subjects, and the researchers who study them.

Conclusion

Maximizing patients' right to autonomous health care decision making is ensured through the process of informed consent. Patients have a constitutionally protected right to privacy, a right that has been upheld repeatedly by the court system in medical malpractice cases. The doctrine of informed consent also applies to human subjects who participate in research. There are few exceptions to the doctrine, and these must be used with caution to minimize the possibility of manipulation and paternalism by researchers and physicians.

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