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## Informed Consent and Human Experimentation

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## NOTES AND COMMENTS

### **Informed Consent and Human Experimentation**

The traditional function of consent has been to differentiate those medical interventions which were legally permissible from those which would subject a physician to liability for an unauthorized experiment on his patient. Recently courts have concluded that a patient's assent to a medical procedure is valid, i.e. voluntary, only if it is based on adequate information about the intervention, including its attendant risks.<sup>1</sup> A physician may now be held liable either for negligence in a malpractice suit, if he fails to inform a patient, or battery, if his failure to inform is found to have vitiated the patient's consent. In order to comprehend this very important concept of informed consent, one must examine, first, some of the constructions which courts have given to informed consent; then one must explore some of the functions which informed consent could serve for the human experimentation process; and finally, one must certainly study the inadequacies of informed consent.<sup>2</sup>

The concept of informed consent was most strongly set forth in the code adopted by the United States Military Tribunal at Nuremberg as a standard by which twenty-five German scientists accused of medical atrocities were to be judged. This code is one of the most highly publicized and carefully developed set of precepts specifically written to meet the problem of human experimentation. The code is particularly relevant in the United States since it operated according to American procedural rules and its principles on human experimentation are consistent with the ethics governing American medical practice.<sup>3</sup> Although this code does not have the authority of an American statute, decisions of the United States Military Tribunal based upon it should be considered the main articulation of American standards governing human experimentation. The tribunal stated that the voluntary consent of the human subject is absolutely essential:

This means that the person involved should have legal capacity to consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved so as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative de-

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<sup>1</sup> J. KATZ, *EXPERIMENTATION WITH HUMAN BEINGS* 523 (1972).

<sup>2</sup> *Id.*

<sup>3</sup> Mulford, *Human Experimentation*, 20 *STAN. L. REV.* 99, 103 (1967).

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cision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.<sup>4</sup>

Each individual who initiates, directs, or engages in the experiment is responsible for ascertaining the quality of the consent; this responsibility may not be delegated to another. The tribunal further stipulated that the human subject be at liberty to bring the experiment to an end should he reach the physical or mental state where continuation of the experiment seemed to him to be impossible.<sup>5</sup>

Using the Nuremberg military tribunal code as an example, the House of Delegates of the American Medical Association adopted the report of their Judicial Council on requirements for human experimentation, formulating three main principles; 1) The voluntary consent of the person on whom the experiment is to be performed must be obtained (informed consent); 2) The danger of each experiment must have been investigated previously by means of animal experimentation; and 3) The experiment must be performed under proper medical protection.<sup>6</sup>

The only federal or state statute dealing with research on human beings requires informed consent. Section 505(i) of the Federal Food, Drug, and Cosmetic Act (1964), which applies only to experimental drugs, stipulates that the Secretary of Health, Education, and Welfare shall promulgate regulations concerning drugs intended solely for investigational use. This statute requires a sponsor of research to obtain certification from investigators that the investigators will obtain the informed consent of all human beings to whom they will administer experimental drugs. This statute appears to give investigators a disturbing amount of freedom in that these investigators may refrain from obtaining the informed consent of their subjects where they deem it not feasible or, in their best professional judgment, contrary to the best interests of such human beings.<sup>7</sup> To compensate for this apparent weakness in the statute, the Commissioner of Food and Drugs, as the Secretary's delegate, promulgated strict regulations in 1966, distinguishing between therapeutic and non-therapeutic experimentation. Informed consent must be obtained in all cases in which experimentation with drugs is performed mainly for the accumulation of knowledge, i.e. non-therapeutic administering of drugs. In cases in which patients are under treatment with investigational drugs, i.e. therapeutic

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<sup>4</sup> *Id.* at 103.

<sup>5</sup> M. PAPPWORTH, HUMAN GUINEA PIGS 188 (1967).

<sup>6</sup> *Id.* at 189.

<sup>7</sup> 52 Stat. 1040 (1938), as amended, 21 U.S.C. #301-392 (1964, Supp. 11, 1965-1966). See Food and Drug Reg. #130-137, 32 Fed. Reg. 8753 (rev. June 20, 1967). For legal discussion see Morse, Legal Implications of Clinical Investigations, 20 VAND. L. REV. 747 (1967).

experimentation, informed consent is required in all but exceptional cases.

