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The History of the Informed Consent Requirement

in United States Federal Policy

I.

Introduction

The informed consent provision in United States federal policy serves a crucial function by protecting human subjects participating in medical research experiments. This paper will trace the development of informed consent as a legal doctrine. The paper will first consider numerous landmark cases, including those that established the basic consent requirement and those that extended the requirement to medical research. In addition to case law, the major scholarly publications and social incidents that spurred the American government to draft protective legislation will be examined. Finally, the paper will explore the numerous efforts by US policymakers to arrive at acceptable legislation. After taking an in-depth look at both two government agencies' attempts to adequately define informed consent, the analysis will conclude with a discussion of the current rule regarding informed consent in medical research.

II. The Birth of the Legal Informed Consent Requirement

A. The Creation of the Basic Consent Requirement

The introduction of informed consent into American legal doctrine came gradually through the pronouncement of a series of important court decisions. Although there were a few nineteenth-century cases implicating consent, the truly significant cases began to come before the courts in the early twentieth-century.[1] Before courts could deal with informed consent, however, they had to deal with basic consent cases. American courts' first forays into the consent arena arose in the context of battery cases. According to Ruth Faden, "Four battery decisions between 1905 and 1914 are almost universally credited with formulating the basic features of informed consent in American law."[2] These cases were *Mohr v. Williams*, *Pratt v. Davis*, *Rolater v. Strain*, *Schloendorff v. Society of New York Hospitals*.

The first two cases, *Mohr* and *Pratt*, can easily be evaluated together. Although they occurred in different states, they went before the courts over roughly the same time period. The two courts also seemed to influence each other; even though *Pratt* went before the lower court later than *Mohr*, the final *Mohr* ruling wound up citing the *Pratt* lower court decision.[3] More importantly, they came out the same way. They can be seen to introduce in American courts the concept that a patient has the right to make her own decisions about medical treatment and procedures performed on her body.[4]

[1] Ruth R. Faden & Tom L. Beauchamp, A History and Theory of Informed Consent 119 (1986). Hereinafter "Faden."
[2] *Id.* at 120.
[3] Mohr v. Williams, 95 Minn. 261, 104 N.W. 12 (1905).
[4] Faden at 120.

Mohr v. Williams (1905) can be regarded as the first significant consent case. In that case, Mrs. Mohr consented to an operation on her right ear, to remove diseased portions of her ear. She consented after conferring with her family physician, who was also present during the operation. Once the plaintiff was anesthetized, however, the defendant surgeon discovered that her right ear was not as sick as he had previously thought, but that her left ear had serious problems. The surgeon felt that the plaintiff's left ear, and not the right, should be operated on, so he performed the procedure on the left ear.[5] Mrs. Mohr sued the surgeon after the operation further impaired her hearing. She claimed that the operation, "not having been consented to by her, was wrongful and unlawful, constituting an assault and battery."[6]

The Supreme Court of Minnesota held that the surgeon should have consulted with the patient and obtained her consent before performing any surgery. A doctor cannot assume that a patient has consented to surgery merely because the patient seeks the doctor's advice about treatment.[7] The court, citing *Pratt v. Davis*, stated:

> Under a free government, at least, the free citizen's first and greatest right, which underlies all others—the right to the inviolability of his person; in other words, the right to himself—is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise, and prescribe (which are at least necessary first steps in treatment and care), to violate, without permission, the bodily integrity of his patient by a major or capital operation, placing him under an anaesthetic for that purpose, and operating upon him without his consent or knowledge.[8]

The court thus placed the utmost importance on the patients' right to decide about the course of treatment. Battery liability was predicated on this right, which gave patients the freedom to protect their bodily integrity from unwanted interference. In exercising this right, patients were entitled to know about the dangers and risks of the procedure, as well as have a chance to evaluate them before coming to a decision.[9]

[5] Mohr, 104 N.W. at 13.
[6] *Id.* at 13.
[7] *Id.* at 15.
[9] *Id.*

In reaching its decision, the court relied on a torts treatise to show that the consent requirement exists not just to authorize a touching, but also to make sure that the patient makes an informed decision. The court cites Kinkead on Torts, § 375, for the general rule:

> The patient must be the final arbiter as to whether he will take his chance with the operation, or take his chances of living without it. Such is the natural right of the individual, which the law recognizes as a legal one. Consent, therefore, of an individual, must be either expressly or impliedly given before a surgeon may have the right to operate.[10]

The court evaluates the logic of this principle by pointing out that all other trades and occupations involve contracts, entered into by the mutual agreement of the interested parties, which specify exactly how activities are to be performed. The concept of consent in the doctor-patient context can be viewed as the logical application of the contract idea to the medical field.[11]

The court did acknowledge, however, that there would be situations in which a doctor has implied consent to perform a procedure. However, this implied consent would only arise in an emergency, such as if the patient were unconscious or if her injuries were so serious as to require immediate attention, in order to save his life. In addition, if during the course of an operation, a doctor were to discover previously-unknown conditions that without redress would endanger the patient's life, the doctor would be entitled to perform the additional procedure without consent.[12] However, in this case, the court felt that operating on the other ear did not fall into any of these exceptions, so the surgeon was perceived as operating without consent, thereby committing battery.[13]

In *Pratt v. Davis* (1906), the Supreme Court of Illinois likewise underscored the importance of the consent requirement. In this case, Mrs. Pratt sued a physician for battery after he performed a hysterectomy on her

[11] *Id.*
[12] *Id.* at 15; *see also* FADEN, at 121.
[13] Mohr, 104 N.W. at 15.

without first obtaining her consent.[14] The physician had gotten her consent for an earlier operation, but he admitted that he had not even attempted to get consent for the second procedure. In fact, he acknowledged that he had intentionally misled her and had taken chances of which she had been completely unaware. The doctor claimed that because Mrs. Pratt was an epileptic, she was incompetent to give consent or to deliberate intelligently about her situation.[15]

The court held the physician liable for operating without consent. As in *Mohr*, the court cited certain emergency cases in which implied consent could be inferred. However, the general rule required consent.[16] Rejecting the contention that Mrs. Pratt was incapable of giving consent simply because she was an epileptic, the court wrote, "Ordinarily, where the patient is in full possession of all his mental faculties and in such physical health as to be able to consult about his condition without the consultation itself being fraught with dangerous consequences to the patient's health, and when no emergency exists making it impracticable to confer with him, it is manifest that his consent should be a prerequisite to a surgical operation."[17]

The third important case, *Rolater v. Strain*, extended the reasoning earlier prescribed in *Mohr* and *Pratt* to other factual situations. In *Rolater*, a woman sued her physician after he removed a bone from her foot during an operation, to which she had consented, to drain an infection.[18] The woman claimed that the doctor had violated her order that he not remove any bones from her foot, so that the removal constituted a trespass to her person, as well as an assault and battery. The doctor argued that *Mohr* and *Pratt* were inapplicable to this case because he had in fact obtained the patient's consent to foot surgery, and he had performed the surgery on the proper foot.[19] The Supreme Court of Oklahoma, however, held that the principles of the earlier cases were indeed applicable because the doctor had not carried out the operation in the manner that

[14] Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906).
[15] *Id.* at 564.
[16] *Id.*
[17] *Id.* at 564.
[18] Rolater v. Strain, 39 Okla. 572, 137 P. 96, 97 (1913).
[19] *Id.*

the patient had specified.[20] *Rolater* highlighted the extent of a patient's self-determination by stressing that the patient could give carefully constrained consent, thereby dictating precisely what the doctor could do, even if the procedure was within the doctor's field and the doctor felt that such procedure was necessary.[21] The final important early case in the area of consent is *Schloendorff v. Society of New York Hospitals* (1914).[22] In this case, the patient had consented to an ether examination of a fibroid tumor but notified the doctor that she wanted no operation. Once the patient was unconscious from the ether, the tumor was removed, and the patient later developed gangrene in her left arm, which required amputation of several fingers.[23] The patient sued the hospital for torts committed by surgeons using the hospital facilities, rather than the actual surgeon who performed the procedure. Because she sued the hospital, the Court of Appeals of New York held that there was no violation of informed consent.[24]

Despite the fact that the court found for the hospital, *Schloendorff* remains a crucial case in the history of informed consent. Writing for the court, Justice Cardozo affirmed a patient's right of self-determination when he wrote:

> In the case at hand, the wrong complained of is not merely negligence. It is trespass. 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 for which he is liable in damages. This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained.[25]

This statement underscored that patients have the right to protect their bodily integrity by making their own decisions about their medical treatment. Furthermore, a doctor's interference with this right may be considered a battery.