Informed consent is "not feasible" only, when the patient's inability to communicate renders consent impossible. An example of such a situation occurs when the patient is unconscious and when it is necessary to administer the drug before the patient's representative can be reached. Informed consent is "contrary to the best interests" of the subject when the communication of information would seriously affect the patient's disease status. These regulations also require the investigator to obtain the patient's consent in writing and to inform the subject fully and clearly of all the facts prior to obtaining the consent, including information about alternative forms of treatment.<sup>8</sup>

Experiments conducted within the scope of the doctor-patient relationship must certainly include the important factor of informed consent. The physician treating his patient is guided by the professional maxim, *primum non nocere* ("first of all, do no harm"), which dates back to the Hippocratic Oath. Since the doctor's dedication to this principle may be sufficient to protect the interests of the patient in cases of therapeutic experimentation, informed consent, while desirable, is not considered necessarily vital. The law does impose civil liability for battery on any doctor who performs a therapeutic operation without the express or implied consent of the patient, even if the operation benefits the patient. The Declaration of Helsinki, published by the World Medical Association, and officially endorsed by the American Medical Association (1964), states that in instances in which clinical research is combined with professional care, informed consent may be dispensed with, where full disclosure is not consistent with patient psychology.<sup>9</sup>

However, in non-therapeutic experiments in which the doctor may be more concerned with advancing the state of medical knowledge than with his patient's recovery, informed consent is essential to protect the subject's welfare. The Declaration of Helsinki requires informed consent in all cases in which the experiments are intended for non-therapeutic purposes.<sup>10</sup>

The Declaration of Helsinki is one of several codifications by international and national professional medical bodies. These formulations essentially embody the well-known criteria of the Nuremberg Code. In addition, and of special legal significance, there are several important regulations, directives, and policy memoranda discussing procedures within research institutions themselves.

In the United States, the most important of these quasi-legal mandates originate within the federal government and its health agencies. In July,

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<sup>8</sup> Mulford, *supra* note 3, at 104.

<sup>9</sup> *Id.* at 104, 105.

<sup>10</sup> *Id.* at 105.

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1966, the Surgeon General issued a policy and procedure statement to all grantee institutions, in which requirements to insure the rights of persons involved in clinical research were set forth. This directive stipulated that no grants in support of research were to be continued or awarded unless arrangements were made for consideration of proposals for research involving human subjects by institutional associates of an interdisciplinary committee. These institutional committees are responsible for determining

- 1) That the rights and welfare of those involved are protected,
- 2) That appropriate methods are used to obtain informed consent, and
- 3) That the risks of the procedure are proportionate to the potential medical benefits.<sup>11</sup>

The Office of the Director of the National Institutes of Health (NIH) issued a statement in 1966, outlining the group consideration and informed consent practices which would be used by each Institute. An ascending system of review committees, beginning in each Institute, rising to a clinical research committee of the Medical Board, and culminating in the Medical Board itself, was arranged to transmit all research projects involving the participation of normal volunteers; non-diagnostic, non-therapeutic studies involving patients which might be referred for approval; and therapeutic or diagnostic studies with unusual hazards which might be referred for approval.<sup>12</sup> Expectations of voluntary and informed consent of patients and volunteers were set forth, along with procedures for making records of this information. The statement emphasized these principles as central to clinical research

- 1) Group consideration,
- 2) Informed consent of the patient or volunteer, and
- 3) The freedom of the subjects to withdraw from a project at any time.<sup>13</sup>

Since many research institutions model their practices after NIH, the effects of the statement, added to the significant changes brought about by the policy statements of the Surgeon General, extend far beyond their source.

Another governmental regulation which requires informed consent to non-therapeutic experiments is *Air Force Regulation* No. 169-8 (Use of Volunteers in Aerospace Research), which states: "The voluntary informed consent of the human subject is essential."<sup>14</sup> The subject must have the legal capacity to consent and must be able to withdraw his consent

<sup>11</sup> Fletcher, *Human Experimentation*, 32 LAW & CONTEMP. PROB. 620, 621 (1967).