[20] *Id.* at 98.
[21] FADEN at 123.
[22] *Id.*
[23] Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92, 93 (1914).
[24] FADEN at 123.

B. The Introduction of Informed Consent

After *Schloendorff*, courts throughout the country continued to hear battery cases, judging them based on the duty to obtain consent and the self-determination principle introduced in these four early cases.[26] The next major court case dealing with consent did not come for several decades, until *Salgo v. Leland Stanford Jr. University Board of Trustees* in 1957. The *Salgo* case marked the introduction of the term "informed consent" and a new legal duty.[27]

In *Salgo*, Mr. Salgo brought a malpractice suit against his physicians alleging negligence when he became permanently paralyzed after having undergone a translumbar aortography. Mr. Salgo's doctor had recommended the surgery, but Mr. Salgo claimed that the doctor had never explained the various possible complications of the suggested procedures or warned him about the risk of potential paralysis.[28] A California Court of Appeals decided that the physician was liable for not disclosing relevant information to the patient.[29]

Although the consent issue in the case was not the main grounds for appeal, the court nonetheless set an important precedent when it created a heightened duty to disclose on the part of doctors.[30] The court determined that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[31] This new type of consent focused on whether the doctor had provided the patient with all the

[26] FADEN at 125.

[27] Jay Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 University of Pittsburgh Law Review 137, 149 (1977). Hereinafter "Katz, *Law's Vision.*"

[28] Salgo v. Leland Stanford Jr. University Board of Trustees, 317 P.2d 170, 173 (1957).

[29] *Id.* at 181.

[30] Jay Katz, *Informed Consent—Must It Remain A Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69, 72 (1993). Hereinafter "Katz, *Remain a Fairy Tale?.*" *See also* Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 161 (1998). Hereinafter "Morin."

[31] Salgo, 317 P.2d at 181.

information needed to make an intelligent decision, such information including the harms, benefits, risks and alternatives of the proposed procedure. Such disclosure went much beyond the disclosure that was required to defeat a battery claim, which simply involved information about the nature of the procedure.[32]

In addition to imposing a disclosure requirement, however, the court also placed some limits on this new requirement by subjecting it to physicians' discretion. The court seemed to recognize the need for a therapeutic exception, exercisable at a physician's discretion. Under this exception, a doctor could either explain every risk to a patient, potentially frightening the patient out of treatment, or use some discretion to reveal only those facts that are needed to obtain valid informed consent.[33] This allowance for discretion, however, seemed to contradict the idea of maximum disclosure by physicians, leaving the new requirement broad and undefined.

Despite the breakthrough introduction of informed consent, courts remained unclear about how to actually apply the new rule.[34] According to scholar Jay Katz, this opportunity for discretion created a judicial dilemma that has continued to plague the doctrine of informed consent. Reflecting on the history of informed consent, Katz wrote:

> The conflict created by uncertainties about the extent to which individual and societal well-being is better served by encouraging patients' self-determination or supporting physicians' paternalism is the central problem of informed consent. This fundamental conflict, reflecting a thoroughgoing ambivalence about human beings' capacities for taking care of themselves and need for care-taking, has shaped judicial pronouncements on informed consent more decisively than is commonly appreciated. The assertion of a 'need' for physicians' discretion—-for a professional expert's rather than a patient's judgment as to what constitutes well-being—-reveals this ambivalence.[35]

Regardless of the confusion *Salgo* caused, however, Katz suggests that the court had at least highlighted the

[32]Katz, *Law's Vision* at 150.
[33]Morin at 157.
[34]Katz, *Law's Vision* at 150.

necessity of adequate disclosure by doctors, paving the way for further development of the informed consent requirement.[36]

While *Salgo* introduced the duty of informed consent, *Natanson v. Kline* (1960) marked the first time that physician liability was rooted in the negligence theory, rather than battery.[37] In this case, Mrs. Natanson, suffering from breast cancer, had a mastectomy and then endured cobalt therapy to the mastectomy site to reduce the chance that the cancer would recur or spread. After she was injured from the cobalt radiation therapy, she sued her radiologist for negligence both in the performance of the procedure and in failing to warn her about the nature and hazards of the treatment.[38] The Kansas Supreme Court held that the radiologist was liable for failing to meet his duty of disclosure. The court outlined the duty of disclosure as "the obligation of a physician to disclose and explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body."[39]

Like all the earlier cases, the court justified this duty by pointing to the importance of patient self-determination. The court writes:

> Anglo-American law starts with the premise of thorough-going self-determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment. A doctor might well believe that an operation or form of treatment is desirable or necessary but the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception.[40]

However, as in *Salgo*, the court faced some confusion as to how to implement this self-determination principle in the law.[41] On the one hand, since this was a negligence claim, the standard of care imposed on

[36] *Id.* at 149.

[37] FADEN at 129. *See also* Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63, 76 (1993). Hereinafter "Goldner."

[38] Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, 1095 (1960).

[39] *Id.* at 1107.

[41] Katz, *Law's Vision* at 151.

the defendant doctor was that of a reasonable and prudent medical doctor in the same school of practice, working under similar circumstances. On the other hand, because the court was trying to honor the principle of self-determination, it specified that the defendant doctor had to make a reasonable disclosure about the nature and probable consequences of the proposed treatment, as well as the possible dangers he knew about. The problem was that this second standard encompassed much more than the first standard, that of the "reasonable and prudent medical doctor" would.[42]

Forced to choose a standard, the court decided to treat this case in negligence. It determined that the standard was that of a reasonable doctor: "the duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."[43] Further separating this case from a battery claim, it also mandated a causation requirement, showing that the doctor's failure to make reasonable disclosure was indeed a proximate cause of the injury.[44] Therefore, "the court firmly cemented liability for failure to disclose necessary information in the law of negligent malpractice by recognizing its traditional requirements: violation of a professional standard of care and proximate cause."[45] The *Natanson* court thus firmly established that the negligence theory applied to informed consent cases.

[42] *Id.* at 152.
[43] Natanson, 350 P.2d. at 1106.
[44] FADEN at 131.
[45] Katz, *Law's Vision* at 152-3.

C.

Further Exploration of the Informed Consent Requirement

Natanson's reasonable doctor/professional practice standard of disclosure proved quite important when it became the standard that was adopted in most states.[46] However, in 1972, *Canterbury v. Spence* changed the disclosure standard to that of the reasonable person, while affirming that a doctor does indeed bear the duty of due care and must warn a patient of any risks so that the patient may make an intelligent decision about treatment.[47] The case involved a young man who underwent a laminectomy for back pain, without being told about the risk of paralysis. One day after the operation, Mr. Canterbury fell from his hospital bed; several hours later, the lower half of his body was paralyzed. After a second operation failed to correct the paralysis, he sued, alleging that the doctor negligently failed to disclose the risk of paralysis before the first operation.[48]

The *Canterbury* court, held that the doctor was liable for failure to disclose the risk.[49] The DC Court of Appeals, building on the tradition established in *Schloendorff* and the other early cases, based its decision around the patient's right to self-determination. The attainment of self-determination required a heightened disclosure duty:

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.[50]

[46] Morin at 2.
[47] Faden at 132. *See also* Judith Areen et al., Law , Science and Medicine 372-82 (1984). Hereinafter "Areen."
[48] Canterbury v. Spence, 464 F.2d 772, 778 (D.C. Cir. 1972).
[49] *Id.* at 781.

In order for the patient to make an intelligent decision, the doctor had to provide reasonable disclosure of the risks of and alternatives to the treatment. The physician-patient relationship provided the link of why the doctor had to afford such disclosure; the patient trusted and relied on the doctor to reveal any information that would be important for the patient to know.[51]

In addition to the self-determination argument, however, the court also incorporated a physician due care argument. The doctor bears a duty to treat the patient with reasonable skill and due care; this duty includes an obligation to disclose certain relevant information, such as side effects of medication and advice about the consultation of specialists as needed.[52] Significantly, "due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve."[53] Since the process of obtaining informed consent would be worthless if the physician had not first explained the risks clearly to the patient, the physician must make adequate disclosure to each patient.[54]

While the *Canterbury* court affirmed the disclosure requirement, however, it departed from prior cases by adopting the reasonable person standard in place of the professional practice standard.[55] The court felt that "to bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[56]

The court rejected the subjective standard, choosing to focus on the reasonable person. The extent of disclosure therefore had to be measured according to what would be important to the average patient, instead of what the average doctor revealed in usual practice.[57] The court's reliance on the reasonable person stan-

[51] *Id.* at 782.
[52] FADEN at 134.
[53] Canterbury, 464 F.2d at 781.
[54] FADEN at 134.
[55] *Id.* at 132.
[56] Canterbury, 464 F.2d at 784.
[57] *Id.*

dard seemed to reflect a greater concern for adequately fulfilling patients' rights, while still limiting doctors' liability from individual patients' subjective claims. The *Canterbury* case ultimately combined elements of both the battery and negligence cases, while addressing the importance of patients' self-determination and the realities of the doctor-patient relationship.

III.

The Consent Requirement Applied to Medical Research

A. Important Cases

All the battery and negligence cases discussed thus far, from *Mohr* through *Canterbury*, dealt with consent in the medical treatment setting. In several other important cases, however, American courts also addressed the consent requirement as applied to medical research. The earliest significant American case was *Carpenter v. Blake* (1871), in which the patient sued her physician for negligence and malpractice in the setting and treatment of a dislocated limb.[58] The patient alleged that the doctor did not properly set the dislocated arm, and also that the doctor did not attempt to reset the bones after the patient developed an obvious swelling at the elbow joint. The physician defended his actions by claiming that his unusual treatment method was not negligence but rather a new type of treatment; he did not claim to be engaging in research, but organized research had not yet become a common practice.[59]

[58] Carpenter v. Blake, 60 Barb. N.Y. 488 (1871).
[59] FADEN at 190.

The *Carpenter* court held that a doctor who departs from the usual, established method of treatment is liable for any resulting problems. According to the court, "the rule protects the community against reckless experiments, while it admits the adoption of new remedies and modes of treatment only when their benefits have been demonstrated."[60] This rule treated experimentation as a negligent departure from traditional practice and accepted the validity of new remedies and treatments only after their benefits had already been proven, making experimentation a dangerous pursuit for doctors.[61]

The *Carpenter* rule dominated the American medical world's approach to experimentation for many years. In 1934, however, the Supreme Court of Colorado initiated a slightly more tolerant attitude regarding experimentation.[62] In *Brown v. Hughes*, Mr. Hughes' widow sued a dentist and a physician after they removed her husband's tonsils and sixteen of his teeth without his consent and against his will; Mr. Hughes died soon afterward. The widow alleged that the doctors' negligence and malpractice caused her husband's death.[63] The court did not find the defendants liable and opened the door to allow some experimentation by doctors. The court determined that some experimentation had to be allowed or else science would never advance: "there must be a clearer case of total abandon than here attaches before liability occurs, otherwise the learned judgment of our skilled profession would be lost to the human race. Without such, we could not enjoy the advancement of science."[64]

The most important case in the field of experimentation came the following year, when the Michigan Supreme

[60] Carpenter, 60 Barb. N.Y. at 521.
[61] Goldner at 72. *See also* Henry K. Beecher, Research and the Individual 37 (1970). Hereinafter "Beecher, Individual."
[62] Faden at 190.
[63] Brown v. Hughes, 94 Colo. 295, 30 P.2d 259 (1934).
[64] *Id.* at 263.

Court acknowledged that medical progress required some research involving human subjects.[65] In *Fortner v. Koch* (1935), Mr. Fortner, though actually suffering from syphilis, was treated for sarcoma. He sued the physician, alleging negligence in his diagnosis and treatment; he claimed that the physician did not use the various diagnostic methods available, including taking x-rays or microscopically examining tissue specimens from the infected area. The court held the doctor liable for his negligence.[66]

In a crucial step, however, the court for the first time allowed that some human experimentation must be permitted, writing: "we recognize the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure."[67] Therapeutic research, allowing experiments that could potentially benefit the patient, was the type of experimentation protected by this decision. The court imposed two important limits on such experimentation, namely that the subject consent and that the procedure not deviate too much from established practice.[68] These considerations of valid consent and an acceptable risk-benefit analysis would later become the two main concerns in the debate about whether research on human subjects should be justified.[69] The importance of the *Fortner* case thus stems from both its unprecedented tolerance towards and justifications for experimentation on humans.

[65] Morin at 169.
[66] Fortner v. Koch, 272 Mich. 273, 261 N.W. 762 (1935).
[67] *Id.* at 765.
[68] Goldner at 73.
[69] FADEN at 191.

B. Promulgation of Significant Early Codes

Despite the *Fortner* court's acknowledgment of the importance of research on human subjects, such research did not actually become widespread in the United States until the mid-twentieth century, shortly before the beginning of World War II.[70] Internationally, however, research on humans was a common occurrence, and it was a reaction to experiments conducted by Nazi physicians during World War II that prompted the first attempt by any group to regulate research.[71]

The focus on informed consent in research "grew gradually after the occurrence of what is still today the most important watershed event: the unprecedented cruelties and generally inferior science, administered by what were often well-trained physicians of prominence, during the Nazi reign in Germany."[72] Nazi scientists and doctors widely engaged in racial hygiene, in an effort to control reproduction in society and achieve racial cleansing. They followed three main programs: the Sterilization Law, the Nuremberg Laws, and the euthanasia operation. These three practices allowed doctors to determine which citizens would survive, marry, and reproduce.[73]

In 1946, the Nazi physicians were tried before the Nuremberg military tribunal for the biomedical experiments they conducted during World War II.[74] The twenty-three defendants in *United States v. Karl Brandt* were doctors and administrators, many of whom were high-ranking in the Third Reich's medical hierarchy. The defendants were charged with conducting human experimentation on unconsenting prisoners and performing such "medical" experiments as injecting prisoners with infectious diseases, mutilating bones and muscles, and forcing prisoners to ingest poisons.[75] Their subjects included Jews, gypsies, Poles and Russians imprisoned