<sup>12</sup> *Id.* at 622.

<sup>13</sup> *Id.* at 622.

<sup>14</sup> Mulford, *supra* note 3, at 104.

at any time during the research project. Research centers of the National Aeronautics and Space Administration (NASA) seem to follow similar procedures. Furthermore, NASA employees must witness both the briefing of the subject and the signing of the consent form.<sup>15</sup>

The legal situation in regard to judicial decisions related to human experimentation is sketchy at present. Governmental regulations, such as the ones described above, appear to provide the most significant sources of standards governing consent. A few important decisions by American public bodies have come forth in the past two decades. However, these decisions have mainly dealt with specific cases and did not consider research in terms of right and liability of a trained professional to use a living patient or a normal subject as a means of research not necessarily of direct benefit to that patient or subject.

A significant decision of this type was the 1966 censure by the Regents of the University of the State of New York of Drs. Southam and Mandel, who had not obtained adequate informed consent for the injection of cancer cells into twenty-two patients at the Jewish Hospital for Chronic Illness. The object of the procedure was not in question, but the method of obtaining consent was. Even though the cells were felt to be harmless to the patients, it was judged that because the investigators had not specifically stated what kind of cells were being injected, material information necessary to make an informed decision had been withheld. The Regents suspended the licenses of the doctors for one year, but the suspensions were stayed, and the doctors were placed on probation for one year.<sup>16</sup> This decision is of legal significance because it was made by a legislatively appointed body and could possibly be persuasive to a court deciding a case involving similar circumstances. It is important to note also that this widely publicized decision had the effect of sharpening the public awareness of medical research on humans and the central importance of informed consent.

Informed consent remains a relatively ill-defined concept, despite some of the interesting constructions briefly discussed above. Another aspect which deserves examination is the functional relevance of informed consent for human experimentation. Most clearly, requiring informed consent serves society's desire to respect each individual's autonomy and his right to make choices concerning his own life. This function of informed consent involves safeguarding the concept of freedom, protecting the status of the subject as a human being, and avoiding fraud and duress over the subject. A landmark case in this functional aspect of informed consent

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<sup>15</sup> *Id.*

<sup>16</sup> Fletcher, *supra* note 11, at 622-624. The board imposed sanctions, under the authority given it by New York Education Law #6514(2) to revoke, suspend, or annul the license of a practitioner of medicine upon determining "After due hearing . . . that a physician . . . is guilty of fraud, or deceit . . . or has been guilty of unprofessional conduct."

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occurred in 1957, in *Masden v. Harrison*,<sup>17</sup> and concerned the consent of a minor to donate a kidney for his identical twin brother, who suffered from a chronic renal disease that would soon prove fatal. The judge found the operation was necessary for the continued good health and future well-being of the healthy twin, who would doubtlessly have been emotionally disturbed for the rest of his life if this sick twin should have died without the transplant. This decision reaffirmed the principle that the individual is physically inviolable; his interests are paramount; and consent for any action that may violate the integrity of the physical being must be based upon the assumption that such action will be for his benefit.<sup>18</sup>

Another interesting case involved in the concept of informed consent deserves brief reiteration here. In *Natanson v. Kline*,<sup>19</sup> the plaintiff, Irma Natanson, suffering from a cancer of the breast had a radical left mastectomy performed on May 29, 1955. The plaintiff engaged Dr. John R. Kline, a radiologist, for radiation therapy to the site of the mastectomy and the surrounding areas. The plaintiff, as a result of injuries sustained from this radiation therapy, alleged that she had been given an excessive amount of radiation. She brought an action for malpractice against the hospital and the physician in charge of its radiology department. In essence, the patient consented to the treatment, but alleged that the nature and consequences of the risks of the treatment were not explained to her. This case was tried before a jury which returned a verdict in favor of both defendants. This case, however, sparked a series of investigations into the legality of informed consent, and examinations of what constituted informed consent.<sup>20</sup>