[70] *Id.* at 151.
[71] Thomas John Babbo, *Begging the Questions: Fetal Tissue Research, The Protection of Human Subjects, and the Banality of Evil,* 3 DePaul J. Health Care L. 383, 387 (2000). Hereinafter "Babbo."
[72] Faden at 153.
[73] George J. Annas and Michael A. Grodin, The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation 17-24 (1992). Hereinafter "Annas, Nazi Doctors."
[74] Babbo at 387.
[75] Annas, Nazi Doctors at 132.

in the concentration camps.[76] In the trial's opening statement, the prosecutor stated:

> The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science... All of them have in common a callous lack of consideration and human regard for, and an unprincipled willingness to abuse their power over the poor, unfortunate, defenseless creatures who had been deprived of their rights by a ruthless and criminal government. All of them violated the Hippocratic commandments which they had solemnly sworn to uphold and abide by, including the fundamental principles never to do harm—"*primum non nocere.*"[77]

Witnesses in the trial testified that the experiments had no valid medical justification and simply exposed the subjects to extreme cruelty.[78]

The judges at the Nuremberg Military Tribunal condemned the defendants' behavior. They found that Nazi doctors had violated their subjects' rights and ignored their ethics as doctors. They also established the "certain basic principles [that] must be observed in order to satisfy moral, ethical, and legal concepts" while conducting research on human subjects.[79] These ten principles became the Nuremberg Code, promulgated in 1948. The Nuremberg Code focused on protecting the human subject by requiring the subject's consent and setting boundaries within which the investigator may conduct research.[80]

Principle One states that "the voluntary consent of the human subject is absolutely essential."[81] Such consent must have at least four characteristics; it must be voluntary, competent, informed, and comprehending.[82] Although all ten brief principles were significant, a brief examination of several other principles reveals how the drafters tried to protect subjects by imposing limits on how investigators could perform their experiments and convince subjects to participate. Principle Four directs physicians to conduct experiments so as

[76] FADEN at 153.
[78] FADEN at 154.
[79] Judgment in United States v. Karl Brandt, *reprinted in* KATZ, EXPERIMENTATION at 305.
[80] ANNAS, NAZI DOCTORS at 152. *See also* Kenneth L. Vaux and Stanley G. Schade, *The Search for Universality in the Ethics of Human Research: Andrew C. Ivy, Henry K. Beecher, and the Legacy of Nuremberg*, *in* THE USE OF HUMAN BEINGS IN RESEARCH 3-16 (Stuart F. Spicker et al eds, 1988).
[81] Nuremberg Code, *reprinted in* ANNAS, NAZI DOCTORS at 2.
[82] *Id.*

to avoid all unnecessary physical and mental suffering and injury. Principle Seven commands investigators to make the appropriate preparations to protect subjects against any chance of injury or death. Finally, Principle Nine grants subjects the right to terminate the experiment at any time.[83] The promulgation of the Nuremberg Code was a monumental first step in the effort to regulate research on humans and would soon influence many professional organizations and governments who were beginning to contemplate similar regulation.

The Declaration of Helsinki was the first major code produced after the Nuremberg Code appeared. After the atrocities committed by the Nazis attracted significant attention, the medical community realized that it needed to issue better regulation surrounding clinical research.[84] As a result, the World Medical Association (WMA) drafted the Declaration of Helsinki, which was adopted in 1964 by the 18^{th} World Medical Assembly.[85] While the Nuremberg Code was seen as the courts' imposing strict legal obligations on doctors, the Declaration garnered praise as a non-legal code promulgated internally by the medical community, offering standards meant simply to guide doctors.[86]

As the Nuremberg Code had, the Declaration focused on the need for consent while conducting research. However, "by order of priority, the Declaration of Helsinki placed scientific expertise and the goals of medicine before the informed consent of the research subject."[87] The Declaration operated primarily by distinguishing between therapeutic and non-therapeutic research.[88] Non-therapeutic research, which was defined as purely scientific studies without therapeutic value for the subject, could not be performed without consent.[89] Principle One, section nine reads: "In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort

[83] *Id.*
[84] Goldner at 92.
[85] Annas, Nazi Doctors at 158.
[86] Babbo at 389.
[87] *Id.*
[88] Robert J. Levine, Ethics and Regulation of Clinical Research 6 (1981). Hereinafter "Levine."
[89] *Id.*

it may entail... The physician should then obtain the subject's freely-given informed consent, preferably in writing."[90]

On the other hand, therapeutic research, defined as medical research combined with professional care, did not require informed consent by the subject. Rather, the physician was free to pursue new measures in his own judgment, subject to only a modest check on his judgment in the form of review by an independent review committee.[91] It should be noted that the Declaration, which did not involve an American group and was not legally binding, probably did not significantly alter research practices in the United States.[92] Nonetheless, the Declaration of Helsinki became an influential document in the history of informed consent after many American medical groups endorsed it and the federal government turned to it as guidance while developing its own rules.[93]

C. Influential Scholarly Publications

While the Declaration of Helsinki marks the medical community's response to the Nazi doctors' barbarisms, the publications of several important scholarly works demonstrate the reactions of various scholars. Henry K. Beecher could arguably be cited as the most influential scholar to comment on the deficiencies of research ethics.[94] In several influential works, Beecher, a physician at Harvard, called for stricter protection of research subjects. His earliest offering, *Experimentation in Man*, which appeared in 1959, argued that the activities in Germany and the continued growth in human experimentation "indicate the need for a long,

[90] World Medical Association Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, *reprinted in* 277 JAMA 11 (1997).
[91] Faden at 157-8.
[92] Goldner at 92.
[93] Faden at 157.
[94] Paul M. McNeill, The Ethics and Politics of Human Experimentation 59 (1993). Hereinafter "McNeill."

straight look at our current practices."[95] While Beecher acknowledged the need for human experimentation, he believed that the subjects' consent had to be obtained prior to research.[96]

Beecher's goal in *Experimentation* intended to call attention to the moral problems associated with research on humans and to demand that the medical community adopt practices that complied with moral requirements.[97] He did not actually propose a new system to follow, since he did not believe in codes and rules delineating adherence to specific rules. According to Beecher, rules "are more likely to do harm than good. Rules are not going to curb the unscrupulous. Such abuses as have occurred are usually due to ignorance and inexperience. The most effective protection for all concerned depends upon a recognition and an understanding of the various aspects of the problem."[98]

In 1966, Beecher produced two other crucial works that helped draw attention to the ethical violations that routinely occurred in human research. In "Ethics and Clinical Research," published in the *New England Journal of Medicine*, Beecher discussed twenty-two examples of questionable experiments and stated that of the fifty cases he originally compiled, the subjects' consent had been obtained in only two cases.[99] He wrote, "Evidence is at hand that many of the patients in the examples to follow never had the risk satisfactorily explained to them, and it seems obvious that further hundreds have not known that they were the subjects of an experiment although grave consequences have been suffered as a direct result of experiments described here."[100] Beecher argued that unethical or questionably ethical practices occurred with significant frequency, producing a serious situation that had to be addressed.[101]

That same year, Beecher wrote an editorial in the *Journal of the American Medical Association*, in which he

[95] Henry K. Beecher, *Experimentation in Man*, *in* Clinical Investigation in Medicine 2-39 (Irving Ladimer & Roger W. Newman eds., 1963). Hereinafter "Beecher, *Experimentation*."
[96] *Id.*
[97] Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 234 (1979).
[98] Beecher, *Experimentation* at 27.
[99] McNeill at 60.
[100] Henry K. Beecher, *Ethics and Clinical Research*, 274 New Eng. J. Med. 1354 (1966).
[101] *Id. See also* George Annas, The Rights of Patients 146 (1992). Hereinafter "Annas, Rights."

again argued that codes were not the best way to ensure that the requirement of informed consent is met.[102] Rather, he appealed to the virtue of physicians, stating that the patient's "great safeguard in experimentation as in therapy is the presence of the skillful, informed, intelligent, honest, responsible, compassionate physician."[103] Even though Beecher did not support the promulgation of an American code, his writings ultimately greatly influenced the development of American federal policy regarding informed consent in research.

Another instrumental scholar was M.H. Pappworth, an Englishman who himself influenced Beecher.[104] In 1967, Pappworth published *Human Guinea Pigs*, in which he revealed his findings about more than 500 cases of unethical experiments. He highlighted experiments performed on numerous types of people, including children, the mentally ill, and dying patients who either were incapable or had difficulty giving consent. Pappworth noted that many physicians took unreasonable risks with their patients' lives and were generally unconcerned with their patients' overall well-being.[105] He therefore demanded that new legislative procedures be developed to safeguard patients' rights.[106]

The final scholar to contribute important work in this field was psychiatrist Jay Katz, who published the anthology *Experimentation with Human Beings* in 1972.[107] Katz collected writings relating to the ethics of human experimentation from a variety of fields, including law, medicine, biology, sociology, and psychology. He gathered trial transcripts, panel discussions, editorial comments, legislation, and newspaper stories, among other materials, to address the crucial questions of what limits should be placed on scientific inquiry, and who should have the authority to impose those limits.[108] According to Katz:

[102] Henry K. Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 JAMA 34, 35 (1966).
[103] *Id.*
[104] Beecher, Individual at 17.
[105] M.H. Pappworth, Human Guinea Pigs: Experimentation on Man 12-27 (1967).
[106] *Id.* at 208.
[107] Morin at 186-7. *See also* Bradford Gray, Human Subjects in Medical Experimentation 202-3 (1975).
[108] Katz, Experimentation at 3.

> The real need to which this volume speaks is for greater conscious awareness and relentless scholarly analysis of the conflicting purposes of human experimentation—protecting man, advancing science, and improving the well-being of society and future generations. Only if students and decisionmakers are prepared to sort out these conflicts and to acknowledge the reality of harm to individuals and society can they begin to formulate rules and procedures which will minimize harm without erecting insuperable impediments to the acquisition of knowledge.[109]

Katz' anthology aimed, and largely succeeded, at stimulating discussion about the importance of conducting scientific studies while still protecting subjects' rights.

D. Significant Cases Involving Consent Violations

At the same time as scholars such as Beecher and Katz began voicing their concerns about experiments conducted without subjects' consent, a number of cases and studies showcasing consent violations attracted public attention. The earliest significant episode involved a cancer study undertaken in 1963 at the Jewish Chronic Disease Hospital (JCDH) in Brooklyn, New York.[110] Three doctors at the Hospital injected live cancer cells into twenty-two chronically ill and debilitated patients. The doctors had obtained the permission of the hospital medical director, but they did not obtain consent from any of the patients involved, even though the research was completely non-therapeutic. Some patients were informed that they were involved in an experiment, but none were told that they were receiving cancer cells. Likewise, none of the patients were notified that the test was unrelated to their usual therapeutic treatment.[111]

Many of JCDH's other doctors expressed concern about this cancer study. As a result, William Hyman, a member of the hospital's board of directors, filed suit to force the hospital to disclose its records. Hyman, an attorney, was concerned about both the abuse of the patients and the hospital's potential liability for having given experimental injections without consent.[112] Disclosure ultimately revealed that the investigators had

[110] Goldner at 74. *See also* Mark S. Frankel, *The Development of Policy Guidelines Governing Human Experimentation in the United States: A Case Study of Public Policy-Making for Science and Technology*, 2 Ethics in Sci. & Med. 43, 49-50 (1975).
[111] Katz, Experimentation at 9.
[112] Frankel at 49-50.

not presented the study to the hospital research committee and that the subjects' attending doctors had not been consulted before their patients received the injections.[113]

Hyman's suit helped bring attention to the cancer study, and in 1966 the Board of Regents of the University of the State of New York brought suit against two of the doctors involved; these two doctors were found guilty of fraud, deceit, and unprofessional conduct.[114] The Board of Regents' Discipline Committee determined:

> A patient has the right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason, intelligent or otherwise, well-informed or prejudiced. A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision... There is evidenced in the record in this proceeding an attitude on the part of some physicians that they can go ahead and do anything which they conclude is good for the patient, or which is of benefit experimentally or educationally and is not harmful to the patient, and that the patient's consent is an empty formality. With this we cannot agree.[115]

The Board of Regents thus placed great importance on obtaining subjects' informed consent, regardless of the degree of harm or possible therapeutic benefits to the subject.[116] Although the two doctors involved received minimal punishment, namely one year probation, the case showcased the potential abuses of human subjects and the inadequacy of current federal guidelines.[117] The JCDH case would soon affect the development of federal policy regarding human experimentation.

Several years later, a longer, more egregious study captured the nation's attention. Since the early 1930s, the United States Public Health Service (PHS) had been conducting a study on the effects of untreated syphilis on black men in Alabama.[118] The purpose of the Tuskegee Syphilis Experiment was simply to compile data about the progression of syphilis in black males. The study had no therapeutic value for the subjects, and

[113] Faden at 161-2.
[114] The Board of Regents' Discipline Committee Reviews the Recommendations, *reprinted in* Katz, Experimentation at 60-2.
[116] Beecher, Individual at 171.
[117] Frankel at 50.
[118] Areen at 936.

in fact men with syphilis were actively prevented from receiving the known treatment until the horrors of the study had been exposed.[119]

The PHS doctors shockingly failed to obtain consent or inform their subjects about the circumstances of the study. The subjects were not told the name of their disease or that they were participating in a non-therapeutic experiment. They were told only that they were being treated for "bad blood," a term which was never defined for them.[120] In addition, they were informed that certain painful research procedures, such as spinal taps, were "special free treatments," which was a clear lie on the doctors' parts. In sum, the doctors clearly manipulated the subjects, relying on the fact that the subjects would trust the doctors' statements and opinions.[121]

The study continued unaltered until 1972, when the reporter Jean Heller published a profile of the situation on the first page of the *New York Times*.[122] With public attention focused on the Tuskegee Experiment, the Department of Health, Education, and Welfare appointed an advisory panel to examine the problem and address the issue of protecting human subjects.[123] The panel ruled that the Tuskegee Experiment should be discontinued and that subjects requiring care be given the proper treatment. The panel judged that the study was "ethically unjustified in 1932... One fundamental ethical rule is that a person should not be subjected to avoidable risk of death or physical harm unless he freely and intelligently consents. There is no evidence that such consent was obtained from the participants in this study."[124]

[119] James H. Jones, Bad Blood: The Tuskegee Syphilis Experiment 2 (1981).
[120] McNeill at 61.
[121] Faden at 165.
[122] Jones at 1.
[123] *Id.* at 210.
[124] Final Report of the Tuskegee Syphilis Study Ad Hoc Panel to the Department of Health, Education and Welfare, *in* Katz, Experimentation at 948.