The United States Public Health Service also issued a directive giving guidelines for clinical investigations using human beings as subjects. No subject may participate in an investigative type of procedure unless he is mentally competent and has sufficient mental and communicative capacity to understand his choice to participate. The volunteer must be twenty-one years of age or more. If he is less than twenty-one, he may participate in a procedure intended to protect or improve his personal health or otherwise for his personal benefit if the informed written consent of his parents or legal guardian be obtained as well as the written consent of the subject.<sup>21</sup>

A significant function of informed consent is the encouragement of rational decisionmaking. First of all, the subject must be given a fair and

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<sup>17</sup> No. 68657 Eq. Mass. Sup. Jud. CT., June 12, 1957. See: *Huslay v. Harrison*, No. 68666 Eq., Mass. Sup. Jud. CT., Aug. 30, 1957. *Foster V. Harrison*, No. 68674 Eq., Mass. Sup. Jud. CT., Nov. 20, 1957. In these two cases, similar opinions were rendered after hearings by Justices Whittemore and Cutter respectively. See also Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. REV. 891 (1959). See also Restatement, Torts § 59, comment a (1939).

<sup>18</sup> KATZ, *supra* note 1, at 529-539.

<sup>19</sup> 186 Kan. 393, 350 P.2d 1093 (1960).

<sup>20</sup> Fletcher, *supra* note 11, at 630, 631.

<sup>21</sup> KATZ, *supra* note 11, at 540-550.

reasonable explanation of the proposed treatment, including the probable effect and any special or unusual risks. In *Halushka v. University of Saskatchewan*,<sup>22</sup> the appellants, Drs. Wyant and Merriman were found to have committed a trespass against the plaintiff since they did not obtain his consent to the type of test that they performed. These doctors were also found negligent in the performance of the test since they did not fully explain it to the plaintiff, and did not acquire his complete medical history before the test was made. The plaintiff was given a previously untested anesthetic and was not "informed" as to its potential dangers.<sup>23</sup> The findings of the court certainly reinforced the notion that true informed consent must be obtained in clinical experimentation on human beings. This informed consent means that the subject has been given a thorough explanation of the procedure and all inherent dangers. Ideally, a patient will be informed of all possible collateral risks of contemplated therapy and his consent to confronting them will then insulate his physician from liability if any described risk materializes.

A function of informed consent which is of great significance to the investigators is its protection of the experimental process. This protection involves several aspects which bear brief discussion. In conceptualizing the relationship between patient and physician or between subject and investigator, the term *partnership* rather than contract, might more accurately describe their joint adventure in a common cause. This type of conceptualization would increase investigator-subject communication by a mutual feeling of fidelity between two individuals.<sup>24</sup>

The experimental process, when performed under the proper exigencies of informed consent, does not become subject to unfavorable public reactions. There is no doubt, for example, as to the community reaction to the administration, even in the name of research, of live cancer cells to unwitting patients. Unless the advances of science are used with discrimination, the constructive and productive use of these advances may be drastically and unnecessarily restricted by a fearful community.<sup>25</sup>

At the other end of the "consent" spectrum lies the problem of physicians who attempt to comply with the principle of informed consent, even where compliance is not in conformance with good medical practice. This required informed consent may create delay, apprehension, and restrictions on the use of new techniques that will impair the progress of medicine. The same law which protects the interests of the patient or the subject, should also encourage self-reliant surgeons to whom patients may safely entrust their bodies, and not intimidate those who may be tempted to shirk from duty for fear of a law suit. Civil and criminal liability

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<sup>22</sup> 52 W. W. R. 608 (Sask. 1965).

<sup>23</sup> KATZ, *supra* note 1, at 569-573.

<sup>24</sup> *Id.* at 589, 590.

<sup>25</sup> *Id.* at 591-594.

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must be removed in some cases in which implied consent is justifiable and preferable to informed consent.<sup>26</sup> The delicate balance between the rights of both physician and patient, or researcher and subject must somehow be maintained.