More broadly, the panel determined that no American government agency had a uniform policy for reviewing experimental procedures or obtaining subjects' consent. Instead, the investigators in the biomedical profession who were conducting the experiments were the ones who regulated research practices.[125] The panel decried the current situation and "offered procedural and substantive recommendations for safeguarding subjects, the most important of which was the creation by Congress of a permanent body to regulate all federally sponsored research on human subjects."[126] In fact, by the early 1970s, the US government had begun to mobilize efforts to draft a federal policy regulating human experimentation.[127] The Tuskegee Syphilis Experiment served as one other strong reminder that the policy needed to be finalized and implemented as soon as possible to prevent further abuse of human subjects.

IV. Development of Federal Policies Concerning Human Research

A. Initial Attempt at Regulation

The United States government did not really begin to formulate policies protecting human research subjects until the 1960s.[128] Although courts and international organizations had earlier recognized the importance of explicitly offering such protection, US federal policies were slower to develop. When concern did arise, however, two agencies within the Department of Health, Education and Welfare (DHEW) responded.[129] Both the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) eventually

[125] Jones at 211.
[126] *Id.* at 211-12.
[127] McNeill at 61.
[128] Faden at 200.
[129] William J. Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, 98 Daedalus 542 (1969). Note that the DHEW is now called the Department of Health and Human Services.

reacted to the problem of unregulated research and proposed their own solutions. The two agencies had different purposes, with the FDA responsible for regulation and the NIH in charge of funding and conducting biomedical and behavioral research.[130] Nonetheless, both agencies' concern about the lack of informed consent in medical research shaped the development of the ultimate US policy.

The first federal policy regarding research on human subjects emerged at the Clinical Center of the NIH. The Clinical Center at Bethesda, which opened in 1953, was a research hospital that conducted clinical research for the NIH.[131] The Center commands attention because it had a strict internal code that dictated specific points needed to obtain the subject's informed consent.[132] Research subjects were treated as members of the research team, showcasing "one of the earliest expressions of the concept of medical research as encompassing the subjects as well as the investigators as colleagues in a cooperative enterprise."[133] The Clinical Center's landmark principles represent the first established policy regarding the treatment of research subjects in a US government health-care facility.[134]

Officials at the Clinical Center hoped that their policy of detailed instructions for obtaining informed consent would be adopted by other government agencies. Unfortunately, however, other agencies did not follow suit, as the results of the Law-Medicine Institute Study of 1960 revealed.[135] Boston University's Law-Medicine Research Institute conducted a three-year study, looking at actual clinical research practice in the US. The study showed that very few (nine out of fifty-two) medical departments had any formal guidelines regarding clinical research; even worse, only two of those nine had guidelines that were generally applicable to all clinical

[130] *Id.* at 542.
[131] FADEN at 201.
[132] *Id.* at 202.
[133] Curran at 575.
[134] FADEN at 202.
[135] *Id.*

research.[136] Most of the investigators polled expressed dislike for self-regulation by committees, preferring instead to leave all oversight directly to the investigators.[137] It appears that despite the atrocities overseas and the increasing regulations by international organizations, American investigators still felt little need to protect human subjects. Throughout the 1950s and early 1960s, it seems that US federal policymakers were willing to allow investigators the latitude they wanted.

B. FDA Reaction and Policy Established

In the early 1960s, however, the attitude of policymakers at the FDA changed with the promulgation of the Drug Amendments of 1962. The Drug Amendments of 1962, formally the Kefauver-Harris Bill, made important changes in the central laws governing the ethical drug industry.[138] The most significant changes included the requirements that drug advertising be more carefully controlled; that drug labeling fully disclose precautions and harmful side effects; that there be proof of therapeutic efficacy for drugs; and that the FDA establish complete regulations for clinical testing of new drugs.[139]

The bill emerged largely after Congressional concern about the use and control of drugs. Although hearings before Senator Estes Kefauver's Subcommittee on Antitrust and Monopoly had focused mostly on price regulation and drug costs, the bill gained extra support after the Thalidomide problem in Europe demonstrated the dangerous side effects of drugs.[140] The fact that Thalidomide proved to cause serious side effects in fetuses highlighted the necessity for more stringent drug testing and warning requirements.[141] The drug testing situation spurred Senator Jacob Javits to add a consent requirement, marking the first time such a requirement was included in US legislation.[142]

[136] Frankel at 48.
[137] Faden at 158.
[138] Curran at 551. *See also* William M. Wardell & Louis Lasagna, Regulation and Drug Development 16-17 (1975).
[139] Curran at 551-2.
[140] Frankel at 48-9. *See also* Beecher, Individual at 174.
[141] Peter Temin, Taking Your Medicine: Drug Regulation in the United States 123 (1980).
[142] Faden at 203.

Introduced by amendment on the floor, the provision required that investigators both inform subjects if a drug was experimental and obtain the subject's consent before beginning the study. However, the investigators would not have to obtain consent if they felt it were unfeasible or if obtaining consent was, in their professional judgment, contrary to the subject's best interests.[143] Javits' argument that "the job of the Senate was to 'weigh in the balance' the obligations to obtain consent and to support experimentation" helped bring the first consent requirement into American law.[144]

When Congress passed the Drug Amendments of 1962, the FDA promulgated new regulations regarding the new provisions. The regulations, effective in February 1963, addressed mainly research design and procedures. However, they did not tackle the consent provisions, which were still broad and vaguely worded.[145] The consent provision went largely ignored, perhaps because the FDA staff was busy enforcing other provisions of the bill or because there had been no legislative debate about the meaning of the terms to help guide the FDA.[146] One of the few FDA administrators to speak out about the consent requirement was Dr. Frances Kelsey, Chief of the Investigational Drug Branch, Division of New Drugs. In a paper published by the Law-Medicine Research Institute, Kelsey argued that the best-interests exception could be validly invoked in only a few isolated cases, such as dealing with children or in emergency cases; Kelsey's argument would have significantly limited the exception and crafted a much tighter consent requirement.[147]

The FDA finally took action regarding the patient consent provision in August 1966, with the publication of the *Statement of Policy Concerning Consent for Use of Investigational New Drugs on Humans*.[148] The FDA's move to action was the result of two important events, namely a change in administration and a growing realization, in part spurred by the controversy of the Jewish Chronic Disease Hospital case, that

[143] Curran at 553.
[144] FADEN at 203-4.
[145] *Id.* at 204.
[146] Curran at 557.
[147] *Id.*
[148] *Id.* at 560.

many investigators were failing to obtain valid consent.[149]

The statement relied heavily on the general guidelines of the Nuremberg Code and the Declaration of Helsinki. Some of the language from these codes was adopted almost verbatim, particularly the definition of consent from the Nuremberg Code.[150] The FDA also adopted the Declaration's distinction between therapeutic and non-therapeutic research, demanding patient's consent for therapeutic purposes, unless the patient could not communicate.[151] Finally, the FDA required that subjects give written consent and receive a fair explanation of all material information.[152] The statement reflects an important move by the FDA to conform the policy of the US to that proposed by international organizations. FDA administrators seemed to acknowledge the danger of placing too much liberty in investigators' hands and moved to curtail the freedom that investigators could take with subjects.

C. NIH Policy Developed

Unfortunately, however, the FDA regulations applied only to experimental drugs and devices, but not to all research.[153] In the early-1960s, Director of NIH James Shannon became increasingly concerned about the lack of federal policy governing human research. Shannon's motivation came from the public anger surrounding the Jewish Chronic Disease Hospital Case, as well as the results from the 1960 Law-Medicine Institute Study.[154] Shannon commissioned a study scrutinizing research protocols.

[149] FADEN at 204.
[150] Babbo at 391. In fact, the current version of the FDA regulation titled "Informed Consent of Human Subjects," last amended in March 1999, still relies on the Nuremberg Code's definition on informed consent. It reads: "No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."
[151] *Id.*
[152] Curran at 564.
[153] FADEN at 205.
[154] *Id.* at 206.

The resulting report, submitted by Dr. Robert Livingston in November 1964, discussed the dearth of an acceptable code to govern research and focused on the dangers of risk and liability surrounding research performed without consent.[155] However, Livingston concluded that the NIH could not regulate research ethics without overstepping its bounds and intruding on investigators' authority.[156] Livingston's conclusion seems to represent an unfortunate step backward for American policy formulation. Although he acknowledged the lack of adequate regulations, he ultimately gave priority to investigators' judgment, rather than individuals' protection.

Shannon accepted Livingston's conclusion, but nonetheless opted to press forward to address the other recommendations in the report, such as review by investigators' peers and broad consultation with doctors, lawyers and clergy regarding the ethics of clinical investigation.[157] Shannon thus met with the National Advisory Health Council (NAHC) in September 1965, in an effort to convince NAHC to establish formal controls on investigators' independent judgment.[158] NAHC saw the importance of regulating research on humans and adopted a resolution to address the moral and ethical issues of clinical research:

> Be it resolved that the National Advisory Health Council believes that Public Health Service support of clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates to assure an independent determination of the protection of the rights and welfare of the individual or individuals involved, of the appropriateness of the methods used to secure informed consent, and of the risks and potential medical benefits of the investigation.[159]

With this statement, the NAHC acknowledged the significance of obtaining informed consent; however, it made no mention of the definition of informed consent.[160] These recommendations reflect a willingness by American policymakers to reach out across disciplines and take a firm stand to protect individual research

[155] Frankel at 49.
[156] *Id.* at 50.
[157] *Id.* at 51.
[158] *Id.* at 51-2.
[160] Faden at 208.

subjects.

NAHC's resolution soon led to a watershed event in the history of informed consent in the United States: the publication in February 1966 of the *Statement of Policy on Clinical Investigations Using Human Subjects*. The statement, issued by Surgeon General William Stewart, for the first time required institutions receiving research grants to obtain prior committee review for proposed research, rather than relying simply on the judgment of the individual investigator.[161] The independent review should include consideration of three key elements: the rights and welfare of the subjects involved; the appropriateness of the methods used to obtain informed consent; and the risks and potential medical benefits of the investigation.[162]

This statement paved the way for the requirement of informed consent in studies by federally-funded institutions. Shortly after this initial statement, NIH's original 1953 Clinical Center policy was replaced with an updated version, entitled *Group Consideration and Informed Consent in Clinical Research*.[163] These new guidelines demanded written consent by the subject and incorporated a variety of informed consent requirements, including a detailed disclosure of the study and its risks, a list of procedures to be disclosed, and an oral explanation that the subject could understand.[164] With this document, informed consent finally had some specific parameters within the research world. The elements that made up informed consent had been finally highlighted, and "the Clinical Center document was the most careful and comprehensive statement issued to this point on the subject of the ethics of research and its integral connection to problems of informed consent."[165]

In May 1966, the Clinical Center guidelines were revised, in part because of criticism that the term "informed consent" was unclear. The new document attempted to eliminate confusion by offering a further explanation of informed consent. The new revision stated that a person must have the freedom to choose

[161] *Id.*
[162] Curran at 577. *See also* Morin at 174.
[163] Faden at 209.
[164] *Id.*
[165] *Id.*

and receive "a fair explanation of the procedures to be followed, their possible benefits and attendant hazards and discomforts, and the reasons for pursuing the research and its general objectives.[166] To address concerns, the policymakers chose to draft only minimal substantive prerequisites for how to obtain consent. To compensate, they inserted a significant procedural requirement that local review boards were to examine local research facilities, to determine how to apply national standards to local research institutions.

The reliance on local review boards was an "attempt to achieve a uniform package of national standards while permitting broad latitude and diversity at the local review level."[167] Unfortunately, the intensity of local review varied from location to location, causing concern that subjects were not in fact receiving adequate disclosure and revealing that the US government would indeed need to institute a more thorough form of review. However, the 1966 NIH policy merits careful consideration because it proved to be "the harbinger of the current practice of Institutional Review Boards required by federal regulation."[168]

The two 1966 statements, themselves important, led to the publication of an even more significant work: the *Institutional Guide to DHEW Policy on Protection of Human Subjects*, published in 1971.[169] Known as the "Yellow Book," it contained specific guidelines about institutional review.[170] "Informed consent" was defined as "the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity."[171] The Book listed six components of informed consent: a fair explanation of the procedure; a disclosure of alternative procedures; a description of risks and discomforts; a description of benefits; an opportunity to ask questions about the procedure; and an instruction that the subject is free to withdraw consent and terminate participation.[172]

[166] *Protection of the Individual as a Research Subject* at 3 *cited in* FADEN at 209.
[167] FADEN at 209.
[168] Babbo at 392.
[169] FADEN at 212.
[170] Morin at 174.
[171] *Id.*
[172] *Id.*

With this system, DHEW had crafted a regulatory system whereby a review panel composed of both medical and non-medical members monitored investigators to make sure that informed consent was obtained and subjects were protected. Unlike some earlier efforts, DHEW's system included a specific definition of informed consent and seemingly tightened the consent requirements to better protect subjects.

D.

By the time DHEW's Yellow Book was published in the early 1970s, both the FDA regulations and NIH guidelines had been reviewed and amended several times.[173] Despite the efforts that had been made over the last decade, however, US policymakers remained concerned about the lack of both adequate protections for subjects and adequate consent provisions.[174] Outrage over potential studies on human fetuses, as well as the recent Tuskegee Experiment, generated much discussion within the Congress.[175] In response, Congress passed the National Research Act in 1974. The Act served two important purposes. First, it required DHEW to adopt as federal regulation the NIH guidelines about protecting human research subjects.[176] Second, it created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose purpose was to conduct a comprehensive investigation to identify the basic ethical principles underlying research on humans and to recommend acceptable guidelines to DHEW, Congress and the President.[177]

The National Commission's mandate extended from 1974 to 1978, culminating in the 1979 Belmont Report. The Commission based its discussion around what it perceived to be the three main ethical principles involv-

[173] Babbo at 392.
[174] FADEN at 213.
[175] *Id.* at 215.
[176] Babbo at 392.
[177] Goldner at 96.

ing human research: respect for persons, beneficence and justice.[178] Each principle was then tied to a specific policy guideline, with respect for persons applied to informed consent, beneficence applied to risk/benefit assessment, and justice applied to the selection of subjects and the distribution of benefits of research.[179] Following this format, the Commission determined that the principle of respect for persons required some form of consent, to protect individual's autonomy and personal dignity.[180] The Commission assessed informed consent in terms of three necessary conditions, namely information, comprehension and voluntariness.[181] The Report adopted the standard of the reasonable volunteer, proposing that the extent of disclosure should be such that a reasonable volunteer could decide whether to participate.[182]

The Commission also placed great emphasis on institutional review boards (IRBs). The National Research Act had ordered the Secretary to develop regulations dealing with the composition of these boards. In addition, the Commission sponsored a study at the University of Michigan to examine functioning IRBs. The study revealed that most research institutions were happy with the local IRB system and felt that the IRB system adequately protected subjects.[183] Although these results led the Commission to support continued expansion of the IRB system, the Michigan study also disclosed that the forms used for informed consent needed to be more carefully modified. In response, the Commission put out a well-received separate report on IRBs, discussing how to better craft the IRB system.[184]