The concept of consent has been much derided as unrealistic and artificial, and of course it encompasses a range of responses that differ in their degree of autonomy and understanding. The psychological constraints and compulsions that operate on a seriously ill patient differ from those that affect a person attracted to an experiment through an advertisement. Nevertheless, a requirement of "voluntary, informed consent" does have values beyond that of the symbolic respect for individual autonomy and personality. One such very important function of consent is its reflexive effect on the management of the experiment itself. To analyze an experiment in terms of risks and benefits to particular groups by way of presentation for consent is an excellent procedure for self-scrutiny by the investigator.<sup>27</sup>

The above discussion of the functions of voluntary, informed consent leads quite naturally to the primary problems involved: the limitations and inadequacies of informed consent. In order to give effective protection to the subjects' rights and the integrity of the human experimentation process, the concept of informed consent must take into account the existent limitations on the subjects' ability to make intelligent and insightful decisions. One must consider the impediments to self-determination and informed consent inherent in the psychological forces, intellectual capacities, and social pressures operating in and on man. Is it possible that an awareness of these problems on the part of investigators and subjects can overcome the failures of understanding, communication, and intelligent decisionmaking which now disturb the research process? The definitions of the limitations inherent in informed consent go far beyond the human experimentation process and often reflect contradictory assumptions about the nature and rights of man.<sup>28</sup>

A closer look at a few specific inadequacies of informed consent will help to demonstrate some of its inherent problems. While informed consent is an important prerequisite to conducting experiments on human beings, it may often be insufficient to protect the subject. The complexities of modern research often make informed consent virtually impossible to achieve. The subject is ordinarily not very qualified to evaluate the true risks and expected benefits of any given experimental procedures. An investigator might minimize, either consciously or unconsciously experimental risks and uncertainties. The investigator, in fact, may not be aware of all the risks. Consent is an equally troublesome factor since many experiments

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<sup>26</sup> Rosenberg, *Informed Consent—The Latest Threat*, 189 J. LEGAL MEDICINE 17-19 (1973).

<sup>27</sup> KATZ, *supra* note 1, at 603-606.

<sup>28</sup> *Id.* at 609-611.

are performed on medical students and on prisoners. The desire to please a professor or a parole board might preclude these individuals from giving truly voluntary consent. Likewise, the special relationship of trust between a patient and his physician may induce many patients to consent to any medical practices their doctors propose.<sup>29</sup>

Requiring the informed consent of every experimental subject raises problems for investigators. Disclosure of enough facts to enable the subject to make an informed decision may, in some cases, hinder legitimate scientific inquiry. Investigators face an additional problem when they must use minors as subjects. In general, the consent of the legally incompetent is no defense to civil tort liability. Some courts have made an exception so that the consent of a mature minor capable of understanding the consequences of his act will protect a physician from liability not based on negligence; but this exception has been held to be inapplicable where the operation is non-therapeutic. The researcher should be required to obtain the consent of the minor's guardian, which would usually be sufficient to protect the minor's interests. Whenever the minor is old enough to be capable of intelligent consideration of the issues involved, his consent should be obtained as an additional precaution.<sup>30</sup>

The inherent limitations in and impediments to informed consent raise certain significant questions to which there are no ready, apparent answers. How and to what extent would the dynamics of the inner and outer world, inherent in the nature of man, be considered in defining his capacity for self-determination and informed consent? How are these dynamics affected by the nature and extent of the information given to the subject? To what extent can and should the investigator ascertain from the subject that informed consent has been obtained? The answers to these questions most certainly have implications for the formulation, administration, and review of the human experimentation process.<sup>31</sup>

LAWRENCE EMMA

### **Deed Absolute in Lieu of Foreclosure— A Cost and Delay Internalizer**

A deed absolute in lieu of foreclosure<sup>1</sup> may be defined as a "mortgagor/debtor's" reconveyance of his equity of redemption in the defaulted property to the "mortgagee/creditor" in consideration for the creditor's prom-

<sup>29</sup> Mulford, *supra* note 3, at 106.

<sup>30</sup> *Id.* at 107, 108.

<sup>31</sup> KATZ, *supra* note 1, at 610.

<sup>1</sup> BLACK'S LAW DICTIONARY 775 (4th ed. 1951). Foreclosure is a termination of all rights of the mortgagor or his grantee in the property covered by the mortgage, thus the definition covers court foreclosure, strict foreclosure and the power of sale.