After the National Commission's four-year term expired, a new group was formed to continue to study the ethical issues surrounding research on humans. In 1978, Congress established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[185] During its three-

[178] Morin at 176.
[179] *Id. See also* The National Commission, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* 4-20 (1979).
[180] FADEN at 216.
[181] *Id.*
[182] Goldner at 99.
[183] FADEN at 217.
[184] *Id. See also* The National Commission, *Report and Recommendations: Institutional Review Boards* (1979).
[185] Morin at 182.

year run, the President's Commission built on the work begun by the National Commission, with a special mandate to report every two years on the adequacy of federal rules, and their implementation procedures, for the protection of human subjects.[186]

While the President's Commission never really focused on informed consent in its reports, it did urge implementation of many of the recommendations about informed consent that the National Commission had advocated.[187] The Commission did promote the adoption of a model of shared decision-making, in which both patients and medical workers participated equally, but it failed to address adequately the potentially-unequal relationship between physicians and patients.[188] In general, however, the President's Commission seemed to take a conservative approach to informed consent, declining to push for stricter protections for human subjects.[189]

F. New Regulations

Both Commissions ultimately helped shape the new regulations issued by DHHS in 1981.[190] The amended regulations, which replaced those that had been issued in 1974, dealt with requirements for obtaining informed consent, as well as the organization and functions of IRBs.[191] The DHHS draft regulations initially adopted the same regulatory framework for all types of research, rejecting a proposal to draft separate rules for behavioral and social sciences and for biomedical sciences.[192] Instead, the draft wanted to make certain types of research (mostly behavioral and social research) either exempt or subject to expedited review.[193]

[186] Faden at 221.
[187] Morin at 183.
[188] *Id. See also* The President's Commission, *Protecting Human Subjects: The Adequacy and Uniformity of Federal Rules and Their Implementation* (1981).
[189] Morin at 183.
[190] Babbo at 395.
[191] McNeill at 64.
[192] Faden at 218.
[193] *Id.*

Behavioral and social scientists, however, balked at being regulated by the federal government.[194]

In the end, the 1981 regulations were applied only to research receiving federal funds. The main change from the 1974 regulations was that research that posed little or no harm to subjects was now exempt from institutional review.[195] These new regulations wound up removing a layer of protection for subjects who were participating in research that was either not federally-funded or presented little risk of danger; such research included a great deal of behavioral and social science research. Although the government insisted that these regulations offered merely a floor for protection of human subjects, with institutions free to impose more stringent consent requirements if they chose, the regulations seem less strict than they could have been. The government appeared to be shying from the drive to impose informed consent provisions in all possible areas of research.

G. Current Policy

The enactment of 45 C.F.R. §46 in 1991 extended the scope of the 1981 DHHS regulations. In June 1991, sixteen federal agencies, including the FDA, the Department of Defense, and the Department of Energy, adopted the DHHS regulations into their individual codes dealing with the protection of human subjects.[196] The common Federal Policy for the Protection of Human Subjects essentially governs all federally-sponsored research, as well as commercially-sponsored research that is performed for pharmaceutical companies and medical device manufacturers.[197] The uniform standard requires that research be considered by an IRB; it also lists guidelines for IRB organization and performance, including criteria for how to approve research.[198]

[194] *Id.*
[195] *Id.*
[196] Babbo at 396.
[197] *Id.*
[198] Annas, Rights at 151-2.

The common rule also includes a prolonged section detailing the general requirements for informed consent. §46.116 requires that the information be provided in language understandable to the subject; without such clear language, no consent (oral or written) will be considered informed.[199] In addition, the Code defines essential elements of informed consent. The eight basic elements are:

(1)

(2)

(3)

(4)

(5)

(6)

(7)

(8)

[199] 45 C.F.R. §46.116.

The same section also includes further additional factors that may be applicable to certain special subjects at heightened risk, such as fetuses, pregnant women or prisoners.[201] These highly specific requirements clearly delineated the boundaries of informed consent. The code therefore worked hard to assure that all subjects would receive protection against unfair research and adequate, understandable information about the experiments in which they were involved.

45 C.F.R. §46 is still in effect. Today, the current regulations include three fundamental ways to protect research subjects. First, DHHS' Office for the Protection of Research Risks (OPRR) provides federal regulatory oversight of research facilities. Second, federally-sanctioned IRBs grant studies internal approval. Finally, human subjects give voluntary informed consent.[202] Of these three, "the operative regulatory mechanism is the requirement for authentic, uncoerced informed consent–the oversight of OPRR and the approval of an IRB merely providing the government the opportunity to check compliance."[203] Informed consent therefore forms the backbone of current federal policy, signaling that the US government has finally formally acknowledged the necessity of monitoring investigators and ensuring that human subjects receive the information they need to give informed consent.

V. Conclusion

Although current regulations now offer human research subjects significant protections, US policymakers clearly struggled considerably while developing these informed consent provisions. The US strikingly lagged behind other countries and international organizations in formulating such policies; note the twenty-year lag period between the Nuremberg Code's promulgation in 1948 and the publication of several important US

[201] *Id.*
[202] Babbo at 396.
[203] *Id.*

policy statements in 1966. In addition, even though the early international codes were not legally binding, the US seemed hesitant to support them. The US' reluctance seems particularly odd given that European countries are often more lax than the US in their regulatory measures, often approving new medications (such as RU-486) and procedures much earlier than the American FDA.

It is also surprising that US legislators took so long to act when American courts had long recognized the importance of informed consent, as well as subjects' self-determination and autonomy. However, the *Fortner* court's 1935 decision acknowledging the necessity for research on human subjects may help explain the US government's delay in issuing informed consent regulations. Even though the *Fortner* case did impose limits on experimentation on humans, US drafters could also point to the case as a justification for such experimentation and as an early signal that investigators should be allowed discretion. This tendency to rely on investigators' judgments appeared to govern American policy until the public outcry following consent violations, such as the Tuskegee Syphilis Experiment, forced legislators to step in and offer subjects greater protections.

Interestingly, it was NIH, not FDA, that took the lead and worked particularly hard to make the informed consent requirement meaningful for human subjects. Even though FDA was the regulatory body, FDA administrators appeared to have trouble adequately defining and narrowing the informed consent provision. NIH, on the other hand, was much more proactive in crafting specific parameters around informed consent, in order to extend the applicability of the provision from experimental drugs and devices to research. Most notably, NIH was responsible for introducing many of the major elements of informed consent, such as demanding independent review by outside committees, detailed disclosure of the experiment and its risks, and oral explanations that would be understandable by subjects. Surprisingly, these landmark events in our regulatory history were initiated by the agency responsible for funding and conducting government research. However, perhaps NIH's willingness to regulate comes precisely from the fact that it, unlike FDA, actually

conducted experiments and thus witnessed first-hand the dangers for human subjects in medical experiments. The current regulations do offer significant protections for human subjects. In addition, the recognition that certain groups, such as children and prisoners, require special protections demonstrates that legislators are indeed committed to overseeing research and ensuring that subjects are not exploited. As medical science progresses, legislators may want to expand such protections; for example, with the boom in genetics studies, they might want to impose additional limits on studies on human fetuses or pregnant women. The future will require a continued application of an important balancing test: US government agencies will have to remain vigilant about protecting subjects' rights, while still allowing crucial medical research to continue.